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Kedrion Biopharma and Sobi sign on to ground-breaking PARTNERS programme working towards sustainable haemophilia treatment and care in Europe

Kedrion Biopharma, an Italian plasma-derived haemophilia treatment manufacturer, and Swedish Orphan Biovitrum AB (Sobi™), supplier of extended half-life (EHL) haemophilia treatment products, signed a Memorandum of Understanding (MoU) with the European Haemophilia Consortium (EHC) in support of the EHC **Procurement of Affordable Replacement Therapies – Network of European Relevant Stakeholders (PARTNERS)** programme. Through this agreement, the companies commit to supporting the PARTNERS programme to increase access to vital treatment for over 5000 people with haemophilia in European countries that currently significantly undertreat haemophilia patients, substantially improving their quality of life.

Background

Through systematic data gathering and close collaboration with its National Member Organisations (NMOs), the EHC has long been monitoring the level of haemophilia care throughout Europe. Though there have been improvements in many areas, there remain disparities in access to treatment and quality of care for people with haemophilia. In several countries with developed health care systems but limited budgets, sustainable levels of factor replacement to effectively treat haemophilia are not available. This results in lack of treatment or under-treatment, which in turn can lead to debilitating, or even potentially fatal, consequences for the people with haemophilia in those countries. It also places a burden on those countries' broader health and social systems.

PARTNERS programme

To address these urgent issues, the EHC has developed a new and innovative approach to create a sustainable procurement model for treatment for haemophilia A and haemophilia B in countries located both inside and outside of the European Union. The main objectives of the PARTNERS programme are to work with national health care systems in order to:

1. Enable countries to provide adequate levels of factor concentrate that will result in improved levels of treatment for people with haemophilia. Governments will be able to purchase much larger quantities of quality treatment without significantly increasing their national haemophilia budget.

2. Formally involve haemophilia clinicians and patient representatives in the national procurement process in an effort to inform selection and the sustainability of health

care systems. In the experience of the EHC, this type of model leads to a more cost-effective process.

3. Encourage collaboration between all stakeholders, including companies willing to participate in a fair and transparent tendering system that seeks to improve standards of care for people with haemophilia within these countries.

The criteria for country participation in PARTNERS are based on the latest set of recommendations from the Council of Europe's European Directorate for the Quality of Medicines and Healthcare (EDQM) consensus meetings for the optimal treatment of haemophilia in Europe. Eligible countries are those that **do not** meet the recommended minimum treatment levels of 4 International Units (IU) factor VIII replacement therapy per capita (2016 recommendations), minimum treatment levels of 0.5 IU factor IX replacement therapy per capita (2016 recommendations) and **do not** provide prophylactic treatment for all children with severe haemophilia. These minimum levels of treatment are recommended on the basis that they allow for all children to be on some form of prophylaxis, all adults to be at least on on-demand treatment with home therapy, no restriction on a required surgery and possible access to Immune Tolerance Therapy for patients with inhibitors. Governments need to also agree to formally include haemophilia clinicians and patient representatives in national tender/procurement systems as part of the supplier bid evaluation process (2016 recommendations).

Brian O'Mahony, EHC president:
"Today in Europe we still see countries where people affected by haemophilia have the same level of joint damage and poor quality of life as we saw in patients before the advent of modern coagulation factor concentrates in the 1970s and this is unacceptable.

We believe that, with this programme, existing national haemophilia budgets can lead to increased quantities of treatment purchased through better tender systems. This ambitious project aims to provide an increased access to treatment but also to include patients and health care professionals in the decision-making process of the organisation of haemophilia care in any given countries. We are also very thankful for the support of all of our partners without which this project would not become a reality."

