

MEDIA RELEASE

Project Recovery turns unused blood products from Canadian blood donations into hemophilia medicine for developing countries

MONTREAL, September 26, 2013 — In what's being hailed as a world first, precious proteins left over from the manufacture of plasma products from Canadian blood donors are being turned into life- and limb-saving treatments for thousands of people living with hemophilia in developing countries.

A lifelong inherited bleeding disorder, hemophilia affects about 1 in 10,000 people worldwide. Close to seventy-five percent of them receive little or no treatment. Hemophilia is one of a number of such disorders that prevent blood from clotting properly. People with hemophilia experience prolonged internal bleeding that can result from a seemingly minor injury. Bleeding into joints and muscles causes severe pain and disability while bleeding into major organs, such as the brain, can cause death. Hemophilia A (factor VIII deficiency) is treated with factor VIII, a protein necessary for blood coagulation.

The World Federation of Hemophilia (WFH), in partnership with Canadian Blood Services (CBS) and two manufacturers of plasma products, BIOTEST AG and GRIFOLS, will officially announce the launch of **Project Recovery** during the WFH Global Forum on the safety and supply of treatment products for bleeding disorders in Montreal, Canada, on September 26. This humanitarian aid project, first conceived by the Canadian Hemophilia Society (CHS), now becomes a reality after a dozen years of effort.

Project Recovery will transform previously discarded cryoprecipitate from Canadian blood donors into BIOTEST's factor VIII concentrate, called Haemoctin[®], to treat people with hemophilia. It will be channeled through the WFH Humanitarian Aid Program, which focuses on providing for patients in developing countries who have little or no access to these life- and limb-saving medicines and would otherwise be at risk of death or severe disability.

"Project Recovery has the potential to improve the lives of thousands of people with hemophilia all over the world," said Alain Weill, WFH president. "It also allows the WFH to carefully plan where and when these essential medicines will be distributed thereby maximizing the benefits of this wonderful humanitarian endeavour."

It is estimated that in each year of the project at least five million International Units of factor VIII will be donated. This will allow the annual treatment of approximately 5,000 joint hemorrhages, the most common symptom of hemophilia, in children and adults. Without such treatments, the people experiencing these hemorrhages would endure weeks of excruciating pain and, over time, serious joint damage leading to crippling. In addition, early treatment or prevention of these hemorrhages will mean that caregivers—parents, spouses, siblings—will not have to miss work or school to care for the person immobilized at home or in hospital.

This is the first time anywhere in the world that such a partnership has been created to transform surplus cryoprecipitate into factor VIII for humanitarian use. Contracts for this international cooperation were signed in July of 2013 and the first production steps have begun. The WFH will receive the first deliveries of this factor VIII in 2014.

"The CHS was at the origin of Project Recovery more than a decade ago," said Craig Upshaw, Canadian Hemophilia Society president. "We truly appreciate how the partners were able to work through the many legal, technical, commercial and regulatory barriers to success, and hope that other countries will follow the Canadian example."

Factor VIII, a protein essential to blood clotting, is contained in cryoprecipitate, one of the components of plasma. Not all of the cryoprecipitate contained in plasma from Canadian Blood Services donors is needed to make factor VIII for Canadian patients and until now the excess was discarded. With Project Recovery, the cryoprecipitate will be harvested by GRIFOLS at its plant in the U.S., transported by BIOTEST to Germany for manufacturing. This finished pharmaceutical product will be manufactured and released under the BIOTEST license and trademarked Haemoctin, a high purity and double virus inactivated factor VIII product for the treatment of hemophilia A. A portion will be marketed by BIOTEST and the remainder allocated to CBS for donation to the WFH. BIOTEST will also support the WFH in distributing the donated Haemoctin to recipient countries. The partnership is cost neutral for all parties.

“We are a proud partner in Project Recovery,” said Ian Mumford, Canadian Blood Services chief operating officer. “In addition to maximizing the generous gift we receive from our donors, the persistence and strong relationships with stakeholders that have gotten us here will help thousands of deserving patients.”

This Haemoctin donation will be a milestone for the WFH. This project will enable the WFH to expand its Humanitarian Aid Program as part of its comprehensive activities to achieve treatment for all people with bleeding disorders.

About hemophilia and other bleeding disorders

Hemophilia, von Willebrand disease, inherited platelet disorders, and other factor deficiencies are lifelong bleeding disorders that prevent blood from clotting properly. People with bleeding disorders do not have enough of a particular clotting factor, a protein in blood that controls bleeding, or else it does not work properly. The severity of a person's bleeding disorder usually depends on the amount of clotting factor that is missing or not functioning. People with hemophilia can experience uncontrolled bleeding that can result from a seemingly minor injury. Bleeding into joints and muscles causes severe pain and disability while bleeding into major organs, such as the brain, can cause death.

About BIOTEST AG

BIOTEST is a specialist in innovative hematology and immunology with the integrated approach of a pharmaceuticals and biotherapeutics group operating worldwide and develops, produces and sells medicinal products for the treatment of blood and immune disorders. The principal starting material for BIOTEST pharmaceuticals is human plasma, which is processed into medicinal products that are used in the treatment of life-threatening conditions such as coagulation disorders (hemophilia), severe infections or disorders of the immune system. Visit BIOTEST online at biotest.com.

About Canadian Blood Services

Canadian Blood Services is a national, not-for-profit charitable organization that manages the supply of blood and blood products in all provinces and territories outside of Quebec. Canadian Blood Services also oversees the OneMatch Stem Cell and Marrow Network, and provides national leadership for organ and tissue donation and transplantation. Canadian Blood Services operates 42 permanent collection sites and more than 20,000 donor clinics annually. The provincial and territorial Ministries of Health provide operational funding to Canadian Blood Services. The federal government, through Health Canada, is responsible for regulating the blood system.

About the Canadian Hemophilia Society

Founded in 1953, the Canadian Hemophilia Society (CHS) is a national voluntary health charity. Its mission is to improve the health and quality of life of all people with inherited bleeding disorders and ultimately to find a cure. Its vision is a world free from the pain and suffering of inherited bleeding disorders. The CHS is a founding member of the World Federation of Hemophilia. Visit the CHS online at www.hemophilia.ca.

About GRIFOLS

GRIFOLS improves people's lives with high quality innovative hospital products and services. The plasma-derived therapies have outstanding records of efficacy and safety and GRIFOLS is also a world-leading manufacturer of medical devices, analyzers and reagents used by blood banks, transfusion centers, and clinical laboratories. GRIFOLS is one of two custom plasma fractionators for Canadian Blood Services.

About the World Federation of Hemophilia

For 50 years, the World Federation of Hemophilia (WFH), an international not-for-profit organization, has worked to improve the lives of people with hemophilia and other inherited bleeding disorders. Established in 1963, it is a global network of patient organizations in 122 countries and has official recognition from the World Health Organization. Visit WFH online at www.wfh.org.

For more information:

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