

Publikationen

Navigating the orphan medicinal product designation: Evidence requirements for gene therapies in Europe. Gloria M Palomo, Tomas Pose-Boirazian, Frauke Naumann-Winter, Enrico Costa, Dinah M Duarte, Maria E Kalland, **Eva Malikova**, Darius Matusevicius, Dinko Vitezic, Kristina Larsson, Armando Magrelli, Violeta Stoyanova-Beninska, Segundo Mariz. *Mol Ther.* 2025 Jun 4;33(6):2834-2841. doi: 10.1016/j.ymthe.2024.10.015. Epub 2024 Oct 28.

Advancing rare disease treatment: EMA's decade-long insights into engineered adoptive cell therapy for rare cancers and orphan designation. Kalland ME, Pose-Boirazian T, Palomo GM, Naumann-Winter F, Costa E, Matusevicius D, Duarte DM, **Malikova E**, Vitezic D, Larsson K, Magrelli A, Stoyanova-Beninska V, Mariz S. *Gene Ther.* 2024 Jul;31(7-8):366-377. doi: 10.1038/s41434-024-00446-0. Epub 2024 Mar 14. PMID: 38480914

The European landscape for gene therapies in orphan diseases: 6-year experience with the EMA Committee for Orphan Medicinal Products. Palomo GM, Pose-Boirazian T, Naumann-Winter F, Costa E, Duarte DM, Kalland ME, **Malikova E**, Matusevicius D, Vitezic D, Larsson K, Magrelli A, Stoyanova-Beninska V, Mariz S. *Mol Ther.* 2023 Dec 6;31(12):3414-3423. doi: 10.1016/j.ymthe.2023.09.020. Epub 2023 Oct 4. PMID: 37794679

Licensing of Orphan Medicinal Products-Use of Real-World Data and Other External Data on Efficacy Aspects in Marketing Authorization Applications Concluded at the European Medicines Agency Between 2019 and 2021. Naumann-Winter F, Wolter F, Hermes U, **Malikova E**, Lilienthal N, Meier T, Kalland ME, Magrelli A. *Front Pharmacol.* 2022 Aug 11;13:920336. doi: 10.3389/fphar.2022.920336. eCollection 2022. PMID: 36034814

Availability and Accessibility of Orphan Medicinal Products to Patients in Slovakia in the Years 2010-2019. Foltanova T, Majernik A, **Malikova E**, Kosirova S. *Front Pharmacol.* 2022 Jan 26;13:768325. doi: 10.3389/fphar.2022.768325. eCollection 2022. PMID: 35153774

Pioglitazone restores phosphorylation of downregulated caveolin-1 in right ventricle of monocrotaline-induced pulmonary hypertension. **Malikova E**, Kmecova Z, Doka G, Pivackova LB, Balis P, Trubacova S, Velasova E, Krenek P, Klimas J. *Clin Exp Hypertens.* 2022 Feb 17;44(2):101-112. doi: 10.1080/10641963.2021.1996589. Epub 2021 Nov 7. PMID: 34747283

Altered serum levels of neprilysin in heart failure patients with reduced ejection fraction. Nemcekova V, **Malikova E**, Goncalvesova E, Krenek P, Klimas J. *Bratisl Lek Listy.* 2021;122(1):28-33. doi: 10.4149/BLL_2021_002. PMID: 33393317

Defining Satisfactory Methods of Treatment in Rare Diseases When Evaluating Significant Benefit-The EU Regulator's Perspective. Sheean ME, Naumann-Winter F, Capovilla G, Kalland ME, **Malikova E**, Mariz S, Matusevicius D, Nistico R, Schwarzer-Daum B, Tsigkos S, Tzogani K, Larsson K, Magrelli A, Stoyanova-Beninska V. *Front Med (Lausanne).* 2021 Aug 27;8:744625. doi: 10.3389/fmed.2021.744625. eCollection 2021. PMID: 34513895

Disease severity-related alterations of cardiac microRNAs in experimental pulmonary hypertension. Kmecova Z, Veteskova J, Lelkova-Zirova K, Bies Pivackova L, Doka G, **Malikova E**, Paulis L, Krenek P, Klimas J. *J Cell Mol Med.* 2020 Jun;24(12):6943-6951. doi: 10.1111/jcmm.15352. Epub 2020 May 12. PMID: 32395887

Effects of inorganic nitrate in a rat model of monocrotaline-induced pulmonary arterial hypertension. **Malikova E**, Carlström M, Kmecova Z, Marusakova M, Zsigmondova B, Krenek P, Klimas J, Henrohn D. *Basic Clin Pharmacol Toxicol*. 2020 Feb;126(2):99-109. doi: 10.1111/bcpt.13309. Epub 2019 Sep 12. PMID: 31429204

Nonclinical data supporting orphan medicinal product designations in the area of rare infectious diseases. Sheean ME, **Malikova E**, Duarte D, Capovilla G, Fregonese L, Hofer MP, Magrelli A, Mariz S, Mendez-Hermida F, Nistico R, Leest T, Sipsas NV, Tsigkos S, Vitezic D, Larsson K, Sepodes B, Stoyanova-Beninska V. *Drug Discov Today*. 2020 Feb;25(2):274-291. doi: 10.1016/j.drudis.2019.10.015. Epub 2019 Nov 5. PMID: 31704277

Hepatocyte growth factor plays a particular role in progression of overall cardiac damage in experimental pulmonary hypertension. Radik M, Kmecova Z, Veteskova J, **Malikova E**, Doka G, Krenek P, Klimas J. *Int J Med Sci*. 2019 Jun 2;16(6):854-863. doi: 10.7150/ijms.31690. eCollection 2019. PMID: 31337959

Opposite alterations of endothelin-1 in lung and pulmonary artery mirror gene expression of bone morphogenetic protein receptor 2 in experimental pulmonary hypertension. Veteskova J, Kmecova Z, **Malikova E**, Doka G, Radik M, Vavrinc P, Krenek P, Klimas J. *Exp Lung Res*. 2019 Feb-Mar;45(1-2):30-41. doi: 10.1080/01902148.2019.1605426. Epub 2019 Apr 23. PMID: 31012341

Downregulation of myogenic microRNAs in sub-chronic but not in sub-acute model of daunorubicin-induced cardiomyopathy. Doka G, **Malikova E**, Galkova K, La Rocca G, Kruzliak P, Adamek M, Rodrigo L, Krenek P, Klimas J. *Mol Cell Biochem*. 2017 Aug;432(1-2):79-89. doi: 10.1007/s11010-017-2999-8. Epub 2017 Mar 16. PMID: 28303410

Ramipril restores PPAR β/δ and PPAR γ expressions and reduces cardiac NADPH oxidase but fails to restore cardiac function and accompanied myosin heavy chain ratio shift in severe anthracycline-induced cardiomyopathy in rat. Cernecka H, Doka G, Srankova J, Pivackova L, **Malikova E**, Galkova K, Kyselovic J, Krenek P, Klimas J. *Eur J Pharmacol*. 2016 Nov 15;791:244-253. doi: 10.1016/j.ejphar.2016.08.040. Epub 2016 Aug 31. PMID: 27592051

Local and systemic renin-angiotensin system participates in cardiopulmonary-renal interactions in monocrotaline-induced pulmonary hypertension in the rat. **Malikova E**, Galkova K, Vavrinc P, Vavrincova-Yaghi D, Kmecova Z, Krenek P, Klimas J. *Mol Cell Biochem*. 2016 Jul;418(1-2):147-57. doi: 10.1007/s11010-016-2740-z. Epub 2016 Jun 25. PMID: 27344167