Stakeholders

One of the most important aspects, without which this programme would not be possible, is the involvement of pharmaceutical companies. Companies supplying treatment products for haemophilia A and haemophilia B (namely Factor VIII and FIX replacement therapies, respectively) that have signed a Memorandum of Understanding with the EHC and who support the PARTNERS programme, express willingness to participate in national tender processes of the eligible and participating countries under standard, bi-lateral and confidential bidding conditions within the national procurement processes in a way that enables the increase in purchasing commitment from the national government in an affordable way.

Lorenzo Melani, Hemophilia Marketing Manager, Kedrion Biopharma:

"Nowadays, we know very well how a patient needs to be treated. Now that we know the goal, we have to speed up the process. We strongly believe that a breakthrough programme, such as PARTNERS, will help patients in a number of countries where treatment levels are not optimal."

Philip Wood, Head of Haemophilia, Sobi:
The PARTNERS programme has the potential to create one unified voice amongst physicians and patients in the tender process. This approach takes sustainable access to a whole new level as people living with haemophilia will have the possibility to access the latest treatments on a long-term basis, raising the standard of care.

Current standing

PARTNERS has received endorsement from the European Patients' Forum and EURORDIS – Rare Diseases Europe, as well as from many Members of the European Parliament (MEPs). To solidify this support on both a European and national level, the EHC officially launched the PARTNERS programme on November 28th in the European Parliament in the presence of MEPs, EU institutions, pharmaceutical companies and patient organisations involved in PARTNERS.

In 2017, the EHC visited several of the eligible 14 countries for a meeting with representatives of their Ministries of Health, Insurance Funds and haemophilia patient organisations to discuss interest in the programme, and an implementation schedule is now being elaborated on.

About Haemophilia

Haemophilia is a rare congenital bleeding disorder resulting from a deficiency in either clotting factor VIII (haemophilia A) or clotting factor IX (haemophilia B), which are essential proteins for the blood clotting process.

Having haemophilia means that when a blood vessel is damaged in that individual's body, the bleeding that occurs lasts for a prolonged amount of time. These bleeds can either be spontaneous or they can be caused by trauma and stress. If the bleed is not stopped with treatment products and properly managed, it can severely and permanently damage the patient's joints (such as ankles, hips and knees), causing affected individuals to have significantly reduced mobility, increased pain and decreased quality of life. Untreated bleeds can also lead to death.

About Kedrion Biopharma

Kedrion Biopharma is an international company that collects and fractionates blood plasma to produce and distribute plasma-derived therapeutic products for use in treating and preventing serious diseases, disorders and conditions such as haemophilia, primary immune system deficiencies and Rh-sensitization.
Kedrion acts as a bridge between donors and the people who need treatments, and works on a global scale to expand patients' access to available treatments.
Additional information about Kedrion Biopharma can be found at www.kedrion.com.

About Sobi

Sobi is an international specialty healthcare company dedicated to rare diseases. Sobi's mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on Haemophilia, Inflammation and Genetic diseases. Sobi also markets a portfolio of specialty and rare disease products across Europe, the Middle East, North Africa and Russia for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2016, Sobi had total revenues of SEK 5.2 billion (USD 608 M) and about 760 employees. The share (STO: SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

Additional Resources

For a detailed description of the consensus recommendations coming out of the EDQM meetings, also known as the "Wildbad Kreuth" meetings, please visit:
http://www.ehc.eu/kreuth-iv-consensus-recommendations/

For more information on the PARTNERS programme, please visit:
https://www.ehc.eu/partners/

To learn more about haemophilia and other congenital bleeding disorders, visit:
www.EHC.eu

Haemophilia Stories is a documentary produced for the EHC, which depicts the daily lives of people with haemophilia in five European countries. It shows the different outcomes that disparities in access to treatment lead to:
https://www.ehc.eu/document/haemophilia-stories-short-videos/

Inhibitor Stories is a follow-up documentary that focuses on people with haemophilia and inhibitors and the various challenges they face:
https://www.ehc.eu/community/2017/10/30/inhibitor-stories-documentary-living-haemophilia-inhibitors/

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