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- 10 **Mirikizumab – začátek nové éry protilátek proti interleukinu 23 v léčbě idiopatických střevních zánětů**
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Biologická léčba u IgA nefropatie

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- Schena, F. P. – Nistor, I.: Epidemiology of IgA nephropathy: a global perspective. *Semin Nephrol*, 2018, 38, s. 435–442.
- Rovin, B. H. – Adler, S. G. – Barratt, J., et al.: Executive summary of the KDIGO 2021 Guideline for the Management of Glomerular Diseases. *Kidney Int*, 2021, 100, s. 753–779.
- Wheeler, D. C. – Toto, R. D. – Stefánsson, B. V., et al.: A Pre-specified analysis of the DAPA-CKD Trial demonstrates the effects of dapagliflozin on major adverse kidney events in patients with IgA nephropathy. *Kidney Int*, 2021, 100, s. 215–224.
- Cesualdo, L.: lead principal investigator(s): A randomized, multicenter, double-blind, parallel-group, active-control study of the efficacy and safety of sparsentan for the treatment of immunoglobulin A nephropathy – 021IGAN17001. Traver Therapeutics, Inc. Dostupné z: <https://www.erknet.org/research/research-projects/project-details?uid=183>, vyhledáno 1. 2. 2024.
- Heerspink H. J. – Radhakrishnan, J. – Alpers Ch. E., et al.: PROTECT Investigators: Sparsentan in patients with IgA nephropathy: a pre-specified interim analysis from a randomised, double-blind, active-controlled clinical trial. *Lancet*, 2023, 401, s. 1584–1594.
- Stamellou, E. – Seikrit, C. – Tang, S. C. W., et al.: IgA nephropathy. *Nat Rev Dis Primers*, 2023, 9, s. 67.
- Barratt, J. – Rovin, B. H. – Catran, D., et al.: Why target the gut to treat IgA nephropathy? *Kidney Int Rep*, 2020, 5, s. 1620–1624.
- Coppo, R. – Mariat, C.: Systemic corticosteroids and mucosal-associated lymphoid tissue-targeted therapy in immunoglobulin A nephropathy: insight from the NEFIGAN Study. *Nephrol Dial Transplant*, 2020, 35, s. 1291–1294.
- Fellström, B. C. – Barratt, J. – Cook, H., et al.: Targeted-release budesonide versus placebo in patients with IgA nephropathy (NEFIGAN): a double-blind, randomised, placebo-controlled phase 2b trial. *Lancet*, 2017, 389, s. 2117–2127.
- Barratt, J. – Lafayette, R. – Kristensen, J., et al.: NeflgArd Trial Investigators: Results from part A of the multi-center, double-blind, randomized, placebo-controlled NeflgArd trial, which evaluated targeted-release formulation of budesonide for the treatment of primary immunoglobulin A nephropathy. *Kidney Int*, 2023, 103, s. 391–402.
- Barratt, J.: Interim analysis of a phase 2 dose ranging study to investigate the effect and safety of iptacopan in primary IgA nephropathy. Dostupné z: <https://era-edta.conference2web.com/#resources/interim-analysis-of-a-phase-2-dose-ranging-study-to-investigate-the-efficacy-and-safety-of-iptacopan-in-primary-iga-nephropathy-20ec3f83-fd34-441e-8745-44587bda74da>, vyhledáno 1. 2. 2024.
- Novartis Announces Iptacopan Met Phase II Study Primary Endpoint in Rare Kidney Disease IgA Nephropathy (IgAN). Dostupné z: <https://www.novartis.com/news/media-releases/novartis-announces-iptacopan-met-phase-ii-study-primary-endpoint-rare-kidney-disease-iga-nephropathy-igan>, vyhledáno 1. 2. 2024.
- Barratt, J. – Rovin, B. – Zhang, H., et al.: POS-546 efficacy and safety of iptacopan in IgA nephropathy: results of a randomized double-blind placebo-controlled phase 2 study at 6 months. *Kidney International Reports*, 2022, 7, s. S236.
- Rizk, D. V. – Rovin, B. H. – Zhang, H., et al.: Targeting the alternative complement pathway with iptacopan to treat IgA nephropathy: design and rationale of the APPLAUSE-IgAN study. *Kidney International Reports*, 2023, 8, s. 968–979.
- Cheung, C. K. – Rajasekaran, A. – Barratt, J., et al.: An update on the current state of management and clinical trials for IgA nephropathy. *J Clin Med*, 2021, 10, s. 2493.
- Schubart, A. – Anderson, K. – Mainolfi, N., et al.: Small-molecule factor B inhibitor for the treatment of complement-mediated diseases. *Proc Natl Acad Sci USA*, 2019, 116, s. 7926–7931.
- Muri, L. – Ispasanie, E. – Schubart, A., et al.: Alternative complement pathway inhibition abrogates pneumococcal opsonophagocytosis in vaccine-naïve, but not in vaccinated individuals. *Front Immunol*, 2021, 12, 732146.
- Ispasanie, E. – Muri, L. – Schubart, A., et al.: Alternative complement pathway inhibition does not abrogate meningococcal killing by serum of vaccinated individuals. *Front Immunol*, 2021, 12, 747594.
- Wong, E. K. – Praga, M. – Nester, C. M., et al.: LNP023: a novel oral complement alternative pathway factor B inhibitor safely and effectively reduces proteinuria in C3 glomerulopathy. *J Am Soc Nephrol*, 2020, 31, s. 55.
- Lafayette, R. A. – Rovin, B. H. – Reich, H. N., et al.: Safety, tolerability and efficacy of narsoplimab, a novel MASP-2 inhibitor for the treatment of IgA nephropathy. *Kidney Int Rep*, 2020, 5, s. 2032–2041.
- Wire, B.: Omeros Announces Results From Nearly Three-Year Follow-up of Patients in Phase 2 IgA Nephropathy Trial. Dostupné z: <https://www.benzinga.com/node/23920855>, vyhledáno 1. 2. 2024.
- Yuan, X. – Gavrilaki, E. – Thanassi, J. A., et al.: Small-molecule factor D inhibitors selectively block the alternative pathway of complement in paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome. *Haematologica*, 2017, 102, s. 466–475.
- Barratt, J. – Weitz, I.: Complement factor D as a strategic target for regulating the alternative complement pathway. *Front Immunol*, 2021, 12, 712572.
- Liu, L. – Zhan, Y. – Duan, X., et al.: C3a, C5a renal expression and their receptors are correlated to severity of IgA nephropathy. *J Clin Immunol*, 2014, 34, s. 224–232.
- Open-Label Study to Evaluate Safety and Efficacy of CCX168 in Subjects With Immunoglobulin A Nephropathy on Stable RAAS Blockade. Dostupné z: <https://www.clinicaltrials.gov/study/NCT02384317>, vyhledáno 1. 2. 2024.
- Li, W. – Peng, X. – Liu, Y., et al.: TLR9 and BAFF: their expression in patients with IgA nephropathy. *Mol Med Rep*, 2014, 10, s. 1469–1474.
- Zhai, Y.-L. – Zhu, L. – Shi, S.-F., et al.: Increased APRIL expression induces IgA1 aberrant glycosylation in IgA nephropathy. *Medicine*, 2016, 95, e3099.
- Barratt, J. – Koienga, L. – Hour, B., et al.: MO212. Updated Interim Results of a Phase 1/2 Study to Investigate the Safety, Tolerability, PK, PD, and Clinical Activity of BION-1301 in Patients with IgA Nephropathy. 59th European Renal Association (ERA) Congress 2022; Paříž, Francie. Dostupné z: https://www.chinooktx.com/file.cfm/52/docs/era_2022-bion-1301_cohort-19620update_mo212.pdf, vyhledáno 1. 2. 2024.
- Zhang, Y. M. – Zhang, H.: Insights into the role of mucosal immunity in IgA nephropathy. *Clin J Am Soc Nephrol*, 2018, 13, s. 1584–1586.
- Mathur, M. – Barratt, J. – Suzuki, Y., et al.: Safety, tolerability, pharmacokinetics, and pharmacodynamics of VIS649 (sibeprenlimab), an APRIL-neutralizing IgG2 monoclonal antibody, in healthy volunteers. *Kidney Int Rep*, 2022, 7, s. 993–1003.
- Visterra NCT04287985: Safety and Efficacy Study of VIS649 for IgA Nephropathy. Dostupné z: <https://www.clinicaltrials.gov/ct2/show/NCT04287985?term=nct04287985&draw=2&rank=1>, vyhledáno 1. 2. 2024.
- Mathur, M. – Barratt, J. – Chacko, B., et al.: A phase 2 trial of sibeprenlimab in patients with IgA nephropathy. *N Engl J Med*, 2024, 390, s. 20–31.
- Phase 2/3 open-label trial of sibeprenlimab in the treatment of immunoglobulin A nephropathy. Clinical Trials Listing Service. Dostupné z: <https://www.centerwatch.com/clinical-trials/listings/NCT05248659/phase-2-3-open-label-trial-of-sibeprenlimab-in-the-treatment-of-immunoglobulin-a-nephropathy>, vyhledáno 4. 2. 2024.
- Barratt, J. – Tumlin, J. A. – Suzuki, Y., et al.: 24-week interim analysis of a randomized, double-blind, placebo-controlled phase 2 study of ataccept in patients with IgA nephropathy and persistent proteinuria. ASN Annual Meeting 2020; Digital Meeting. *J Am Soc Nephrol*, 2020, 31, s. 54A.
- Vera Therapeutics, Inc. NCT04716231: A Phase IIb Randomized, Double-Blinded, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of Ataccept in Subjects With IgA Nephropathy (IGAN); 2022. Dostupné z: <https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-004892-41/CZ>, vyhledáno 1. 2. 2024.
- Lafayette, R., et al.: ERA 2023 late breaking. Přednáška 17. 6. 2023.
- Lv, J. – Liu, L. J. – Hao, C. M., et al.: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Trial of Telitaccept in Patients with IgA Nephropathy and Persistent Proteinuria. ASN Kidney Week 2021. Dostupné z: <https://www.asn-online.org/education/kidneyweek/2021/program-abstract.aspx?controlid=3639668>, vyhledáno 1. 2. 2024.
- A phase 2, randomized, double-blind, multicenter study of telitaccept for injection (RC18) in subjects with IgA nephropathy. Clinical Trials.gov Identifier: NCT04905212. 2022. Dostupné z: <https://classic.clinicaltrials.gov/ct2/show/NCT04905212>, vyhledáno 4. 2. 2024.
- Khodadadi, L. – Cheng, Q. – Radbruch, A., et al.: The maintenance of memory plasma cells. *Front Immunol*, 2019, 10, s. 721.
- He, J.-W. – Zhou, X.-J. – Lv, J.-C. – Zhang, H.: Perspectives on how mucosal immune responses, infections and gut microbiome shape IgA nephropathy and future therapies. *Theranostics*, 2020, 10, s. 11462–11478.
- Chang, S. – Li, X.-K.: The role of immune modulation in pathogenesis of IgA nephropathy. *Front Med*, 2020, 7, s. 92.
- Wang, Y. Y. – Zhang, L. – Zhao, P.-W., et al.: Functional implications of regulatory B cells in human IgA nephropathy. *Scand J Immunol*, 2014, 79, s. 51–60.
- A double blind, randomized, placebo-controlled, multicenter phase IIIa, clinical trial to assess efficacy and safety of the human anti-CD38 antibody felzartamab in IgA nephropathy. Clinical Trials.gov Identifier: NCT05065970. 2021. Dostupné z: <https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-005054-19/CZ>, vyhledáno 4. 2. 2024.
- Khodadadi, L. – Cheng, Q. – Radbruch, A., et al.: The maintenance of memory plasma cells. *Front Immunol*, 2019, 10, s. 721.
- Lafayette, R. A. – Canetta, P. A. – Rovin, B. H., et al.: A randomized, controlled trial of rituximab in IgA nephropathy with proteinuria and renal dysfunction. *J Am Soc Nephrol*, 2017, 28, s. 1306–1313.
- Yiu, W. H. – Chan, K. W. – Chan, L. Y. Y., et al.: Spleen tyrosine kinase inhibition ameliorates tubular inflammation in IgA nephropathy. *Front Physiol*, 2021, 12, 650888.
- Lechner, S. M. – Abbad, L. – Boedec, E., et al.: IgA1 protease treatment reverses mesangial deposits and hematuria in a model of IgA nephropathy. *J Am Soc Nephrol*, 2016, 27, s. 2622–2629.

