Terumo BCT Announces First Patient Enrolled in North American Clinical Trial of Mirasol® Pathogen Reduction Technology System

The Associated Press

LAKEWOOD, Colo.--(BUSINESS WIRE)--Feb 12, 2013--Terumo BCT announces that the first patient, in the ongoing PREPAReS (Pathogen Reduction Evaluation & Predictive Analytical Rating Score study) trial, has been enrolled in Canada. Sponsored by the Sanquin Blood Supply Foundation, Netherlands, this international study is designed to compare the effectiveness of standard platelets versus platelets treated with the Mirasol system to prevent bleeding in a variety of patient populations.

While blood donations are commonly screened for specific pathogens to minimize risks for transmitting infectious disease, the Mirasol system is designed to further enhance the safety of platelet and plasma transfusions by using a combination of riboflavin (vitamin B2) and ultraviolet (UV) light to inactivate viruses, bacteria, parasites and white blood cells that might be present in collected blood products. The system is intended to produce a treated product to benefit patients receiving platelet and plasma products worldwide.

KEY FACTS: The PREPAReS trial is a non-inferiority, single-blinded study designed to compare the clinical efficacy of Mirasol (riboflavin/vitamin B2)-pathogen-reduced platelet concentrates with standard platelet concentrates using clinically relevant end points. The first patient was enrolled in Canada in January 2013The study began patient accrual in November 2010 in the HAGA hospital (the Hague, Netherlands) and currently has 173 participating patients.In addition to Canada, four Dutch transfusion centers are participating in the study.The study is estimated to complete enrollment by late 2013 or early 2014. An estimated 10 million platelet units are transfused to patients in North America, Europe and Asia each year. Experts estimate that as many as one in every 2,000 units of platelets collected could contain bacteria. Inactivating bacteria that might be present in collected platelets may be of benefit to patients receiving platelet transfusions, as bacterial contamination in platelets represents the single greatest infectious risk in transfusion medicine today.

KEY QUOTES: Ray Goodrich, Ph.D., Terumo BCT, Vice President of Scientific and Clinical Affairs “We have worked very closely with Sanquin, Canadian Blood Services and Health Canada on the Canadian arm of the PREPAReS Trial. The trial has been designed to establish that Mirasol-treated platelets are comparable to untreated platelets, in terms of efficacy for patients requiring platelet transfusion support. The study is also designed to determine if the use of Mirasol-treated platelets reduces the risk of HLA-alloimmunization in patients who require transfusions.” Jean-Louis Kerkhoffs, Sanquin Blood Supply Foundation “Safe and effective platelet transfusions are essential in the supportive care of hematology patients. Scientists,

hematologists and transfusion specialists as well as numerous other dedicated colleagues are collaborating on the PREPAReS study, a unique transatlantic experience to further improve the safety of platelet transfusions and the care for hematology patients." Dana Devine, Vice President, Medical, Scientific & Research Affairs, Canadian Blood Services "Canadian Blood Services is very pleased that this trial is under way. We look forward to the day that pathogen reduction technologies for treatment of cellular blood products are available for use in Canada. This trial is a first step toward licensure of this technology in Canada."

KEY RESOURCES: Mirasol System Fact Sheet Note: The Mirasol system is not FDA-approved for sale in the United States.

About Terumo BCT:
Terumo BCT, a global leader in blood component, therapeutic apheresis and cellular technologies, is the only company with the unique combination of apheresis collections, manual and automated whole blood processing, and pathogen reduction coupled with leading technologies in therapeutic apheresis and cell processing. We believe in the potential of blood to do even more for patients than it does today. This belief inspires our innovation and strengthens our collaboration with customers.

About Sanquin Blood Supply Foundation:
The Sanquin Blood Supply Foundation ensures the safe and efficient blood supply in the Netherlands. Sanquin also develops and produces pharmaceutical products, conducts high-quality scientific research, and develops and performs a multitude of diagnostic services.

Source URL (retrieved on *08/31/2014 - 6:59am*):
http://www.mdtmag.com/news/2013/02/terumo-bct-announces-first-patient-enrolled-north-american-clinical-trial-mirasol%C2%AE-pathogen-reduction-technology-system?qt-most_popular=0