Curriculum Vitae

Personal information

Niklas Ekman

Work experience

1. Employer: Finnish Medicines Agency
   - Start date: 01/2018
   - End date:
   - Position: Head of Biological Section
   - Activities: Management of the Biological Section, assessment of biological medicinal products; marketing authorisation applications and scientific advices
   - Country: Finland
2. Employer: Finnish Medicines Agency
   - Start date: 12/2006
   - End date: 12/2017
   - Position: Senior Researcher
   - Activities: Quality assessor for biological medicinal products; Marketing authorisation and variation applications (centralised, MRP/DCP, and national applications), Scientific advices (EMA and national), Clinical trial applications (national)
   - Country: Finland
3. Employer: Cancer Cell Circuitry Laboratory, Biomedicum Helsinki, University of Helsinki, Finland
   - Start date: 01/2004
   - End date: 12/2006
   - Position: Finnish Academy Postdoctoral Researcher
   - Activities: Laboratory research in the field of cell cycle regulation
   - Country: Finland
4. Employer: Molecular/Cancer Biology Laboratory, Biomedicum Helsinki and Helsinki Biomedical Graduate School, University of Helsinki, Finland
   - Start date: 01/1999
   - End date: 01/2004
   - Position: Ph. D student, Postdoctoral researcher
   - Activities: Laboratory research in the field of intracellular signal transduction
   - Country: Finland

Education and training

1. Subject: Ph. D. student at Molecular/Cancer Biology Laboratory, Biomedicum Helsinki and Helsinki Biomedical Graduate School, University of Helsinki, Finland
   - Start date: 12/1999
   - End date: 06/2003
   - Qualification: Ph. D
   - Organisation: Planning and conduction of scientific experiments, cell culture research, use of knock-out and transgenic models, production of viral gene therapy vectors for use in in vitro gene transfer, production and characterisation of recombinant proteins
   - Country: Finland
2. Subject: Faculty of Science, University of Helsinki, Finland
   - Start date: 09/1992
   - End date: 12/1999
   - Qualification: M. Sc
   - Organisation: Molecular genetics, biochemistry, human physiology
   - Country: Finland

Additional information

Publications

1. Kirsch-Stefan N, Guillen E, Ekman N et al. Do the Outcomes of Clinical Efficacy Trials Matter in Regulatory Decision-Making for Biosimilars? BioDrugs. 2023 Nov;37(6):855-871
2. Guillen E, Ekman N et al. A Data Driven Approach to Support Tailored Clinical Programs for Biosimilar Monoclonal Antibodies. Clin Pharmacol Ther. 2023 Jan;113(1):108-123
3. Kurki P, Kang HN, Ekman N et al. Regulatory Evaluation of Biosimilars: Refinement of Principles Based on the Scientific Evidence and Clinical Experience. BioDrugs. 2022 May;36(3):359-371.
4. Wadhwa M, Kang HN, Thorpe R, Knezevic I; following participants of the WHO informal consultation on revision of guidelines on evaluation of similar biotherapeutic products; Aprea P, Bielsky MC, Ekman N et al. WHO informal consultation on revision of guidelines on evaluation of similar biotherapeutic products, virtual meeting, 30 June - 2 July 2021. Biologicals. 2022 Apr;76:1-9
5. Kurki P, Ekman N.Biosimilar regulation in the EU. Expert Rev Clin Pharmacol. 2015;8(5):649_59
6. Weise M, Bielsky MC, De Smet K, Ehman F, Ekman N, et al. Biosimilars: what clinicians should know. Blood Oct 23 (2012)
7. Schneider CK, Borg JJ, Ehmann F, Ekman N, et al. In support of the European Union biosimilar framework. Nat Biotechnol. 30(8):745_8 (2012)
8. Weise M, Bielsky MC, De Smet K, Ehmann F, Ekman N, et al. Biosimilars – yhy terminology matters. Nat Biotechnol. 29(8):690_3 (2011)
9. Katajisto P, Vaahtomeri K, Ekman N, et al. LKB1 signaling in mesenchymal cells required for suppression of gastrointestinal polyposis. Nat Genet. 40;455_9 (2008)
10. Londesborough A, Vaahtomeri K, Tiainen M, Katajisto P, Ekman N, et al. LKB1 in endothelial cells is

required for angiogenesis and TGFbeta_mediated vascular smooth muscle cell recruitment. Development 135:2331_8 (2008)
11. Katajisto P., Vallenius T., Vaahtomeri K., Ekman N, et al. The LKB1 tumor suppressor kinase in human disease. Biochim Biophys Acta Aug 16 (2006)
12. Saharinen P., Kerkela K., Ekman N., et al.. Multiple angiopoietin recombinant proteins activate the Tie1 receptor tyrosine kinase and promote its interaction with Tie2. J Cell Biol 169; 239_43 (2005)
13. Paavonen K., Ekman N, et al. Bmx tyrosine kinase transgene induces skin hyperplasia, inflammatory angiogenesis, and accelerated wound healing. Mol Biol Cell 15; 4226_33 (2004)
14. Zhang R., Xu Y., Ekman N, et al. Etk/Bmx transactivates vascular endothelial growth factor 2 and recruits phosphatidylinositol 3_kinase to mediate the tumor necrosis factor_induced angiogenic pathway. J Biol Chem 278; 51267_76 (2003)
15. Abassi, Y.A., Rehn, M., Ekman, N, et al. p130Cas Couples the tyrosine kinase Bmx/Etk with regulation of the actin cytoskeleton and cell migration. J Biol Chem 278, 35636_43 (2003)
16. Rajantie, I., Ekman, N, et al. Bmx tyrosine kinase has a redundant function downstream of angiopoietin and vascular endothelial growth factor receptors in arterial endothelium. Mol Cell Biol 21, 4647_55 (2001)
17. Ekman, N., et al. The Bmx tyrosine kinase is activated by IL_3 and G_CSF in a PI_3K dependent manner. Oncogene 19, 4151_58 (2000)
18. Saharinen, P., Ekman, N, et al. The Bmx tyrosine kinase induces activation of the Stat signaling pathway, which is specifically inhibited by protein kinase Cdelta. Blood 90, 4341_53 (1997)
19. Ekman, N., et al. Bmx tyrosine kinase is specifically expressed in the endocardium and the endothelium of large arteries. Circulation 96, 1729_32 (1997)

Projects

Memberships

CHMP Similar Biological (Biosimilar) Medicinal Working Party (BMWP)

- Vice-chair 2017-
- Member 2009-

CHMP Biological Working Party (BWP)

- Member 2022-
- Alternate member 2013-2021
- Contributing expert 2007-2013

CAT Gene Therapy Working Party (GTWP)

- Member 2011-2012

Other Relevant Information