Proč hraje cílené uvolňování léčiva zásadní roli v terapeutické indikaci

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- Preskripční informace ENTOCORT® EC (budesonide) Capsules. Revize duben 2016. Dostupné z: www.accessdata.fda.gov/drugsatfda_docs/label/2016/021324s012s013lbl.pdf, vyhledáno 31. 1. 2024.
- Entocort CR 3 mg Capsules; SPC, Tillotts Pharma UK Limited. Aktualizováno v září 2023. Dostupné z: www.medicines.org.uk/emc/product/872/smpc/print, vyhledáno 31. 1. 2024.
- Budeno-falk 3 mg gastro-resistant capsules; SPC, Dr. Falk Pharma UK Ltd. Aktualizováno v lednu 2020. Dostupné z: www.medicines.org.uk/emc/product/138/smpc/print, vyhledáno 31. 1. 2024.
- Decentralised Procedure; RMS Day 210 Assessment Report; Budeno-falk 9 mg gastro-resistant granules (Budenosonide); UK/H/2778/001/DC. Publikováno 2010. Dostupné z: www.geneesmiddeleninformatiebank.nl/pars/106117.pdf, vyhledáno 31. 1. 2024.
- Cortiment 9 mg, prolonged release tablets; SPC; Ferring Pharmaceuticals Ltd. Aktualizováno v prosinci 2020. Dostupné z: www.medicines.org.uk/emc/product/1895/smpc/print, vyhledáno 31. 1. 2024.
- Nardelli, S. – Pisani, L. F. – Tontini, G. E. et al.: MMX® technology and its applications in gastrointestinal diseases. *Therap Adv Gastroenterol*, 2017, 10, s. 545–552.
- Preskripční informace Tarpeyo (budesonide) delayed release capsules. Dostupné z: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215935s000lbl.pdf, vyhledáno 31. 1. 2024.
- Dressman, J.: Comparative dissolution of budesonide from four commercially available products for oral administration: implications for interchangeability. *Dissol Tech*, 2023, 30, s. 224–229.
- Ozturk, S. S. – Palsson, B. O. – Donohoe, B. – Dressman, J. B.: Kinetics of release from enteric-coated tablets. *Pharm Res*, 1988, 5, s. 550–565.

Ravulizumab v léčbě atypického hemolyticko-uremického syndromu

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- Fakhouri, F. – Zuber, J. – Frémeaux-Bacchi, V., et al.: Haemolytic uremic syndrome. *Lancet*, 2017, 390, s. 681–696.
- Goodship, T. H. J. – Cook, T. H. – Fakhouri, F., et al.: Atypical hemolytic uremic syndrome and C3 glomerulopathy: conclusions from a „Kidney Disease: Improving Global Outcomes“ (KDIGO) Controversies Conference. *Kidney Int*, 2017, 91, s. 539–551.

- 3 Loirat, Ch. – Fakhouri, F. – Ariceta, G., et al.: An international consensus approach to the management of atypical hemolytic uremic syndrome in children. *Pediatr Nephrol*, 2016, 31, s. 15–39.
- 4 Caprioli, J. – Noris, M. – Brioshi, S., et al.: Genetics of HUS: the impact of MCP, CFH, and IF mutations on clinical presentation, response to treatment, and outcome. *Blood*, 2006, 108, s. 1267–1279.
- 5 Fremeaux-Bacchi, V. – Fakhouri, F. – Garnier, A., et al.: Genetics and outcome of atypical hemolytic uremic syndrome: a nationwide French series comparing children and adults. *Clin J Am Soc Nephrol*, 2013, 8, s. 554–562.
- 6 Keating, G. M.: Eculizumab: a review of its use in atypical haemolytic uremic syndrome. *Drugs*, 2013, 73, s. 2053–2066.
- 7 Legendre, C. M. – Licht, C. – Muus, P., et al.: Terminal complement inhibitor eculizumab in atypical hemolytic-uremic syndrome. *N Engl J Med*, 2013, 368, s. 2169–2181.
- 8 Loirat, C. – Fremeaux-Bacchi, V.: Hemolytic uremic syndrome recurrence after renal transplantation. *Pediatr Transplant*, 2008, 12, s. 619–629.
- 9 Rondeau, E. – Scully, M. – Ariceta, G., et al.: The long-acting C5 inhibitor, ravulizumab, is effective and safe in adult patients with atypical hemolytic uremic syndrome naïve to complement inhibitor treatment. *Kidney Int*, 2020, 97, s. 1287–1296.
- 10 Fakhouri, F. – Hourmant, M. – Campistol, J. M., et al.: Terminal complement inhibitor eculizumab in adult patients with atypical hemolytic uremic syndrome: a single-arm, open-label trial. *Am J Kidney Dis*, 2016, 68, s. 84–93.
- 11 Barbour, T. – Scully, M. – Ariceta, G., et al.: Long-term efficacy and safety of the long-acting complement C5 inhibitor ravulizumab for the treatment of atypical hemolytic uremic syndrome in adults. *Kidney International Reports*, 2021, 6, s. 1603–1613.
- 12 Ariceta, G. – Dixon, B. P. – Kim, S. H., et al.: The long-acting C5 inhibitor, ravulizumab, is effective and safe in pediatric patients with atypical hemolytic uremic syndrome naïve to complement inhibitor treatment. *Kidney Int*, 2021, 100, s. 225–237.
- 13 Syed, Y. Y.: Ravulizumab: A review in atypical haemolytic uremic syndrome. *Drugs*, 2021, 81, s. 587–594.
- 14 Tanaka, K. – Adams, B. – Aris, A. M., et al.: The long-acting C5 inhibitor, ravulizumab, is efficacious and safe in pediatric patients with atypical hemolytic uremic syndrome previously treated with eculizumab. *Pediatr Nephrol*, 2021, 36, s. 889–898.
- 15 Dixon, B. P. – Madris-Aris, A. D. – Adams, B., et al.: Two-year efficacy and safety of ravulizumab in adults and children with atypical hemolytic uremic syndrome (aHUS): analysis of two phase 3 studies. *Blood*, 2021, 138, suppl. 1, s. 769.
- 16 Tomazos, I. – Hatswell, A. J. – Cataland, S., et al.: Comparative efficacy of ravulizumab and eculizumab in the treatment of atypical hemolytic uremic syndrome: An indirect comparison using clinical trial data. *Clin Nephrol*, 2022, 97, s. 261–272.
- 17 Postma, A. J. – Quist, S. – de Jong, L.: Cost-minimisation analysis of ravulizumab compared with eculizumab in patients with atypical hemolytic uremic syndrome (AHUS) in the Netherlands. Poster EES2. ISPOR Europe 2022. Dostupné z: https://www.ispor.org/docs/default-source/euro2022/isporeu22postma-pdf.pdf?sfvrsn=2b1e0718_0_0, vyhledáno 20. 2. 2024.
- 18 Levy, A. R. – Chen, P. – Johnston, K., et al.: Quantifying the economic effects of ravulizumab versus eculizumab treatment in patients with atypical hemolytic uremic syndrome. *J Med Econ*, 2022, 25, s. 249–259.
- 19 Mauch, T. – Chladek, M. – Cataland, S., et al.: Preference for ravulizumab over eculizumab: A real-world patient preference and life impact study on the treatment of atypical hemolytic uremic syndrome [abstract]. Dostupné z: <https://abstracts.isth.org/abstract/preference-for-ravulizumab-over-eculizumab-a-real-world-patient-preference-and-life-impact-study-on-the-treatment-of-atypical-hemolytic-uremic-syndrome/>, vyhledáno 19. 2. 2024.
- 20 Noris, M. – Remuzzi G.: Every fifteen days forever? *Kidney International Reports*, 2023, 8, s. 4–7, doi: <https://doi.org/10.1016/j.ekir.2022.11.006>.
- 21 Cammett, T. – Garlo, K. – Millman, E. E., et al.: Exploratory prognostic biomarkers of complement-mediated thrombotic microangiopathy (CM-TMA) in adults with atypical hemolytic uremic syndrome (aHUS): Analysis of a phase III study of ravulizumab. *Mol Diagn Ther*, 2023, 27, s. 61–74.

Nové monoklonální protilátky v očním lékařství

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- 1 Heier, J. S. – Khanani, A. M. – Quezada Ruiz, C., et al.: TENAYA and LUCERNE Investigators: Efficacy, durability, and safety of intravitreal faricimab up to every 16 weeks for neovascular age-related macular degeneration (TENAYA and LUCERNE): two randomised, double-masked, phase 3, non-inferiority trials. *Lancet*, 2022, 399, s. 729–740.
- 2 Heier, J. S. – Singh, R. P. – Wykoff, C. C., et al.: The angiopoietin/tie pathway in retinal vascular diseases: A review. *Retina*, 2021, 41, s. 1–19.
- 3 Jousseaume, A. M. – Ricci, F. – Paris, L. P., et al.: Angiopoietin/Tie2 signalling and its role in retinal and choroidal vascular diseases: a review of preclinical data. *Eye*, 2021, 35, s. 1305–1316.
- 4 Stewart, M. W.: The expanding role of vascular endothelial growth factor inhibitors in ophthalmology. *Mayo Clin Proc*, 2012, 87, s. 77–88.
- 5 Wykoff, C. C. – Abreu, F. – Adamis, A. P., et al.: YOSEMITE and RHINE Investigators: Efficacy, durability, and safety of intravitreal faricimab with extended dosing up to every 16 weeks in patients with diabetic macular oedema (YOSEMITE and RHINE): two randomised, double-masked, phase 3 trials. *Lancet*, 2022, 399, s. 741–755.
- 6 Vokurka, S.: Tebentafusp. *Klin Onkol*, 2022, 35, s. 502–507.
- 7 Nathan, P. – Hassel, J. C. – Rutkowski, P., et al.: Overall survival benefit with tebentafusp in metastatic uveal melanoma. *N Engl J Med*, 2021, 385, s. 1196–1206.
- 8 Tomsitz, D. – Ruf, T. – Heppt, M., et al.: Tebentafusp in patients with metastatic uveal melanoma: a real-life retrospective multicenter study. *Cancers*, 2023, 15, s. 3430.

