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August 27, 2010

Uniplas[®] Clinical Development Successfully Completed

Universal Plasma Filed for European Approval

LACHEN, SWITZERLAND (August 26, 2010) – Octapharma AG, one of the largest private manufacturers of plasma products in the world, announced today that the clinical development for Uniplas[®] has been successfully completed. The product has been filed for registration in Europe and will be submitted later in the USA.

Uniplas[®], is a novel, blood group independent, universally applicable, prion depleted, solvent/detergent treated, human pooled plasma for infusion. Uniplas[®] can be given to all patients irrespective of their blood group, thus abolishing the risks and serious consequences that can result from a transfusion of an incompatible plasma unit. Uniplas[®] is obtained by optimal mixing of plasma of different blood groups in order to neutralize the unwanted anti-A and anti-B antibodies (both IgM and IgG class) by binding to free A and B substances. When transfusing plasma, incompatibility between donor and patient arises when the donor plasma includes antibodies against the A or B antigens of the recipient. Thus, the transfusion of such incompatible plasma can have serious consequences in patients. At present, only plasma of blood group AB can be used as universal plasma as it contains neither anti-A nor anti-B antibodies. However the availability of AB plasma is limited, with only 3-5% of Caucasians or Afro-Americans having this blood group. Apart from delays in transfusion, mismatch errors in transfusing incompatible plasma can be equally critical and sometimes fatal to the recipient, and such risks would be eliminated by a universal plasma.

The safety measures used in the production of Uniplas[®] are the same as used for the commercially available Octaplas[®]/ OctaplasLG[®](1). For Uniplas[®], the effective and reliable inactivation/ neutralization of both enveloped and non-enveloped viruses is achieved by S/D (Solvent Detergent) treatment and immune neutralization. The additional advantages associated with Uniplas[®] are the same as for the commercially available Octaplas[®], such as: standardized coagulation factors content and no risk of transfusion-associated acute lung injury (TRALI). Furthermore, the newly developed LG technology successfully eliminates prions, so that the total prion removal capacity of the entire Uniplas[®] manufacturing process is greater than 3.0 Log₁₀ (2).

The efficacy of Uniplas[®] (non-LG) has been proven in clinical trials conducted in patients undergoing liver resection or open-heart surgery (3,4). Recently, a new Phase I, randomized, double-blind, active controlled clinical trial has been published. The aim of this study was to demonstrate that the introduction of the LG technology does not affect the efficacy and tolerability of Uniplas[®] and has the same safety profile as the blood group dependent OctaplasLG[®]. Following

plasmapheresis (PPh) of 600mL, the 30 volunteers with blood groups A, B or AB were randomized to receive transfusions of 1,200mL OctaplasLG[®] or Uniplas[®]. One of the measurements performed in the study was the direct antiglobulin test (DAT), which is one of the most sensitive assays for assessing haemolytic reactions. All DAT assays in the volunteers were negative. Thus no sensitizing of red blood cells, leading potentially to haemolytic reactions after transfusions of either Uniplas[®] or octaplasLG[®] occurred. The current investigation in healthy volunteers indicated that haemolysis is unlikely to be an issue when Uniplas[®] is administered at a therapeutic dose. This supports the previous results (Uniplas[®] non-LG) from clinical trials in patients with liver resection and open-heart surgery.

Uniplas[®] is currently under a DCP (Decentralized Procedure) registration procedure in Europe and it is expected to be finished on the Q4 2010. Following European approval, Octapharma plans to start the approval process for Uniplas[®] in the USA.

About Octapharma

The Octapharma Group is an independent, Swiss-based biopharmaceutical company operating worldwide. Octapharma's core business is the development, production, and sale of high-quality human proteins for the treatment of life-threatening diseases.

The Group has more than 4,200 employees in 28 countries, and owns five modern, state-of-the-art production facilities in Austria, France, Germany, Sweden and Mexico, respectively.

Octapharma's company mission is to provide safe and effective biopharmaceutical products derived from human cells or blood plasma to patients in need of lifesaving therapy.

For more information about the company please click [here](#).

About OctaplasLG[®] and Uniplas[®]:

Uniplas[®] and OctaplasLG[®] are both S/D treated coagulation active, pooled plasmas for transfusion. OctaplasLG indicated for a variety of situations, including: complex deficiencies of coagulation factors, massive bleeding, or when there is a requirement for plasma exchange.

Uniplas[®] shares the favorable characteristics of octaplasLG[®] in terms of quality and safety, in addition to offering the advantage of being a blood group independent option in the plasma transfusion setting. It is obtained by optimized integration of well defined ratios of plasma units derived from donations of blood groups A, B and AB.

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