Health Canada Approves INTERCEPT Blood System for Plasma

Cerus’ INTERCEPT Blood System is Indicated to Reduce the Risk of Transfusion-Transmitted Infections from Plasma Components

CONCORD, Calif.--(BUSINESS WIRE) - May 23, 2016 - Cerus Corporation (NASDAQ: CERS) today announced that Health Canada has approved the INTERCEPT Blood System for plasma. The INTERCEPT Blood System for plasma is intended to be used for the ex vivo preparation of pathogen-reduced, whole blood derived or apheresis plasma in order to reduce the risk of transfusion-transmitted infection (TTI).

The INTERCEPT Blood System has been approved for use in Europe since 2002 and in the United States since 2014. It is designed to enhance the safety of donated blood components by inactivating a broad spectrum of enveloped viruses, non-enveloped viruses, Gram-positive and Gram-negative bacteria, spirochetes, and parasites, as well as potentially harmful white blood cells present in donor blood.

“While current screening tests have lowered the risks from transfusion-transmitted infections, these tests are reactive approaches only covering a small number of pathogens that pose a risk to the blood supply,” said Carol Moore, SVP, Regulatory Affairs and Quality at Cerus. “Over 300,000 units of plasma are used in transfusion annually in Canada. Health Canada’s approval of the INTERCEPT Blood System now provides an important proactive safety measure for Canadian blood centers to combat transfusion-transmitted infections.”

Platelets, plasma and red blood cells do not require functional DNA or RNA for therapeutic efficacy. However, pathogens (bacteria, viruses and parasites) and white blood cells do require these nucleic acids in order to replicate. The INTERCEPT Blood System targets this basic biological difference between the therapeutic components of blood, compared to harmful pathogens and donor white blood cells. The system uses a proprietary molecule that when activated, binds to DNA and RNA, preventing nucleic acid replication and rendering the pathogen inactive.

Approval of the INTERCEPT Blood System for plasma also helps move forward Health Canada’s review of the INTERCEPT Blood System for platelets, which will be considered an amendment to the core license.

ABOUT THE INTERCEPT BLOOD SYSTEM FOR PLASMA

The INTERCEPT Blood System for plasma is intended to be used for the ex vivo preparation of pathogen-reduced, whole blood derived or apheresis plasma in order to reduce the risk of transfusion-transmitted infection (TTI).

The safety and efficacy of plasma prepared with the INTERCEPT Blood System has been evaluated in eight clinical studies including a total of over 600 patients requiring plasma transfusions. INTERCEPT plasma has been monitored and shown to be safe in routine use through hemovigilance programs covering over 200,000 INTERCEPT-processed plasma components. For more information, please visit http://intercept-canada.com.
ABOUT CERUS

Cerus Corporation is a biomedical products company focused in the field of blood transfusion safety. The INTERCEPT Blood System is designed to reduce the risk of transfusion-transmitted infections by inactivating a broad range of pathogens such as viruses, bacteria and parasites that may be present in donated blood. The nucleic acid targeting mechanism of action of the INTERCEPT treatment is designed to inactivate established transfusion threats, such as hepatitis B and C, HIV, West Nile virus, and bacteria, as well as emerging pathogens such as chikungunya, malaria, and dengue. Cerus currently markets and sells the INTERCEPT Blood System for both platelets and plasma in the United States, Europe, the Commonwealth of Independent States, the Middle East, and selected countries in other regions around the world. The INTERCEPT red blood cell system is in clinical development. See www.cerus.com for information about Cerus.

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Cerus Investor Relations Contacts:

Stacey Leanos - Associate Director, Investor & Public Relations
Lainie Corten - Vice President, Global Marketing & Investor Relations
(925) 288- 6137
ir@cerus.com