Léčba hepatocelulárního karcinomu

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- 1 Modrá kniha ČOS, 29. vydání, Brno 2023, s. 1–394. Dostupné z: <https://www.linkos.cz/files/modra-kniha/22.pdf>, vyhledáno 13. 3. 2024.
- 2 Sherman, M.: Risk of hepatocellular carcinoma in hepatitis B and prevention through treatment. *Cleve Clin J Med*, 2009, 76, suppl. 3, s. S6–S9.
- 3 de Oliveira Andrade, L. J. – D'Oliveira, A. – Melo, R. C., et al.: Association between hepatitis C and hepatocellular carcinoma. *J Glob Infect Dis*, 2009, 1, s. 33–37.
- 4 Mancebo, A. – González-Diéguez, M. L. – Cadahia, V., et al.: Annual incidence of hepatocellular carcinoma among patients with alcoholic cirrhosis and identification of risk factors. *Clin Gastroenterol Hepatol*, 2013, 11, s. 95–101.
- 5 Jewell, J. – Sheron, N.: Trends in European liver death rates: implications for alcohol policy. *Clin Med*, 2010, 10, s. 259–263.
- 6 SVOD.cz za rok 2021.
- 7 Reig, M. – Forner, A. – Rimola, J., et al.: BCLC strategy for prognosis prediction and treatment recommendation: The 2022 update. *J Hepatol*, 2022, 76, s. 681–693.
- 8 Shin, S. W. – Ahn, K. S. – Kim, S. W., et al.: Liver resection versus local ablation therapies for hepatocellular carcinoma within the Milan criteria: A systematic review and meta-analysis. *Ann Surg*, 2021, 273, s. 656–666.
- 9 Mazzaferro, V. – Regalia, E. – Doci, R., et al.: Liver transplantation for the treatment of small hepatocellular carcinomas in patients with cirrhosis. *N Engl J Med*, 1996, 334, s. 693–699.
- 10 Citores, M. J. – Lucena, J. L. – de la Fuente, S., et al.: Serum biomarkers and risk of hepatocellular carcinoma recurrence after liver transplantation. *World J Hepatol*, 2019, 11, s. 50–64.
- 11 Decaens, T. – Roudot-Thoraval, F. – Badran, H., et al.: Impact of tumour differentiation to select patients before liver transplantation for hepatocellular carcinoma. *Liver Internat*, 2011, doi: [10.1111/j.1478-3231.2010.02425.x](https://doi.org/10.1111/j.1478-3231.2010.02425.x)
- 12 Vibert, E. – Schwartz, M. – Olthoff, K. M.: Advances in resection and transplantation for hepatocellular carcinoma. *J Hepatol Volume*, 2020, 72, s. 262–276.
- 13 Bujold, A. – Massey, Ch. A. – Kim, J. J., et al.: Sequential phase I and II trials of stereotactic body radiotherapy for locally advanced hepatocellular carcinoma. *J Clin Oncol*, 2013, 31, s. 1631–1639.
- 14 Llovet, J. M., et al.: Sorafenib in advanced hepatocellular carcinoma. *N Engl J Med*, 2008, 359, s. 378–390.
- 15 Bruix, J. – Raoul, J.-L. – Sherman, M., et al.: Efficacy and safety of sorafenib in patients with advanced hepatocellular carcinoma: sub-analyses of a phase III trial. *J Hepatol*, 2012, 57, s. 821–829.
- 16 Jackson, R. – Psarelli, E. E. – Berhaneet, S., et al.: Impact of viral status on survival in patients receiving sorafenib for advanced hepatocellular carcinoma: a meta-analysis of randomized phase III trials. *J Clin Oncol*, 2017, 35, s. 622–628.
- 17 Kudo, M. – Finn, R. S. – Shukui Qin, S., et al.: Lenvatinib versus sorafenib in first-line treatment of patients with unresectable hepatocellular carcinoma: a randomised phase 3 non-inferiority trial. *Lancet*, 2018, 391, s. 1163–1173.
- 18 Llovet, J. M. – Kudo, M. – Merle, P., et al.: Lenvatinib plus pembrolizumab versus lenvatinib plus placebo for advanced hepatocellular carcinoma (LEAP-002): a randomised, double-blind, phase 3 trial. *Lancet Oncol*, 2023, 24, s. 1399–1410.
- 19 Peng, Z. – Fan, W. – Zhu, B., et al.: Lenvatinib combined with transarterial chemoembolization as first-line treatment for advanced hepatocellular carcinoma: a phase III, randomized clinical trial (LAUNCH). *J Clin Oncol*, 2023, 41, s. 117–127.
- 20 Cheng, A. L. – Qin, S. – Ikeda, M., et al.: Updated efficacy and safety data from IMbrave150: Atezolizumab plus bevacizumab vs. sorafenib for unresectable hepatocellular carcinoma. *J Hepatol*, 2022, 76, s. 862–873.
- 21 Kumar, V. – Shinagare, A. B. – Rennke, H. G., et al.: The safety and efficacy of checkpoint inhibitors in transplant recipients: a case series and systematic review of literature. *Oncologist*, 2020, 25, s. 505–514.
- 22 Abou-Alfa, G. K. – Lau, G., et al.: Tremelimumab plus durvalumab in unresectable hepatocellular carcinoma. *NEJM Evid*, 2022, 1, 8.
- 23 Verset, G., et al.: Pembrolizumab monotherapy for previously untreated advanced hepatocellular carcinoma: data from the open-label, phase II KEYNOTE-224 trial. *Clin Cancer Res*, 2022, 28, s. 2547–2554.
- 24 Yau, T. – Park, J. W. – Finn, R. S., et al.: Nivolumab versus sorafenib in advanced hepatocellular carcinoma (CheckMate 459): a randomised, multicentre, open-label, phase 3 trial. *Lancet Oncol*, 2022, 23, s. 77–90.
- 25 Yau, T. – Kang, Y. T., et al.: Efficacy and safety of nivolumab plus ipilimumab in patients with advanced hepatocellular carcinoma previously treated with sorafenib. The CheckMate 040 Randomized Clinical Trial. *JAMA Oncol*, 2020, 6, e204564.
- 26 Finn, R. S. – Ryoo, B.-Y. – Merle, P., et al.: Pembrolizumab as second-line therapy in patients with advanced hepatocellular carcinoma in KEYNOTE-240: a randomized, double-blind, phase III trial. *J Clin Oncol*, 2020, 38, s. 193–202.
- 27 Abou-Alfa, G. K. – Meyer, T. – Cheng, A.-L., et al.: Cabozantinib in patients with advanced and progressing hepatocellular carcinoma. *N Engl J Med*, 2018, 379, s. 54–63.
- 28 Zhu, A. X. – Park, J. O. – Ryoo, B.-Y., et al.: Ramucirumab versus placebo as second-line treatment in patients with advanced hepatocellular carcinoma following first-line therapy with sorafenib (REACH): a randomised, double-blind, multicentre, phase 3 trial. *Lancet Oncol*, 2015, 16, s. 859–870.
- 29 Zhu, A. X. – Kang, Y. K., et al.: Ramucirumab after sorafenib in patients with advanced hepatocellular carcinoma and increased α -fetoprotein concentrations (REACH-2): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol*, 2019, 20, s. 282–296.
- 30 Rimassa, L. – Assenat, E. – Peck-Radosavljevic, M., et al.: Tivantinib for second-line treatment of MET-high, advanced hepatocellular carcinoma (METIV-HCC): a final analysis of a phase 3, randomised, placebo-controlled study. *Lancet Oncol*, 2018, 19, s. 682–693.

Imunoonkoterapie v první linii – standard léčby metastatického nemalobuněčného karcinomu plic

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- 1 Reck, M. – Rodríguez-Abreu, D. – Robinson, A. G., et al.: Five-year outcomes with pembrolizumab versus chemotherapy for metastatic non-small-cell lung cancer with PD-L1 tumor proportion score \geq 50. *J Clin Oncol*, 2021, 39, s. 2339–2349.
- 2 Garassino, M. C. – Gadgeel, S. – Speranza, G., et al.: Pembrolizumab plus pemetrexed and platinum in nonsquamous non-small-cell lung cancer: 5-year outcomes from the phase 3 KEYNOTE-189 study. *J Clin Oncol*, 2023, 41, s. 1992–1998.
- 3 Novello, S. – Kowalski, D. M. – Luft, A., et al.: Pembrolizumab plus chemotherapy in squamous non-small-cell lung cancer: 5-year update of the phase III KEYNOTE-407 study. *J Clin Oncol*, 2023, 41, s. 1999–2006.
- 4 Gadgeel, S. M., et al.: OA 14.05 5-year survival of pembrolizumab plus chemotherapy for metastatic NSCLC with PD-L1 tumor proportion score < 1 %. DOI: <https://doi.org/10.1016/j.jtho.2023.09.078>.

Trastuzumab deruxtecan v léčbě pacientů s karcinomem plic

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- 1 Shitara, K. – Bang, Y. J. – Iwasa, S., et al.: Trastuzumab deruxtecan in previously treated HER2-positive gastric cancer. *N Engl J Med*, 2020, 382, s. 2419–2430.
- 2 Cortés, J. – Kim, S. B. – Chung, W. P., et al.: Trastuzumab deruxtecan versus trastuzumab emtansine for breast cancer. *N Engl J Med*, 2022, 386, s. 1143–1154.
- 3 EMA Recommends Extending Indications for Trastuzumab Deruxtecan to Include Treatment of Advanced HER2-mutated NSCLC. Dostupné z: <https://www.esmo.org/oncology-news/ema-recommends-extending-indications-for-trastuzumab-deruxtecan-to-include-treatment-of-advanced-her2-mutated-nsclc>, vyhledáno 12. 3. 2024.
- 4 Liu, S. – Li, S. – Hai, J., et al.: Targeting HER2 aberrations in non-small cell lung cancer with osimertinib. *Clin Cancer Res*, 2018, 24, s. 2594–2604.
- 5 Zhou, J. – Ding, N. – Xu, X., et al.: Clinical outcomes of patients with HER2-mutant advanced lung cancer: chemotherapies versus HER2-directed therapies. *Ther Adv Med Oncol*, 2020, 12, 1758835920936090.
- 6 Li, B. T. – Smit, E. F. – Goto, Y., et al.: Trastuzumab deruxtecan in HER2-mutant non-small-cell lung cancer. *N Engl J Med*, 2022, 386, s. 241–251.
- 7 Goto, K. – Goto, Y. – Kubo, T., et al.: Trastuzumab deruxtecan in patients with HER2-mutant metastatic non-small-cell lung cancer: primary results from the randomized, phase II DESTINY-Lung02 trial. *J Clin Oncol*, 2023, 41, s. 4852–4863.
- 8 SPC Enhertu, poslední revize textu: 18. 10. 2023.

Přehled biologické léčby astmatu – současné možnosti léčby

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- 1 GINA, Global strategy for Asthma Management and Prevention (2023 update), www.ginasthma.org.
- 2 Teřil, M. – Sedláč, V. – Krčmová, I.: *Doporučený postup diagnostiky a léčby těžkého astmatu*. Geum, 2023.
- 3 Busse, W. – Corren, J. – Lanier, B. Q., et al.: Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. *J Allergy Clin Immunol*, 2001, 108, s. 184–190.
- 4 Product information: XOLAIR(R) subcutaneous injection powder, omalizumab subcutaneous injection powder, Genentech Inc. South San Francisco CA. 2016.
- 5 Haldar, P. – Brightling, C. E. – Hargadon, B., et al.: Mepolizumab for severe eosinophilic asthma (DREAM): a multicentre, double-blind placebo-controlled trial. *Lancet*, 2012, 380, s. 651–659.
- 6 Product information: mepolizumab for subcutaneous use. GlaxoSmithKline Research, Triangle Park NC 27709.
- 7 Úhradová kritéria léku Nucala 100 mg inj. sol., www.sukl.cz.
- 8 Maselli, D. – Velez, M. – Rogers, L.: Reslizumab in the management of poorly controlled asthma: the data so far. *J Asthma Allergy*, 2016, 9, s. 155–162.
- 9 Product information: Cinqero epar product information, EMA 2016.
- 10 Úhradová kritéria léku Cinqero 10 mg/ml inf cnc sol 1x 10ml, www.sukl.cz.
- 11 Nair, P. – Wenzel, S. – Rabe, K. F., et al.: Oral glucocorticoid-sparing effect of benralizumab in severe asthma. *N Engl J Med*, 2017, 376, s. 2448–2458.
- 12 Bleeker, E. R. – Fitzgerald, J. M. – Chanez, P., et al.: Efficacy and safety of benralizumab for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting β_2 -agonists (SIROCCO): a randomised, multicentre, placebo-controlled phase 3 trial. *Lancet*, 2016, 388, s. 2115–2127.
- 13 Fitzgerald, J. M. – Bleeker, E. R. – Nair, P., et al.: Benralizumab, an anti-interleukin-5 receptor α monoclonal antibody, as add-on treatment for patients with severe, uncontrolled, eosinophilic asthma (CALIMA): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet*, 2016, 388, s. 2128–2141.
- 14 Agache, I. – Song, Y. – Rocha, C., et al.: Efficacy and safety of treatment with dupilumab for severe asthma: A systematic review of the EAACI guidelines – Recommendations on the use of biologicals in severe asthma. *Allergy*, 2020, 75, s. 1058–1068.
- 15 Úhradová kritéria léku Dupixent 300 mg inj. sol., www.sukl.cz.
- 16 Abdelgaili, M. S. – Elrashedy, A. A. – Awad, A. K., et al.: Safety and efficacy of tezepelumab vs. placebo in adult patients with severe uncontrolled asthma: a systematic review and meta-analysis. *Sci Reports*, 2022, 12, 20905.
- 17 Gauvreau, G. M. – O'Byrne, P. M. – Boulet, L.-P., et al.: Effects of an anti-TSLP antibody on allergen-induced asthmatic responses. *N Engl J Med*, 2014, 370, s. 2102–2110.
- 18 Ando, K. – Fukuda, Y. – Tanaka, A. – Sagara, H.: Comparative efficacy and safety of tezepelumab and other biologics in patients with inadequately controlled asthma according to thresholds of type 2 inflammatory biomarkers: a systematic review and network meta-analysis. *Cells*, 2022, 11, s. 819.
- 19 Corren, J. – Pham, T.-H. – Garcia Gil, E., et al.: Baseline type 2 biomarker levels and response to tezepelumab in severe asthma. *Allergy*, 2022, 77, s. 1786–1796.
- 20 A Study of GSK3511294 (depemokimab) in participants with severe asthma with an eosinophilic phenotype (SWIFT-2). Dostupné z: <https://clinicaltrials.gov/study/NCT04718103>, vyhledáno 16. 2. 2024.
- 21 Deitersen, A. – Krupka, E. – Imberdis, K., et al.: Early improvement in asthma small airway dysfunction after one dose of SAR443765, a novel bispecific anti-thymic stromal lymphopoietin/anti-IL-13 nanobody molecule. *Eur Respi J*, 2023, 62, suppl. 67, OA4296.
- 22 Dose ranging study of SAR443765 compared with placebo-control in adult participants with moderate to severe asthma (AIRCULES). Dostupné z: <https://classic.clinicaltrials.gov/ct2/show/NCT06102005>, vyhledáno 16. 2. 2024.

