Teleflex (TFX) Announces Commencement of Phase I Clinical Study (FDP-1) of RePlas™ Freeze-Dried Plasma

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The U.S. Army is sponsoring clinical trials of novel freeze-dried plasma developed byTeleflex's Vascular Solutions division for the treatment of battlefield trauma and other emergency applications

WAYNE, Pa.--(BUSINESS WIRE)--May 15, 2017-- Teleflex Incorporated (NYSE: TFX), a leading global provider of medical technologies for critical care and surgery, has announced the commencement of the Phase I clinical study of RePlas, a lyophilized fresh frozen plasma product being developed in collaboration with the U.S. Army Medical Materiel Development Activity (USAMMDA).

The product was originally developed by biologic scientists at Vascular Solutions, Inc., which was acquired by Teleflex in February.

RePlas Freeze-Dried Plasma was administered to the first patient as part of a 24-patient Phase I study (FDP-1) being conducted at the Hoxworth Blood Center at the University of Cincinnati. In this first stage of the clinical development program, healthy volunteers receive increased doses of autologous freeze-dried plasma – their own blood plasma that has been processed using the proprietary lyophilization (freeze drying) and packaging techniques, to assess safety and tolerability. "We are pleased to be underway with the clinical study of this novel freeze-dried plasma product, which could have valuable applications in the treatment of military trauma as well as trauma care in a wide variety of other settings," said Jose A. Cancelas, M.D., Ph.D., Director of Research at Hoxworth Blood Center and Professor of Medicine at University of Cincinnati College of Medicine. Dr. Cancelas is serving as Principal Investigator of the Phase I study (FDP-1).

The early administration of plasma has an important role in reducing trauma mortality from uncontrolled bleeding (hemorrhage). Therefore, USAMMDA has made the development of a commercially available source of freeze-dried plasma a top priority. In April 2014, Vascular Solutions entered into a Cooperative Research and Development Program with USAMMDA. Under the CRADA, USAMMDA provides funding for the regulatory and clinical work, and Vascular Solutions owns all intellectual property and commercial rights to the product.

"We are honored to be working with the U.S. Army on this critical, life-saving product, and it is exciting for us to be entering the clinical development phase of this project three years after beginning the collaboration," said Steve Penegor, VP of Biological Development at Vascular Solutions. "The lyophilization of biologic materials is one of our core technical competencies, as we have demonstrated with several successful clinical and commercial endeavors, beginning more than a decade ago with our D-Stat® Dry Hemostatic Bandage. Since entering into the development agreement with the U.S. Army in April of 2014, we have made significant strides, including the development of our commercial-scale production equipment in our new, dedicated biologics manufacturing facility."

Under the terms of the collaboration agreement, Vascular Solutions is responsible for product development and establishing manufacturing operations, including chemistry, manufacturing, and controls (CMC) information to support the submission of the Investigational New Drug (IND) application, which was made in October of 2016. USAMMDA is responsible for sponsoring, managing, and funding all preclinical and clinical studies required to support a Biologic License Application (BLA) for commercialization. Following the FDA review process, Teleflex will be responsible for all post-licensure production, regulatory, and commercial marketing and distribution of RePlas Freeze-Dried Plasma. Teleflex will be entitled to market RePlas Freeze-Dried Plasma, including sales to branches of the military and private sector medical providers.

The only licensed forms of plasma currently available in the United States are fresh frozen plasma (FFP), plasma frozen within 24 hours after phlebotomy (PF24) and liquid plasma (LP). According to the most recent annual Blood Collection, Utilization, and Patient Blood Management Survey Report published by the American Association of Blood Banks (AABB), the U.S. blood banking system distributed 3.5 million units of plasma to hospitals, clinics, and other providers of medical care during 2013. Due to the difficulty of using current forms of plasma in remote locations such as in theater medical facilities and battlefield situations, USAMMDA has sought the development of a stable, durably-packaged freeze-dried plasma product that can be easily stored, transported, and administered in remote conditions.

About Teleflex Incorporated

Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

Teleflex is the home of Arrow®, Deknatel®, Hudson RCI®, LMA®, Pilling®, Rusch®, and Weck® – trusted brands united by a common sense of purpose.

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. Any forward-looking statements contained herein are based on our management's current beliefs and expectations, but are subject to a number of risks, uncertainties, and changes in circumstances, which may cause actual results or company actions to differ materially from what is expressed or implied by these statements. These risks and uncertainties are identified and described in more detail in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K.

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