



Issue 5 - October 2019

HemAffairs holds your regular dose of policy, regulatory and pharma news with impact on hematology in Europe. We also keep you abreast of relevant publications and events to keep an eye on. Enjoy the read.

We are always eager to grow the hematology savvy community and are very happy with you forwarding HemAffairs to individuals and organisations in your network with an interest in the news we share. They can subscribe to this newsletter and from then on be part of our mailing list, in full respect of data protection and privacy. All they need to do is email us at communication@ehaweb.org.

cOAlition S: Open access to scientific research



Research and academic groundwork funded with public means should be free and open to everyone. That is the principle behind Open Access that was formulated in 2003 in the [Berlin Declaration](#). More than a decade has passed since and for years no significant action was taken. Scientific research, paid for by the taxpayer, is still mostly locked behind paywalls. Until 2018, when a group of national research funding organizations, with the support of the European Commission and the European Research Council (ERC), established cOAlition S and presented the 'Plan S'. This initiative is essential towards making full and immediate Open Access to research publications a reality, but still has a long way to go.

[Read more...](#)

Without access to treatment, can we truly innovate in rare diseases?



There have been many developments on rare diseases since the EU [Orphan Medicinal Products Regulation](#) came into force in 2000. As the European Commission is evaluating its effectiveness, EHA discussed with Prof. Giampaolo Merlini, Director of the Amyloidosis Research and Treatment Center and researcher at the Department of Molecular Medicine of the University of Pavia, how far we have come and what still needs to be done to improve access to treatment for rare diseases.

[Read more...](#)

COST Action: EuNet-INNOCHRON



The [new Action](#) of the **European Cooperation in Science and Technology (COST)**, the EU-funded, intergovernmental framework aiming to create pan-European research networks, is entitled the “European Network for Innovative Diagnosis and Treatment of Chronic Neutropenias” (EuNet-INNOCHRON). It will facilitate collaboration among top-level European experts from different scientific areas, e.g. Clinical and Laboratory Hematology, Immunology, Genetics, Molecular Biology and Regenerative Medicine for better characterization, diagnosis and treatment of diseases.

[Read more...](#)

Announcements



EHA's Prof. Jäger elected HCPWP co-chair

Prof. Ulrich Jäger, former EHA President and current member of the EHA European Affairs Committee, was elected on September 24 as co-chair of the Health Care Professionals Working Party (HCPWP) of the European Medicines Agency (EMA). Having represented EHA in the HCPWP for several years, Prof. Jäger was elected by fellow members of the working party as co-chair of the HCPWP for its 2019-2022 mandate.

[Read more...](#)



Prof. Chomienne on Mission Board for Cancer

EHA-supported candidate Christine Chomienne was selected as one of the members of the Mission Board for Cancer, which will advise the European Commission on the development of specific research and innovation programs targeting cancer. The 15-member group of experts was announced in mid-summer, along with four other Mission Boards, to support the 'moonshot mission' approach to Horizon Europe, the EU's next multiannual R&I funding program. Prof. Chomienne is a former EHA President and currently directs the research and innovation division of the Institut National Du Cancer (INCa) in France.

[Read more...](#)

Regulatory news



Three generic medicines approved

The EMA Committee for Medicinal Products for Human Use (CHMP) approved and recommended to grant market authorisation for three hematology-related medicines:

- **Arsenic trioxide Accord (arsenic trioxide)**, used to treat acute promyelocytic leukaemia;
- **Bortezomib Fresenius Kabi (bortezomib)**, a medicine for multiple myeloma and mantle cell lymphoma;
- **Ivozall (clofarabine)**, for the treatment of acute lymphoblastic leukaemia in paediatric patients.

New market authorisations

Xospata (gilteritinib) receives positive opinion: EMA's CHMP adopted a positive opinion regarding market authorisation for Xospata, a medicine used in adults who have relapsed or refractory acute myeloid leukaemia (AML) with a FLT3 mutation. The active substance of Xospata is gilteritinib, a protein kinase inhibitor which inhibits FLT3 proliferation in cells and subsequently induces apoptosis in leukaemia cells.

Ultomiris is authorized: EMA's CHMP authorized Ultomiris, a medicine used to

Xromi gets market authorisation:

The CHMP authorized Xromi, a medicine used in adults, adolescents and children over two years of age who have sickle cell disease. Xromi is used to prevent so-called vaso-occlusive complications – problems that happen when blood vessels become blocked by the abnormal red blood cells, restricting the flow of blood to parts of the body.

treat adults with paroxysmal nocturnal hemoglobinuria (PNH). Ultomiris is used in patients who have symptoms of the disease as well as in patients who have stable blood levels of the enzyme lactate dehydrogenase (LDH).

Pharma news



EU Pharmaceutical organization releases code of practice

The Statutory General Assembly of EFPIA approved its revised [Code of Practice](#) on June 27, 2019. The document consists of ethical rules that member pharmaceutical companies and associations agree to follow for promoting medicinal products to healthcare professionals and organizations, as well as patients.

Publications



[Report on support to quality development in early access approaches](#), July 31, 2019. EMA and the U.S. Food and Drug Administration (FDA) published a report on their 2018 joint stakeholder workshop. The event addressed approaches to tackle quality and manufacturing challenges that medicine producers face under early access programmes, such as the PRiority Medicine Scheme (PRIME) in the European Union.



[Defining value in "value-based healthcare"](#), July 19, 2019. The European Commission's Expert Panel on effective ways of investing in Health (EXPH) has released a report on how to define the value of care, and support healthcare systems in becoming more effective, accessible and resilient.



["Nothing about us without us": How patient advocacy is changing the game](#), August 19, 2019. YoungEHA's Nuno Borges discussed how to get involved in patient advocacy with Zack Pemberton-Whiteley, Patient Advocacy Director at Leukaemia Care (UK) and Chair of the global Acute Leukemia Advocates Network (ALAN).

Events

[2nd European CAR T Cell Meeting](#)

Organized by EHA and the European Society for Blood and Marrow Transplantation

January 30 - February 1, 2020

Sitges, Spain

[Innovation Bootcamp in Rare Diseases 2019](#)

PROFILE Innovative Training Network

November 4-5, 2019

Leuven, Belgium



EHA | Towards a cure for all blood disorders
The European Hematology Association (EHA) promotes excellence in patient care, research and education in hematology. EHA envisions a world without blood disorders by connecting hematologists worldwide, supporting their career development and research, harmonizing hematology education and advocating the interests of hematology and hematologists in the European arena.

EHA Executive Office
Koninginnegracht 12B
2514 AA The Hague, The Netherlands
T: +31 (0) 70 3020 099
W: www.ehaweb.org | E: info@ehaweb.org

EHA | POWERED BY YOU!

You are receiving this email because you are an EHA member.
If you no longer wish to receive any EHA updates, you may change your subscription preferences [here](#).



EHA, Koninginnegracht 12b, 2514 AA, The Hague, Netherlands

You may [unsubscribe](#) or [change your contact details](#) at any time.