Současné možnosti léčby karcinomu ovaria – přehledové sdělení

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Masarykova onkologického ústavu, Brno

- 1 Fínek, J. – Zikán, M., et al.: *Karcinom ovaria*. Praha, Farmakon Press, 2019.
- 2 Harter, P. – Sehouli, J. – Lorusso, D., et al.: A randomized trial of lymphadenectomy in patients with advanced ovarian neoplasms. *N Engl J Med*, 2019, 380, s. 822–832.
- 3 Nezhat, F. R. – Ezzati, M. – Chuang, L., et al.: Laparoscopic management of early ovarian and fallopian tube cancers: surgical and survival outcome. *Am J Obstet Gynecol*, 2009, 200, s. 83.e1–6.
- 4 Nezhat, F. R. – Finger, T. N. – Vetere, P., et al.: Comparison of perioperative outcomes and complication rates between conventional versus robotic-assisted laparoscopy in the evaluation and management of early, advanced, and recurrent stage ovarian, fallopian tube, and primary peritoneal cancer. *Int J Gynecol Cancer*, 2014, 24, s. 600–607.
- 5 Pilka, R., et al.: *Robotická chirurgie v gynekologii*. Praha, Maxdorf, 2014, s. 147–150.
- 6 Klos, D., et al.: *Nádory peritonéálního povrchu*. Praha, Grada Publishing, 2023, s. 181–186.
- 7 Feranec, R. – Chovanec, J.: Role hypertermické intraperitoneální chemoterapie v léčbě pokročilého a recidivujícího karcinomu ovaria. *Onkologie*, 2017, 11, s. 220–223.
- 8 Masarykův onkologický ústav. Dostupné z: <https://www.mou.cz/pipac/t1534>, vyhledáno 3. 2. 2024.
- 9 Modrá kniha ČOS. Dostupné z: <https://www.linkos.cz/> lékař-a-multidisciplinarni-tym/personalizovana-onkologie/modra-kniha-cos/aktualni-vydani-modne-knihy/29-17-zhoubny-novotvar-ovarii-a-tuby-c56-57/, vyhledáno 3. 2. 2024.
- 10 Dostupné z: www.sukl.cz, vyhledáno 3. 2. 2024.
- 11 Chelariu-Raicu, A. – Mahner, S. – Moore, K. N., et al.: Integrating antibody drug conjugates in the management of gynecologic cancers. *Int J Gynecol Cancer*, 2023, 33, s. 420–429.
- 12 Matulonis, U. A. – Lorusso, D. – Oaknin, A., et al.: Efficacy and safety of mirvetuximab soravtansine in patients with platinum-resistant ovarian cancer with high folate receptor alpha expression: results from the SORAYA study. *J Clin Oncol*, 2023, 41, s. 2436–2445.
- 13 Sborník přednášek Brněnské onkologické dny. Redakční rada VÚKEO. Květen 1979, s. 1–45.
- 14 Rob, L. – Cibula, D. – Knapp, P., et al.: Safety and efficacy of dendritic cell-based immunotherapy DCVAC/OvCa added to first-line chemotherapy (carboplatin plus paclitaxel) for epithelial ovarian cancer: a phase 2, open-label, multicenter, randomized trial. *J Immunother Cancer*, 2022, 10, e003190.
- 15 Matulonis, U. A. – Shapira-Frommer, R. – Santin, A. D., et al.: Antitumor activity and safety of pembrolizumab in patients with advanced recurrent ovarian cancer: results from the phase II KEYNOTE-100 study. *Ann Oncol*, 2019, 30, s. 1080–1087.
- 16 Monk, B. J. – Colombo, N. – Oza, A. M., et al.: Chemotherapy with or without avelumab followed by avelumab maintenance versus chemotherapy alone in patients with previously untreated epithelial ovarian cancer (JAVELIN Ovarian 100): an open-label, randomized, phase 3 trial. *Lancet Oncol*, 2021, 22, s. 1275–1289.
- 17 Moore, K. N. – Bookman, M. – Sehouli, J., et al.: Atezolizumab, bevacizumab, and chemotherapy for newly diagnosed stage III or IV ovarian cancer: placebo-controlled randomized phase III trial (IMagyn050/GOG 3015/ENGOT-OV39). *J Clin Oncol*, 2021, 39, s. 1842–1855.
- 18 Monk, B. J. – Coleman, R. L. – Fujiwara, K., et al.: ATHENA (GOG-3020/ENGOT-ov45): a randomized, phase III trial to evaluate rucaparib as monotherapy (ATHENA-MONO) and rucaparib in combination with niraparib (ATHENA-COMBO) as maintenance treatment following frontline platinum-based chemotherapy in ovarian cancer. *Int J Gynecol Cancer*, 2021, 31, s. 1589–1594.
- 19 Gonzalez Martin, A. – Sanchez Lorenzo, L. – Colombo, N., et al.: A phase III, randomized, double blinded trial of platinum based chemotherapy with or without atezolizumab followed by niraparib maintenance with or without atezolizumab in patients with recurrent ovarian, tubal, or peritoneal cancer and platinum treatment free interval of more than 6 months: ENGOT-Ov41/GEICO 69-O/ANITA Trial. *Int J Gynecol Cancer*, 2021, 31, s. 617–622.
- 20 Musacchio, L. – Salutaris, V. – Pignata, S., et al.: Randomized phase III trial on niraparib-TSR-042 (dostarlimab) versus physician's choice

chemotherapy in recurrent ovarian, fallopian tube, or primary peritoneal cancer patients not candidate for platinum retreatment: NITCHE trial (MITO 33). *Int J Gynecol Cancer*, 2021, 31, s. 1369–1373.

21 U. S. National Library of Medicine. ClinicalTrials.gov. Dostupné z: www.clinicaltrials.gov, vyhledáno 4. 2. 2024.

22 Klener, P. jr. – Klener, P.: *Principy systémové protinádorové léčby*. Praha,

Grada Publishing, 2013.

Monoklonální protilátky v léčbě karcinomu děložního čípku

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- Cibula, D. – Raspollini, M. R. – Planchamp, F., et al.: ESGO/ESTRO/ESP Guideline for the management of patients with cervical cancer – update 2023. *Int J Gynecol Cancer*, 2023, 33, s. 649–666.
- Mileshkin, L. R. – Moore, K. N. – Barnes, E. H., et al.: Adjuvant chemotherapy following chemoradiotherapy as primary treatment for locally advanced cervical cancer versus chemoradiotherapy alone (OUTBACK): an international, open-label, randomized, phase III trial. *Lancet Oncol*, 2023, 24, s. 468–482.
- Thigpen, J. T. – Blessing, J. A. – DiSaia, P. J., et al.: A randomized comparison of a rapid versus prolonged (24 hr) infusion of cisplatin in therapy of squamous cell carcinoma of the uterine cervix: a Gynecologic Oncology Group study. *Gynecol Oncol*, 1989, 32, s. 198–202.
- Thigpen, T.: The role of chemotherapy in the management of carcinoma of the cervix. *Cancer J*, 2003, 9, s. 425–432.
- Bonomi, P. – Blessing, J. A. – DiSaia, P. J., et al.: Randomized trial of three cisplatin dose schedules in squamous-cell carcinoma of the cervix: a Gynecologic Oncology study. *J Clin Oncol*, 1985, 3, s. 1079–1085, 833–835.
- Omura, G. A. – Blessing, J. A. – Vaccarello, L., et al.: Randomized trial of cisplatin versus cisplatin plus mitolactol versus cisplatin plus ifosfamide in advanced squamous carcinoma of the cervix: a Gynecologic Oncology Group study. *J Clin Oncol*, 1997, 17, s. 165–171.
- Bloss, J. D. – Blessing, J. A. – Behrens, B. C., et al.: Randomized trial of cisplatin and ifosfamide with or without bleomycin in squamous carcinoma of the cervix: a Gynecologic Oncology Group study. *J Clin Oncol*, 2002, 20, s. 1832–1837.
- Moore, D. H. – Blessing, J. A. – McQuellon, R. P., et al.: Phase III study of cisplatin with or without paclitaxel in stage IVB, recurrent, or persistent squamous cell carcinoma of the cervix: a gynecologic oncology group study. *J Clin Oncol*, 2004, 22, s. 3113–3119.
- Long, H. J. 3rd – Bundy, B. N. – Grendys, E. C., Jr., et al.: Randomized phase III trial of cisplatin with or without topotecan in carcinoma of the uterine cervix: a Gynecologic Oncology Group Study. *J Clin Oncol*, 2005, 23, s. 4626–4633.
- Monk, B. J. – Sill, M. W. – McMeekin, D. S., et al.: Phase III trial of four cisplatin-containing doublet combinations in stage IVB, recurrent, or persistent cervical carcinoma: A Gynecologic Oncology Group Study. *J Clin Oncol*, 2009, 27, s. 4649–4655.
- Moore, K. N. – Herzog, T. J. – Lewin, S., et al.: A comparison of cisplatin/paclitaxel and carboplatin/paclitaxel in stage IVB, recurrent or persistent cervical cancer. *Gynecol Oncol*, 2007, 105, s. 299–303.
- Kitagawa, R. – Katsumata, N. – Shibata, T., et al.: A randomized, phase III trial of paclitaxel plus carboplatin (TC) versus paclitaxel plus cisplatin (TP) in stage IVb, persistent or recurrent cervical cancer: Japan Clinical Oncology Group study (JCOG0505). *J Clin Oncol*, 2012, 30, suppl. 15, s. 5006–5006.
- Tewari, K. S. – Sill, M. W. – Long, H. J., et al.: Improved survival with bevacizumab in advanced cervical cancer. *N Engl J Med*, 2014, 370, s. 734–743.
- Colombo, N. – Dubot, C. – Lorusso, D., et al.: Pembrolizumab for persistent, recurrent or metastatic cervical cancer. *N Engl J Med*, 2022, 385, s. 1856–1864.
- Bradley, J. M. – Takafumi, T. – Xiaouha, W., et al.: Durvalumab versus placebo with chemoradiotherapy for locally advanced cervical carcinoma (CALLA): a randomized double-blind, phase 3 trial. *Lancet Oncol*, 2023, 24, s. 1334–1348.
- Oaknin, A. – Monk, B. J. – Polastro, L., et al.: S19MO Phase III EMPOWER-Cervical 1/GOG-3016/ENGOT-cx9 trial of cemiplimab in recurrent or metastatic (R/M) cervical cancer: Long-term survival analysis. *Ann Oncol*, 2022, 33, s. 5781.

Monoklonální protilátky v léčbě hemofilie

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- Zápotocká, E. – Blatný, J. – Smejkal, P.: Konsenzuální doporučení Českého národního hemofilického programu (ČNHP) pro diagnostiku a léčbu pacientů s vrozenou hemofiilií a s inhibitory FVIII/FIX. *Transfúze Hematol Dnes*, 2021, 27, s. 173–184.
- Smejkal, P. – Blatný, J. – Hajšmanová, Z., et al.: Konsenzuální doporučení Českého národního hemofilického programu (ČNHP) pro diagnostiku a léčbu pacientů s hemofiilií, vydání 3., rok 2021. *Transfúze Hematol Dnes*, 2021, 27, s. 73–90.
- Srivastava, A. – Santangostino, E. – Dougall, A., et al.: WFH guidelines for the management of hemophilia, 3rd edition. *Haemophilia*, 2020, 26, suppl. 6, s. 1–158.
- Shima, M. – Hanabusa, H. – Taki, M., et al.: Factor VIII-mimetic fusion of humanized bispecific antibody in hemophilia A. *N Engl J Med*, 2016, 374, s. 2044–2053.
- Sampei, Z. – Igawa, T. – Soeda, T., et al.: Identification and multidimensional optimization of an asymmetric bispecific IgG antibody mimicking the function of factor VIII cofactor activity. *PLoS One*, 2013, 8, e57479.
- Persson, P. – Amstrup, A. B. – Coester, H. V., et al.: Mim8, a novel factor VIIIa mimetic bispecific antibody, shows favorable safety and pharmacokinetics in healthy adults. *Res Pract Thromb Haemost*, 2023, 7, 102181.
- Swan, D. – Mahlangu, J. – Thachil, J.: Non-factor therapies for bleeding disorders: A primer for the general haematologist. *ElHaem*, 2022, 3, s. 584–596.
- Oldenburg, J. – Mahlangu, J. N. – Kim, B., et al.: Emicizumab prophylaxis in hemophilia A with inhibitors. *N Engl J Med*, 2017, 377, s. 809–818.
- Mahlangu, J. – Oldenburg, J. – Paz-Priel, I., et al.: Emicizumab prophylaxis in patients who have hemophilia A without inhibitors. *N Engl J Med*, 2018, 379, s. 811–822.
- Young, G. – Liesner, R. – Chang, T., et al.: A multicenter, open-label phase 3 study of emicizumab prophylaxis in children with hemophilia A with inhibitors. *Blood*, 2019, 134, s. 2127–2138.
- Pipe, S. W. – Shima, M. – Lehle, M., et al.: Efficacy, safety, and pharmacokinetics of emicizumab prophylaxis given every 4 weeks in people with hemophilia A (HAVEN 4): a multicentre, open-label, non-randomised phase 3 study. *Lancet Haematol*, 2019, 6, s. e295–e305.
- Pipe, S. W. – Collins, P. – Dhalluin, C. D., et al.: Emicizumab prophylaxis for the treatment of infants with severe hemophilia A without factor VIII inhibitors: results for the interim analysis of the HAVEN 7 study. *Blood*, 2022, 140, suppl. 1, s. 457–459.
- Négrier, C. – Mahlangu, J. – Lehle, M., et al.: Emicizumab in people with moderate or mild haemophilia A (HAVEN 6): a multicentre, open-label, single-arm, phase 3 study. *Lancet Haematol*, 2023, 10, s. e168–e177.
- Collins, P. W. – Liesner, R. – Makris, M., et al.: Treatment of bleeding episodes in haemophilia A complicated by a factor VIII inhibitor in patients receiving emicizumab. Interim guidance from UKHCO Inhibitor Working Party and Executive Committee. *Haemophilia*, 2018, 24, s. 344–347.
- Coppola, A. – Castaman, G. – Santoro, R. C., et al.: Management of patients with severe haemophilia A without inhibitors on prophylaxis with emicizumab: AICE recommendations with focus on emergency in collaboration with SiBioC, SIMEU, SIMEUP, SIPMeL and SISET. *Haemophilia*, 2020, 26, s. 937–945.

Imunologická léčba myelomu – bispecifické protilátky v roce 2023

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- Špička I.: Biologická léčba mnohočetného myelomu – 2021. *Acta Medicinæ*, 2022, 11, s. 84–87.
- Madry, C. – Laabi, Y. – Callebaut, I., et al.: The characterization of murine BCMA gene defines it as a new member of the tumor necrosis factor receptor superfamily. *Int Immunol*, 1998, 10, s. 1693–1702.
- Tai, Y. T. – Acharya, C. – An, G., et al.: APRIL and BCMA promote human multiple myeloma growth and immunosuppression in the bone marrow microenvironment. *Blood*, 2016, 127, s. 3225–3236.
- Kochenderfer, J. N. – Wilson, W. H. – Janik, J. E., et al.: Eradication of B-lineage cells and regression of lymphoma in a patient treated with autologous T cells genetically engineered to recognize CD19. *Blood*, 2010, 116, s. 4099–4102.
- Frerichs, K. A. – Broekmans, M. E. C. – Marin Soto, J. A., et al.: Preclinical activity of JNJ-7957, a novel BCMAxCD3 bispecific antibody for the treatment of multiple myeloma, is dependent by daratumumab. *Clin Cancer Res*, 2020, 26, s. 2203–2215.
- Caraccio, C. – Krishna, S. – Phillips, D. J., et al.: Bispecific antibodies for multiple myeloma: A review of targets, drugs, clinical trials, and future directions. *Front Immunol*, 2020, 11, s. 501.
- Hipp, S. – Tai, Y. T. – Blanset, D., et al.: A novel BCMA/CD3 bispecific T-cell engager for the treatment of multiple myeloma induces selective lysis in vitro and in vivo. *Leukemia*, 2017, 31, s. 1743–1751.
- Lakshman, A. – Kumar, S. K.: Chimeric antigen receptor T-cells, bispecific antibodies, and antibody-drug conjugates for multiple myeloma: An update. *Am J Hematol*, 2022, 97, s. 99–118.
- Hua, G. – Scanlan, R. – Straining, R., et al.: Teclistamab-cqyv: The First bispecific T-cell engager antibody for the treatment of patients with relapsed or refractory multiple myeloma. *J Adv Pract Oncol*, 2023, 14, s. 163–171.
- Moreau, P. – Garfall, A. L. – van de Donk, N., et al.: Teclistamab in relapsed or refractory multiple myeloma. *N Engl J Med*, 2022, 387, s. 495–505.
- Bahlis, N. J. – Tomasson, M. H. – Mohty, M., et al.: Efficacy and safety of elranatamab in patients with relapsed/refractory multiple myeloma naïve to B-cell maturation antigen (BCMA)-directed therapies: results from cohort a of the Magnetism-3 study. *Blood*, 2022, 140, s. 391–393.
- Truger, M. S. – Duell, J. – Zhou, X., et al.: Single- and double-hit events in genes encoding immune targets before and after T cell-engaging antibody therapy in MM. *Blood Adv*, 2021, 5, s. 3794–3798.
- Chari, A. – Minnema, M. C. – Berdeja, J. G., et al.: Talquetamab, a T-cell redirecting GPRC5D bispecific antibody for multiple myeloma. *N Engl J Med*, 2022, 387, s. 2232–2244.
- Trudel, S. – Cohen, A. D. – Krishnan, A. Y., et al.: Ceovostamab monotherapy continues to show clinically meaningful activity and manageable safety in patients with heavily pre-treated relapsed/refractory multiple myeloma (RRMM): Updated results from an ongoing phase I study. *Blood*, 2021, 138, s. 157.
- Morillo, D. – Gatt, M. E. – Sebag, M., et al.: First results from the Re-directTT-1 study with teclistamab (tec) + talquetamab (tal) simultaneously targeting BCMA and GPRC5D in patients (pts) with relapsed/refractory multiple myeloma (RRMM). *J Clin Oncol*, 2023, 41, s. 8002.
- Shearer, T. – Williams, R. L. Jr. – Johnson, M., et al.: Pharmacodynamic effects of nirogacestat, a gamma secretase inhibitor, on B-cell maturation antigen in healthy participants. *Blood*, 2022, 140, s. 3080–3081.
- Gantke, T. – Reusch, U. – Kellner, C., et al.: AFM26 is a novel, highly potent BCMA/CD16a-directed bispecific antibody for high affinity NK-cell engagement in multiple myeloma. *J Clin Oncol*, 2017, 35, suppl. 15, s. 8045.
- Gantke, T. – Weichel, M. – Herbrecht, C., et al.: Trispecific antibodies for CD16a-directed NK cell engagement and dual-targeting of tumor cells. *Protein Eng Des Sel*, 2017, 30, s. 673–684.

Bispesifické protilátky v léčbě difuzního velkobuněčného B lymfomu

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- Kontermann, R. E. – Brinkmann, U.: Bispecific antibodies. *Drug Discov Today*, 2015, 20, s. 838–847.
- Falchi, L. – Vardhana, S. A. – Salles, G. A.: Bispecific antibodies for the treatment of B-cell lymphoma: promises, unknowns, and opportunities. *Blood*, 2023, 141, s. 467–480.
- Klein, C. – Schaefer, W. – Regula, J. T.: The use of CrossMAb technology for the generation of bi- and multispecific antibodies. *MAbs*, 2016, 8, s. 1010–1020.
- Engelberts, P. J. – Hiemstra, I. H. – de Jong, B., et al.: DuoBody-CD3x-CD20 induces potent T-cell-mediated killing of malignant B cells in preclinical models and provides opportunities for subcutaneous dosing. *EBioMedicine*, 2020, 52, 102625.
- Hutchings, M. – Mous, R. – Clausen, M. R., et al.: Dose escalation of subcutaneous epcoritamab in patients with relapsed or refractory B-cell non-Hodgkin lymphoma: an open-label, phase 1/2 study. *Lancet*, 2021, 398, s. 1157–1169.
- Thieblemont, C. – Phillips, T. – Ghesquieres, H., et al.: Epcoritamab, a novel, subcutaneous CD3xCD20 bispecific T-cell-engaging antibody, in relapsed or refractory large B-cell lymphoma: dose expansion in a phase I/II trial. *J Clin Oncol*, 2023, 41, s. 2238–2247.
- Cordoba, R. – Falchi, L. – Phillips, T., et al.: P1215: Preliminary phase 1/2 results of subcutaneous epcoritamab + R-DHAX/C IN patients with relapsed or refractory diffuse large B-CELL lymphoma eligible for autologous stem cell transplant. *Hemasphere*, 2022, 6, suppl.
- Wahlin, B. E. – Brody, J. – Phillips, T., et al.: P1213: Subcutaneous epcoritamab with gemox induced high response rates in patients with relapsed/refractory diffuse large B-cell lymphoma ineligible for autologous stem cell transplant. *Hemasphere*, 2022, 6, suppl.
- Falchi, L. – Clausen, M. – Offner, F., et al.: Metabolic response rates of epcoritamab + R-CHOP in patients with previously untreated (1L) high-risk diffuse large B-cell lymphoma, including double-hit/triple-hit lymphoma: Updated EPCORE NHL-2 data. *J Clin Oncol*, 2023, 41, suppl. 16, s. 7519–7519.
- Hutchings, M. – Morschhauser, F. – Iacoboni, G., et al.: Glofitamab, a novel, bivalent CD20-targeting T-cell-engaging bispecific antibody, induces durable complete remissions in relapsed or refractory B-cell lymphoma: a phase I trial. *J Clin Oncol*, 2021, 39, s. 1959–1970.
- Carlo-Stella, C. – Hutchings, M. – Offner, F. C., et al.: Glofitamab step-up dosing: updated efficacy data show high complete response rates in heavily pretreated relapsed/refractory (R/R) non-Hodgkin lymphoma (NHL) patients. *Hematology Oncology*, 2021, 39, S2.
- Dickinson, M. J. – Carlo-Stella, C. – Morschhauser, F., et al.: Glofitamab for Relapsed or refractory diffuse large B-cell lymphoma. *N Engl J Med*, 2022, 387, s. 2220–2231.
- Budde, L. E. – Assouline, S. – Sehn, L. H., et al.: Single-agent mosunetuzumab shows durable complete responses in patients with relapsed or refractory B-cell lymphomas: phase I dose-escalation study. *J Clin Oncol*, 2022, 40, s. 481–491.
- Bannerji, R. – Arnason, J. E. – Advani, R. H., et al.: Odronektamab, a human CD20xCD3 bispecific antibody in patients with CD20-positive B-cell malignancies (ELM-1): results from the relapsed or refractory non-Hodgkin lymphoma cohort in a single-arm, multicentre, phase 1 trial. *Lancet Haematol*, 2022, 9, s. e327–e339.
- Patel, K. – Riedell, P. A. – Tilly, H., et al.: A phase 1 study of plamotamab, an anti-CD20 x anti-CD3 bispecific antibody, in patients with relapsed/refractory non-Hodgkin's lymphoma: recommended dose safety/efficacy update and escalation exposure-response analysis. *Blood*, 2022, 140, suppl. 1, s. 9470–9472.

Biologická léčba hypercholesterolemie

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- Borén, J. – Chapman, M. J. – Krauss, R. M., et al.: Low-density lipoproteins cause atherosclerotic cardiovascular disease: pathophysiological, genetic, and therapeutic insights: a consensus statement from the European Atherosclerosis Society Consensus Panel. *Eur Heart J*, 2020, 41, s. 2313–2330.
- Edwards, J. E. – Moore, R. A.: Statins in hypercholesterolemia: A dose specific meta-analysis of lipid changes in randomised, double blind trials. *BMC Family Practice*, 2003, 4, s. 18.
- Kastelein, J. P. – Akdim, F. – Stroes, E. S. G., et al.: Simvastatin with or without ezetimibe in familial hypercholesterolemia. *N Engl J Med*, 2008, 358, s. 1431–1443.
- Lambert, G. – Sjouke, B. – Choque, B., et al.: The PCSK9 decade. *J Lipid Res*, 2012, 53, s. 2515–2524.
- Sabatine, M. S. – Giugliano, R. P. – Keech, A. C., et al.: Evolocumab and clinical outcomes in patients with cardiovascular disease. *N Engl J Med*, 2017, 376, s. 1713–1722.
- Guadeney, P. – Giustino, G. – Sorrentino, S., et al.: Efficacy and safety of alirocumab and evolocumab: a systematic review and meta-analysis of randomized controlled trials. *Eur Heart J*, 2022, 43, s. e17–e25.
- Wright, R. S. – Ray, K. K. – Raal, F. J., et al.: Pooled patient-level analysis of inclisiran trials in patients with familial hypercholesterolemia or atherosclerosis. *J Am Coll Cardiol*, 2021, 77, s. 1182–1193.
- Ray, K. K. – Raal, F. J. – Kallend, D. G., et al.: Inclisiran and cardiovascular events: a patient-level analysis of phase III trials. *Eur Heart J*, 2023, 44, s. 129–138.
- Kronenberg, F. – Mora, S. – Stroes, E. S. G., et al.: Lipoprotein(a) in atherosclerotic cardiovascular disease and aortic stenosis: A European Atherosclerosis Society consensus statement. *Eur Heart J*, 2022, 43, s. 3925–3946.
- Yeang, C. – Karwatowska-Prokopczuk, E. – Su, F., et al.: Effect of pelacarsen on lipoprotein(a) cholesterol and corrected low-density lipoprotein cholesterol. *J Am Coll Cardiol*, 2022, 79, s. 1035–1046.
- Malick, W. A. – Goonewardena, S. N. – Koenig, W., et al.: Clinical trial design for lipoprotein(a)-lowering therapies: JACC Focus Seminar 2/3. *JACC*, 2023, 81, s. 1633–1645.
- O'Donoghue, M. L. – Rosenson, R. S. – Gencer, B., et al.: Small interfering RNA to reduce lipoprotein(a) in cardiovascular disease. *N Engl J Med*, 2022, 387, s. 1855–1864.

Bezpečnost léčby ixekizumabem

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- Gordon, K. B. – Blauvelt, A. – Papp, K. A., et al.: Phase 3 trials of ixekizumab in moderate-to-severe plaque psoriasis. *N Engl J Med*, 2016, 375, s. 345–356.
- Mease, P. – Roussou, E. – Burmester, G. R., et al.: Safety of ixekizumab in patients with psoriatic arthritis: results from a pooled analysis of three clinical trials. *Arthritis Care Res*, 2019, 71, s. 367–378.
- Griffiths, C. E. M. – Gooderham, M. – Colombel, J. F., et al.: Safety of ixekizumab in adult patients with moderate to severe psoriasis: Data from 17 clinical trials with over 18000 patient-years of exposure. *Dermatol Ther*, 2022, 12, s. 1431–1446.
- Bai, F. – Li, G. G. – Liu, Q., et al.: Short-term efficacy and safety of IL-17, IL-12/23, and IL-23 inhibitors brodalumab, secukinumab, ixekizumab, ustekinumab, guselkumab, tildrakizumab, and risankizumab for the treatment of moderate to severe plaque psoriasis: a systematic review and network meta-analysis of randomized controlled trials. *J Immunol Res*, 2019, 2546161.
- Armstrong, A. – Paul, C. – Puig, L., et al.: Safety of ixekizumab treatment for up to 5 years in adult patients with moderate-to-severe psoriasis: results from greater than 17,000 patient-years of exposure. *Dermatol Ther*, 2020, 10, s. 133–150.
- Blauvelt, A. – Shi, N. – Somani, N., et al.: Comparison of two-year treatment adherence, persistence, discontinuation, reinitiation, and switching between psoriasis patients treated with ixekizumab or secukinumab in real-world settings. *J Am Acad Dermatol*, 2022, 86, s. 581–589.
- Coates, L. C. – Mease, P. – Kronbergs, A., et al.: Efficacy and safety of ixekizumab in patients with active psoriatic arthritis with and without concomitant conventional disease-modifying antirheumatic drugs: SPIRIT-P1 and SPIRIT-P2: 3-year results. *Clin Rheumatol*, 2022, 41, s. 3035–3047.
- Orbai, A. M. – Gratacós, J. – Turkiewicz, A., et al.: Efficacy and safety of ixekizumab in patients with psoriatic arthritis and inadequate response to TNF inhibitors: 3-year follow-up (SPIRIT-P2). *Rheumatol Ther*, 2021, 8, s. 199–217.
- Dougados, M. – Wei, J. C. – Landewé, R.: Efficacy and safety of ixekizumab through 52 weeks in two phase 3, randomised, controlled clinical trials in patients with active radiographic axial spondyloarthritis (COAST-V and COAST-W). *Ann Rheum Dis*, 2020, 79, s. 176–185.
- Deodhar, A. – Poddubnyy, D. – Rahman, P., et al.: Long-term safety and efficacy of ixekizumab in patients with axial spondyloarthritis: 3-year data from the COAST program. *J Rheumatol*, 2023, 50, s. 1020–1028.
- Genovese, M. C. – Mysler, E. – Tomita, T., et al.: Safety of ixekizumab in adult patients with plaque psoriasis, psoriatic arthritis and axial spondyloarthritis: data from 21 clinical trials. *Rheumatology*, 2020, 59, s. 3834–3844.
- Torres, T. – Puig, L. – Vender, R., et al.: Drug survival of IL-12/23, IL-17 and IL-23 inhibitors for psoriasis treatment: a retrospective multicountry, multicentric cohort study. *Am J Clin Dermatol*, 2021, 22, s. 567–579.
- Webers, C. – Ortolan, A. – Sepriano, A., et al.: Efficacy and safety of biological DMARDs: a systematic literature review informing the 2022 update of the ASAS-EULAR recommendations for the management of axial spondyloarthritis. *Ann Rheum Dis*, 2023, 82, s. 130–141.
- Tillet, W. – Birt, J. – Cavanaugh, C., et al.: Changes in musculoskeletal disease activity and patient-reported outcomes in patients with psoriatic arthritis treated with ixekizumab: results from a real-world US cohort. *Front Med*, 2023, 10, 1184028.
- Reich, A. – Reed, C. – Schuster, C., et al.: Real-world evidence for ixekizumab in the treatment of psoriasis and psoriatic arthritis: literature review 2016–2021. *J Dermatolog Treat*, 2023, 34, 2160196.
- Lockshin, B. – Cronin, A. – Harrison, R. W., et al.: Drug survival of ixekizumab, TNF inhibitors, and other IL-17 inhibitors in real-world patients with psoriasis: The Corrona Psoriasis Registry. *Dermatol Ther*, 2021, 34, e14808.
- Yiu, Z. Z. N. – Becher, G. – Kirby, B., et al.: Drug survival associated with effectiveness and safety of treatment with guselkumab, ixekizumab, secukinumab, ustekinumab, and adalimumab in patients with psoriasis. *JAMA Dermatol*, 2022, 158, s. 1131–1141.
- Kojanova, M. – Hugo, J. – Velackova, B., et al.: Efficacy, safety, and drug survival of patients with psoriasis treated with IL-17 inhibitors – brodalumab, ixekizumab, and secukinumab: real-world data from the Czech Republic BIOREP registry. *J Dermatolog Treat*, 2022, 33, s. 2827–2837.
- Deng, Z. – Wang, S. – Wu, C., et al.: IL-17 inhibitor-associated inflammatory bowel disease: A study based on literature and database analysis. *Front Pharmacol*, 2023, 14, 1124628.
- Schreiber, S. – Colobel, J. S. – Feagan, J. B., et al.: Incidence rates of inflammatory bowel disease in patients with psoriasis, psoriatic arthritis and ankylosing spondylitis treated with secukinumab: a retrospective analysis of pooled data from 21 clinical trials. *Ann Rheum Dis*, 2019, 78, s. 473–479.
- Lebwohl, M. – Deodhar, A. – Schwartzman, S., et al.: Long-term safety of ixekizumab treatment in adult patients with psoriasis, psoriatic arthritis or axial spondyloarthritis: A post-hoc analysis of end-of-study program data relative to major adverse cardiovascular events. *Ann Rheum Dis*, 2023, 82, suppl. 1, s. 1780–1781.
- Lebwohl, M. – Deodhar, A. – Blauvelt, A., et al.: Malignancies with long-term use of ixekizumab in adult with psoriasis, psoriatic arthritis or axial spondyloarthritis: A post-hoc analysis of data from 25 randomized clinical trials. *Ann Rheum Dis*, 2023, 82, suppl. 1, s. 1773–1774.
- Ramiro, S. – Nikiphorou, E. – Sepriano, A., et al.: ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. *Ann Rheum Dis*, 2023, 82, s. 19–34.
- Gossec, L. – Baraliakos, X. – Kerschbaumer, A., et al.: EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*, 2020, 79, s. 700–712. www.sukl.cz
- Joven, B. – Manteca, C. F. – Rubio, E., et al.: Real-world persistence and treatment patterns in patients with psoriatic arthritis treated with anti-IL17 therapy in Spain: The Perfil-17 Study. *Adv Ther*, 2023, 40, s. 5415–5431.

Anifrolumab v léčbě systémového lupus erythematosus

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- 1 Bezalet, S. – Guri, K. M. – Elbirt, D., et al.: Type I interferon signature in systemic lupus erythematosus. *Isr Med Assoc J*, 2014, 16, s. 246–249.
- 2 Furie, R. – Petri, M. – Zamani, O., et al.: A phase III, randomized, placebo-controlled study of belimumab, a monoclonal antibody that inhibits B lymphocyte stimulator, in patients with systemic lupus erythematosus. *Arthritis Rheum*, 2011, 63, s. 3918–3930.
- 3 Navarra, S. V. – Guzmán, R. M. – Gallacher, A. E., et al.: Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomised, placebo-controlled, phase 3 trial. *Lancet*, 2011, 377, s. 721–731.
- 4 Furie, R. – Rovin, B. H. – Houssiau, F., et al.: Two-year, randomized, controlled trial of belimumab in lupus nephritis. *N Engl J Med*, 2020, 383, s. 1117–1128.
- 5 Abid, N. – Manaye, S. – Naushad, H., et al.: The safety and efficacy of rituximab and belimumab in systemic lupus erythematosus: a systematic review. *Cureus*, 2023, 15, e40719.
- 6 Merrill, J. T. – Neuwelt, C. M. – Wallace, D. J., et al.: Efficacy and safety of rituximab in moderately-to-severely active systemic lupus erythematosus: the randomized, double-blind, phase II/III systemic lupus erythematosus evaluation of rituximab trial. *Arthritis Rheum*, 2010, 62, s. 222–2233.
- 7 Rovin, B. H. – Furie, R. – Latinis, K., et al.: Efficacy and safety of rituximab in patients with active proliferative lupus nephritis: the lupus nephritis assessment with rituximab study. *Arthritis Rheum*, 2012, 64, s. 1215–1226.
- 8 Felten, R. – Scherlinger, M. – Mertz, P., et al.: New biologics and targeted therapies in systemic lupus: From new molecular targets to new indications. A systematic review. *Joint Bone Spine*, 2023, 90, s. 105523.
- 9 Mackensen, A. – Müller, F. – Mougiakakos, D., et al.: Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus. *Nat Med*, 2022, 28, s. 2124–2132.
- 10 Goldberg, A. – Geppert, T. – Schiopu, E., et al.: Dose-escalation of human anti-interferon- α receptor monoclonal antibody MEDI-546 in subjects with systemic sclerosis: a phase 1, multicenter, open label study. *Arthritis Res Ther*, 2014, 16, s. R57.
- 11 Furie, R. A. – Khamashta, M. – Merrill, J. T., et al.: Anifrolumab, an anti-interferon- α receptor monoclonal antibody, in moderate-to-severe systemic lupus erythematosus. *Arthritis Rheumatol*, 2017, 69, s. 376–386.
- 12 Furie, R. A.: Type I interferon inhibitor anifrolumab in active systemic lupus erythematosus (TULIP-1): a randomised, controlled, phase 3 trial. *Lancet Rheumatol*, 2019, 1, s. e208–e219.
- 13 Morand, E. F. – Furie, R. – Tanaka, Y., et al.: TULIP-2 Trial Investigators: Trial of anifrolumab in active systemic lupus erythematosus. *N Engl J Med*, 2020, 382, s. 211–221.
- 14 Morand, E. F. – Furie, R. A. – Bruce, I. N., et al.: Efficacy of anifrolumab across organ domains in patients with moderate-to-severe systemic lupus erythematosus: a post-hoc analysis of pooled data from the TULIP-1 and TULIP-2 trials. *Lancet Rheumatol*, 2022, 4, s. e282–e292.
- 15 Blomberg, S. – Eloranta, M. L. – Cederblad, B., et al.: Presence of cutaneous interferon-alpha producing cells in patients with systemic lupus erythematosus. *Lupus*, 2001, 10, s. 484–490.
- 16 Kalunian, K. C. – Furie, R. – Morand, E. F., et al.: A randomized, placebo-controlled phase III extension trial of the long-term safety and tolerability of anifrolumab in active systemic lupus erythematosus. *Arthritis Rheumatol*, 2023, 75, s. 253–265.
- 17 Tummala, R. – Abreu, G. – Pineda, L., et al.: Safety profile of anifrolumab in patients with active SLE: an integrated analysis of phase II and III trials. *Lupus Sci Med*, 2021, 8, e000464.
- 18 Fanouraki, A. – Kostopoulou, M. – Andersen, J., et al.: EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. *Ann Rheum Dis*, 2024, 83, s. 15–29.
- 19 Dostupné z: https://prehledy.sukl.cz/prehled_levic.html#/detail-reg/0255465, vyhledáno 1. 2. 2024.
- 20 Strand, V. – O'Quinn, S. – Furie, R. A., et al.: Clinical meaningfulness of a British Isles Lupus Assessment Group-based Composite Lupus Assessment response in terms of patient-reported outcomes in moderate to severe systemic lupus erythematosus: a post-hoc analysis of the phase 3 TULIP-1 and TULIP-2 trials of anifrolumab. *Lancet Rheumatol*, 2022, 4, s. e198–e207.

Jak pokračovat v léčbě revmatoidní artritidy po ukončení léčby prvním inhibítorem TNF

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- 1 Chatzidionysiu, K. – Sfrikakis, P. P.: Low rates of remission with methotrexate monotherapy in rheumatoid arthritis: review of randomised controlled trials could point towards a paradigm shift. *RMD Open*, 2019, 5, e000993.
- 2 Rubbert-Roth, A. – Szabó, M. Z. – Kedves, M., et al.: Failure of anti-TNF treatment in patients with rheumatoid arthritis: The pros and cons of the early use of alternative biological agents. *Autoimmun Rev*, 2019, 18, 102398.
- 3 Smolen, J. S. – Landewé, R. B. M. – Bergstra, S. A., et al.: EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update. *Ann Rheum Dis*, 2023, 82, s. 3–18.
- 4 Fraenkel, L. – Bathon, J. M. – England, B. R., et al.: 2021 American College of Rheumatology Guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*, 2021, 73, s. 1108–1123.
- 5 Lauper, K. – Iudici, M. – Mongin, D., et al.: Effectiveness of TNF-inhibitors, abatacept, IL6-inhibitors and JAK-inhibitors in 31 846 patients with rheumatoid arthritis in 19 registers from the 'JAKpot' collaboration. *Ann Rheum Dis*, 2022, 81, s. 1358–1366.
- 6 Taylor, P. C. – Matucci Cericin, M. – Alten, R., et al.: Managing inadequate response to initial anti-TNF therapy in rheumatoid arthritis: optimising treatment outcomes. *Ther Adv Musculoskelet Dis*, 2022, 14, 1759720X221114101.
- 7 Caporali, R. – Conti, F. – Iannone, F.: Management of patients with inflammatory rheumatic diseases after treatment failure with a first tumour necrosis factor inhibitor: A narrative review. *Mod Rheumatol*, 2023, 34, s. 11–26.
- 8 Migliore, A. – Pompilio, G. – Integlia, D., et al.: Cycling of tumor necrosis factor inhibitors versus switching to different mechanism of action therapy in rheumatoid arthritis patients with inadequate response to tumor necrosis factor inhibitors: A Bayesian network meta-analysis. *Ther Adv Musculoskelet Dis*, 2021, 13, 1759720X211002682.
- 9 Simon, L. S. – Taylor, P. C. – Choy, E. H., et al.: The JAK/STAT pathway: A focus on pain in rheumatoid arthritis. *Semin Arthritis Rheum*, 2021, 51, s. 278–284.

Biosimilární adalimumab (Imraldi) v klinických studiích a běžné praxi v revmatologii

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- 1 Urbánek, K.: Farmakologické charakteristiky subkutánně podávaných monoklonálních protilátek. *Gastroent Hepatol*, 2023, 77, s. 539–543.
- 2 Coghlan, J. – Hea, H. – Schwendeman, A. S.: Overview of Humira biosimilars: current European landscape and future implications. *J Pharm Sci*, 2021, 110, s. 1572–1582.
- 3 Gisbert, J. P. – Gaffney, K. – Young, D., et al.: Current evidence on the use of the adalimumab biosimilar SB5 (Imraldi): a multidisciplinary perspective. *Expert Opin Biol Ther*, 2022, 22, s. 109–121.
- 4 Jorgensen, K. K. – Olsen, I. C. – Goll, G. L., et al.: Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial. *Lancet*, 2017, 389, s. 2304–2316.
- 5 Shin, D., et al.: A phase I pharmacokinetic study comparing SB5, an adalimumab biosimilar, and adalimumab reference product (Humira) in healthy subjects. *Ann Rheum Dis*, 2015, 74, suppl. 2, s. 1265.
- 6 Weinblatt, M., et al.: A phase III, randomized, double-blind clinical study, comparing SB5, an adalimumab biosimilar, with adalimumab reference product (Humira) in patients with moderate to severe rheumatoid arthritis despite methotrexate therapy (24-week results). *Arthritis Rheumatol*, 2015, 67, suppl. 10.
- 7 Weinblatt, M., et al.: FRI0161 sustained efficacy and comparable safety and immunogenicity after transition to SB5 (an adalimumab biosimilar) vs continuation of the adalimumab reference product in patients with rheumatoid arthritis: result of phase III study. *Ann Rheum Dis*, 2016, 75, s. 487.
- 8 Biogen. Imraldi™ low-volume, citrate-free formulation (2023). Dostupné z: <https://lowvolume.imraldi.eu/en/home/low-volume.html>, vyhledáno 13. 3. 2024.
- 9 Ahn, S. S. – Lee, M. – Baek, Y., et al.: A randomized pharmacokinetic study in healthy male subjects comparing a high-concentration, citrate-free SB5 formulation (40 mg/0.4 ml) and prior SB5 (adalimumab biosimilar). *Rheumatol Ther*, 2022, 9, s. 1157–1169.
- 10 Fenwick, S., et al.: Nurse and patient perceptions and preferences for subcutaneous autoinjectors for inflammatory joint or bowel disease: findings from a European survey. *Rheumatol Ther*, 2019, 6, s. 195–206.
- 11 Weinblatt, M. E. – Baranaukaite, A. – Dokoupilova, E., et al.: Switching from reference adalimumab to SB5 (adalimumab biosimilar) in patients with rheumatoid arthritis. *Arthritis Rheumatol*, 2018, 70, s. 832–840.

CT-P13 SC – renesance infliximabu v léčbě revmatoidních onemocnění – reportáž

- 1 Remsima 100 mg. Souhrn údajů o přípravku, dostupné z www.ema.europa.eu/cs/documents/product-information/rem-sima-epar-product-information_cs.pdf, vyhledáno 15. 3. 2024.
- 2 Westhovens, R. – Wiland, P. – Zawadzki, M., et al.: Efficacy, pharmacokinetics and safety of subcutaneous versus intravenous CT-P13 in rheumatoid arthritis: a randomized phase I/III trial. *Rheumatology*, 2021, 60, s. 2277–2287.
- 3 Constantin, A., et al.: Efficacy of subcutaneous vs intravenous infliximab in rheumatoid arthritis: a post-hoc analysis of a randomized phase III trial. *Rheumatology*, 2023, 62, s. 2838–2844.
- 4 Caporali, R., et al.: Efficacy and safety of subcutaneous infliximab versus adalimumab, etanercept and intravenous infliximab in patients with rheumatoid arthritis: a systematic literature review and meta-analysis. *Expert Rev Clin Immunol*, 2021, 17, s. 85–99.

Eskalace dávky secukinumabu u pacienta s ankylozující spondylitidou – kazuistika

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- Ramiro, S. – Nikiphorou, E. – Sepriano, A., et al.: ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. *Ann Rheum Dis*, 2023, 82, s. 19–34.
- Lie, E. – van der Heijde, D. – Uhlig, T. – Mikkelsen, K., et al.: Effectiveness of switching between TNF inhibitors in ankylosing spondylitis: data from the NOR-DMARD register. *Ann Rheum Dis*, 2011, 70, s. 1571–63.
- Sieper, J. – Deodhar, A. – Marzo-Ortega, H., et al.: MEASURE 2 Study Group: Secukinumab efficacy in anti-TNF-naïve and anti-TNF-experienced subjects with active ankylosing spondylitis: results from the MEASURE 2 Study. *Ann Rheum Dis*, 2017, 76, s. 571–592.
- Dougados, M. – Lardy-Cléuad, A. – Desfleurs, E., et al.: Impact of the time of initiation and line of biologic therapy on the retention rate of secukinumab in axial spondyloarthritis (axSpA): data from the French multicentre retrospective FORSYA study. *RMD Open*, 2024, 10, e003942.
- Sivera, F. – Núñez-Monje, V. – Campos-Fernández, C., et al.: Real-world experience with secukinumab in the entire axial spondyloarthritis spectrum. *Front Med*, 2023, 10, 1156557.
- Moreno-Ramos, M. J. – Sanchez-Piedra, C. – Martínez-González, O., et al.: Real-world effectiveness and treatment retention of secukinumab in patients with psoriatic arthritis and axial spondyloarthritis: a descriptive observational analysis of the Spanish BIOBADASER registry. *Rheumatol Ther*, 2022, 9, s. 1031–1047.
- Coates, L. C. – Soriano, E. R. – Corp, N., et al.: Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nature reviews. Rheumatology*, 2022, 18, s. 465–479.
- Braun, J. – Baraliakos, X. – Deodhar, A., et al.: Secukinumab shows sustained efficacy and low structural progression in ankylosing spondylitis: 4-year results from the MEASURE 1 study. *Rheumatology*, 2019, 58, s. 859–868.
- Baraliakos, X. – Østergaard, M. – Gensler, L. S., et al.: Comparison of the effects of secukinumab and adalimumab biosimilar on radiographic progression in patients with ankylosing spondylitis: design of a randomized, phase IIIb study (SURPASS). *Clin Drug Investig*, 2020, 40, s. 269–278.
- Baraliakos, X. – Østergaard, M. – Poddubnyy, D., et al.: Effect of secukinumab versus adalimumab biosimilar on radiographic progression in patients with radiographic axial spondyloarthritis: a randomized phase IIIb study. *Ann Rheum Dis*, 2023, 82, s. 38–40.
- Pavelka, K. – Kivitz, A. – Dokoupilova, E., et al.: Efficacy, safety, and tolerability of secukinumab in patients with active ankylosing spondylitis: a randomized, double-blind phase 3 study, MEASURE 3. *Arthritis Res Ther*, 2017, 19, s. 285.
- Pavelka, K. – Kivitz, A. – Dokoupilova, E., et al.: MEASURE 3 study group: Secukinumab 150/300 mg provides sustained improvements in the signs and symptoms of active ankylosing spondylitis: 3-year results from the phase 3 MEASURE 3 study. *ACR Open Rheumatol*, 2020, 2, s. 119–127.

Abrocitinib a jeho postavení v léčbě atopické dermatitidy – kazuistika

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- Lé, A. M. – Gooderham, M. – Torres, T.: Abrocitinib for the treatment of atopic dermatitis. *Immunotherapy*, 2023, 15, s. 1351–1362.
- Olydam, J. I. – Schlösser, A. R. – Custurone, P., et al.: Real-world effectiveness of abrocitinib treatment in patients with difficult-to-treat atopic dermatitis. *J Eur Acad Dermatol Venereol*, 2023, 37, s. 2537–2542.
- Niculet, E. – Bobeica, C. – Stefanopol, I. A., et al.: Once-daily abrocitinib for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents aged 12 years and over: a short review of current clinical perspectives. *Ther Clin Risk Manag*, 2022, 18, s. 399–407.
- Shi, V. Y. – Bhutani, T. – Fonacier, L., et al.: Phase 3 efficacy and safety of abrocitinib in adults with moderate-to-severe atopic dermatitis after switching from dupilumab (JADE EXTEND). *J Am Acad Dermatol*, 2022, 87, s. 351–358.
- Simpson, E. L. – Silverberg, J. I. – Nosbaum, A., et al.: Integrated safety analysis of abrocitinib for the treatment of moderate-to-severe atopic dermatitis from the phase II and phase III clinical trial program. *Am J Clin Dermatol*, 2021, 22, s. 693–707.
- Cibinqo 200 mg Potahovaná tableta. Mediately. Dostupné z: <https://mediately.co/cz/drugs/Ld1AuWKZVwg8DiLTanHIRpn38M1/cibinqo-200mg-potahovana-tableta>, vyhledáno 5. 3. 2024.
- Cibinqo – opinion on variation to marketing authorisation. Abrocitinib. Dostupné z: <https://www.ema.europa.eu/en/medicines/human/variation/cibinqo>, vyhledáno 5. 3. 2024.

Biologická a cílená nebiologická léčba závažné ložiskové psoriázy v praxi

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- Cetkovská, P. – Kojanová, M. – Arenberger, P., et al.: Současný stav moderní léčby psoriázy – aktualizovaná doporučení ČDS JEP k cílené léčbě závažné chronické psoriázy. *Čes-slov Derm*, 2019, 94, s. 135–162.
- Cetkovská, P. – Kojanová, M.: Česká doporučení k biologické léčbě závažné chronické ložiskové psoriázy. *Čes-slov Derm*, 2012, 87, s. 1–76.
- Cetkovská, P. – Lomicová, I.: Psoriáza. In: Benáková, N.: *Moderní farmakoterapie v dermatologii*. Praha, Maxdorf, 2020.
- Menter, A. – Strober, B. E. – Kaplan, D. H., et al.: Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*, 2019, 80, s. 1029–1072.
- Elmets, C. A. – Leonardi, C. L. – Davis, D. M. R., et al.: Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with awareness and attention to comorbidities. *J Am Acad Dermatol*, 2019, 80, s. 1073–1113.
- Torres, T. – Puig, L.: Apremilast: a novel oral treatment for psoriasis and psoriatic arthritis. *Am J Clin Dermatol*, 2018, 19, s. 23–32.

Screening psoriatické artritidy v reálné klinické praxi dermatologa a revmatologa

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- Haroon, M. – Gallagher, P. – FitzGerald, O.: Diagnostic delay of more than 6 months contributes to poor radiographic and functional outcome in psoriatic arthritis. *Ann Rheum Dis*, 2015, 74, s. 1045–1050.
- Ibrahim, G. H. – Buch, M. H. – Lawson, C., et al.: Evaluation of an existing screening tool for psoriatic arthritis in people with psoriasis and the development of a new instrument: the Psoriasis Epidemiology Screening Tool (PEST) questionnaire. *Clin Exp Rheumatol*, 2009, 27, s. 469–474.
- Kampylafka, E. – Simon, D. – d'Oliveira, I., et al.: Disease interception with interleukin-17 inhibition in high-risk psoriasis patients with subclinical joint inflammation—data from the prospective IVEPSA study. *Arthritis Res Ther*, 2019, 21, s. 178.
- Acosta Felquer, M. L. – LoGiudice, L. – Galimberti, M. L., et al.: Treating the skin with biologics in patients with psoriasis decreases the incidence of psoriatic arthritis. *Ann Rheum Dis*, 2022, 81, s. 74–79.
- Kirkham, B. – de Vlam, K. – Li, W., et al.: Early treatment of psoriatic arthritis is associated with improved patient-reported outcomes: findings from the etanercept PRESTA trial. *Clin Exp Rheumatol*, 2015, 33, s. 11–19.
- Gottlieb, A. – Merola, J. F.: Psoriatic arthritis for dermatologists. *J Dermatolog Treat*, 2020, 31, s. 662–679.
- Dhabale, A. – Nagpure, S.: Types of psoriasis and their effects on the immune system. *Cureus*, 2022, 14, e29536.
- Ogdie, A. – Hur, P. – Liu, M., et al.: Effect of multidomain disease presentations on patients with psoriatic arthritis in the corona psoriatic arthritis/spondyloarthritis registry. *J Rheumatol*, 2021, 48, s. 698–706.
- Gottlieb, A. B. – Merola, J. F.: Axial psoriatic arthritis: An update for dermatologists. *J Am Acad Dermatol*, 2021, 84, s. 92–101.
- Scher, J. U. – Ogdie, A. – Merola, J. F., et al.: Preventing psoriatic arthritis: focusing on patients with psoriasis at increased risk of transition. *Nat Rev Rheumatol*, 2019, 15, s. 153–166.
- Gottlieb, A. B. – Merola, J. F.: A clinical perspective on risk factors and signs of subclinical and early psoriatic arthritis among patients with psoriasis. *J Dermatolog Treat*, 2022, 33, s. 1907–1915.
- Loo, W. Y. – Tee, Y. C. – Han, W. H., et al.: Predictive factors of psoriatic arthritis in a diverse population with psoriasis. *J Int Med Res*, 2024, 52, 3000605231221014.

Dlouhotrvající kompletní remise generalizovaného karcinomu gastroezofageální junkce při léčbě kombinací paklitaxelu a ramucirumabu – kazuistika

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- 1 Al-Batran, S. E. – Homann, N. – Pauligk, C., et al.: Effect of neoadjuvant chemotherapy followed by surgical resection on survival in patients with limited metastatic gastric or gastroesophageal junction cancer: The AIO-FLOT3 trial. *JAMA Oncol*, 2017, 3, s. 1237–1244.
- 2 Al-Batran, S. E. – Goetze, T. O. – Mueller, D. W., et al.: The RENAISSANCE (AIO-FLOT5) trial: effect of chemotherapy alone vs. chemotherapy followed by surgical resection on survival and quality of life in patients with limited-metastatic adenocarcinoma of the stomach or esophagogastric junction – a phase III trial of the German AIO/CAO-V/CAOGL. *BMC Cancer*, 2017, 17, s. 893.
- 3 Kroese, T. E. – van Laarhoven, H. W. M. – Schoppman, S. F., et al.; OMEC collaborators: Definition, diagnosis and treatment of oligometastatic oesophagogastric cancer: A Delphi consensus study in Europe. *Eur J Cancer*, 2023, 185, s. 28–39.
- 4 Le Rhun, E. – Guckenberger, M. – Smits, M., et al.; EANO Executive Board and ESMO Guidelines Committee: EANO-ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up of patients with brain metastasis from solid tumours. *Ann Oncol*, 2021, 32, s. 1332–1347.
- 5 Wilke, H. – Muro, K. – Van Cutsem, E.; RAINBOW Study Group: Ramucirumab plus paclitaxel versus placebo plus paclitaxel in patients with previously treated advanced gastric or gastro-oesophageal junction adenocarcinoma (RAINBOW): a double-blind, randomised phase 3 trial. *Lancet Oncol*, 2014, 15, s. 1224–1235.

Ustekinumab v terapii idiopatických střevních zánětů

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- 1 Lukáš, M.: Ustekinumab, nová biologická léčba pro nemocné s Crohnovou chorobou. *Gastroent Hepatol*, 2017, 71, s. 178–180.
- 2 Sandborn, W. J. – Gasink, C. – Gao, L. L., et al.: Ustekinumab induction and maintenance therapy in refractory Crohn's disease. *N Engl J Med*, 2012, 367, s. 1519–1528.
- 3 Feagan, B. G. – Sandborn, W. J. – Gasink, C., et al.: Ustekinumab as induction and maintenance therapy for Crohn's disease. *N Engl J Med*, 2016, 375, s. 1946–1960.
- 4 Battat, R. – Kopylov, U. – Bessissow, T., et al.: Association of ustekinumab trough concentration with clinical, biochemical and endoscopic outcome. Prezentováno na: 11th Congress of ECCO, Amsterdam, 2016.
- 5 Sandborn, W. J. – Rebutck, R. – Wang, Y., et al.: Five-year efficacy and safety of ustekinumab treatment in Crohn's disease: the IMUNITY trial. *Clin Gastro Hepatol*, 2022, 20, s. 578–590.
- 6 Friedman, K. – Marano, C. – Zhang, H., et al.: Effects of ustekinumab induction therapy on endoscopic and histological healing in the UNIFI phase 3 study in ulcerative colitis. *J Crohn's Colitis*, 2019, 13, suppl. 1, s. S073.
- 7 Sandborn, W. – Sands, B. E. – Panaccione, R., et al.: Efficacy and safety of ustekinumab as maintenance therapy in ulcerative colitis: week 44 results from UNIFI. *J Crohn's Colitis*, 2019, 13, suppl. 1, s. S025–S026.
- 8 Adedokun, O. J. – Xu, Z. – Marano, C., et al.: Pharmacokinetics and exposure-response relationships of intravenously administered ustekinumab during induction treatment patients with ulcerative colitis: results from the UNIFI induction study. *DDW*, 2019, San Diego Tu1749.
- 9 Affif, W. – Arasaradnam, P. R. – Abrue, M. T., et al.: Efficacy and safety of ustekinumab for ulcerative colitis through 4 years: Final results of the UNIFI long-term maintenance study. *Am J Gastro*, 2024, DOI: 10.14309/ajg.0000000000002621.

Mirikizumab – začátek nové éry protilátek proti interleukinu 23 v léčbě idiopatických střevních zánětů

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- 1 SPC Omvoh, dostupné z: https://www.ema.europa.eu/cs/documents/product-information/omvoh-epar-product-information_cs.pdf, vyhledáno 18. 3. 2024.
- 2 Noviello, D. – Mager, R. – Roda, G., et al.: The IL23-IL17 Immune Axis in the treatment of ulcerative colitis: successes, defeats, and ongoing challenges. *Front Immunol*, 2021, 12, 611256.
- 3 Steere, B. – Schmitz, J. – Powell, N., et al.: Mirikizumab regulates genes involved in ulcerative colitis disease activity and anti-TNF resistance: results from a phase 2 study. *Clin Transl Gastroenterol*, 2023, 14, e00578.
- 4 Johnson, T. – Steere, B. – Zhang, P., et al.: Mirikizumab-induced transcriptome changes in ulcerative colitis patient biopsies at week 12 are maintained through week 52. *Clin Transl Gastroenterol*, 2023, 14, e00630.
- 5 Chua, L. – Friedrich, S. – Zhang, X. C.: Mirikizumab pharmacokinetics in patients with moderately to severely active ulcerative colitis: results from phase III LUCENT studies. *Clin Pharmacokinet*, 2023, 62, s. 1479–1491.
- 6 Mitrova, K. – Pipek, B. – Bortlík, M., et al.: Safety of ustekinumab and vedolizumab during pregnancy-pregnancy, neonatal, and infant outcome: a prospective multicentre study. *J Crohn's Colitis*, 2022, 16, s. 1808–1815.
- 7 Feagan, B. G. – Sandborn, W. J. – D'Haens, G., et al.: Induction therapy with the selective interleukin-23 inhibitor risankizumab in patients with moderate-to-severe Crohn's disease: a randomised, double-blind, placebo-controlled phase 2 study. *Lancet*, 2017, 389, s. 1699–1709.
- 8 Sandborn, W. J. – Ferrante, M. – Bhandari, B. R., et al.: Efficacy and safety of mirikizumab in a randomized phase 2 study of patients with ulcerative colitis. *Gastroenterology*, 2020, 158, s. 537–549.e10.
- 9 D'Haens, G. – Dubinsky, M. – Kobayashi, T., et al.: Mirikizumab as induction and maintenance therapy for ulcerative colitis. *N Engl J Med*, 2023, 388, s. 2444–2455.
- 10 Travis, S. – Potts Bleakman, A. – Dubinsky, M. C., et al.: The communicating needs and features of IBD experiences (CONFIDE) Study: US and European patient and health care professional perceptions of the experience and impact of symptoms of moderate-to-severe ulcerative colitis. *Inflamm Bowel Dis*, 2023, doi: 10.1093/ibd/izad142.
- 11 Dubinsky, M. C. – Clemow, D. B. – Hunter Gibble, T., et al.: Clinical effect of mirikizumab treatment on bowel urgency in patients with moderately to severely active ulcerative colitis and the clinical relevance of bowel urgency improvement for disease remission. *Crohn's Colitis 360*, 2022, doi: 10.1093/crocol/otac044.
- 12 D'Haens, G. – Higgins, P. D. R. – Peyrin-Birolet, L., et al.: Extended induction and prognostic indicators of response in patients treated with mirikizumab with moderately to severely active ulcerative colitis in the LUCENT trials. *Inflamm Bowel Dis*, 2024, doi: 10.1093/ibd/izae004.
- 13 Sands, B. E. – D'Haens, G. – Clemow, D. B., et al.: Two-year efficacy and safety of mirikizumab following 104 weeks of continuous treatment for ulcerative colitis: results from the LUCENT-3 open-label extension study. *Inflamm Bowel Dis*, 2024, doi: 10.1093/ibd/izae024.