

# FDA Approves U.S. Market Return for octagam® Following Octapharma's Implementation of Enhanced Safety Measures

**04.11.2011**

*Product Expected to Be Available for Distribution in a Few Weeks*

**HOBOKEN, N.J. (November 4, 2011)** – The U.S. Food and Drug Administration (FDA) yesterday cleared the way for the U.S. market return of octagam® [Immune Globulin Intravenous (human)] 5% Liquid Preparation], the Octapharma USA product used to treat disorders of the immune system.

In August 2010, Octapharma initiated a voluntary market withdrawal of selected lots of octagam® 5% in the U.S. in response to an observed increase in thromboembolic events (TEEs) and subsequently expanded the voluntary withdrawal to all lots of octagam®, illustrating the biopharmaceutical company's preference to exercise the highest level of patient safety.

Over the last year, Octapharma has collaborated with the FDA in analyzing the issue of procoagulant activity in industry-wide immune globulin products, which in some cases lead to TEEs in many IVIG products on the market today.

The FDA approval was based on changes Octapharma has made in the octagam® 5% manufacturing process and the company's decision to implement a quality control test on every batch of the product that is released to the marketplace. Additionally, Octapharma will implement post-marketing studies to ensure product safety.

"We are extremely pleased that the FDA has authorized the market return of octagam® 5%," said Octapharma USA President Flemming Nielsen. "Our collaboration with the FDA over the last year has enhanced awareness of the industry-wide concerns regarding procoagulant activity and TEEs. Octapharma has always believed that patient safety comes first so the octagam® 5% that we will return to the U.S. market in a few weeks will enjoy the highest level of safety scrutiny available today and the same level of tolerability that our patients have come to expect from Octapharma therapies."

Thromboembolic events occur due to the formation of a clot or thrombus in an artery or vein that breaks loose and is carried by the blood stream to occlude another vessel. Over the last year,

the FDA has identified several immune globulin products on the U.S. market that may have suspect levels of procoagulant activity. Multiple industry research initiatives indicate that TEEs can be caused by a number of different biochemical/physiological factors in susceptible individuals. For those TEE cases involving octagam® 5%, however, the root cause was determined to be associated only with activated Factor XI, one of the many coagulation factors involved in the complex clotting cascade.

Octapharma collaborated with the FDA's Center for Biologics Evaluation and Research to develop and validate a scientific method to measure the amount of activated Factor XI, the root cause of the TEEs, both during the manufacturing process and at the finished product stage. Although other procoagulant factors, such as kallikrein, have been linked to TEEs in other IVIG products, these were shown not to have contributed to the TEEs seen in association with octagam® 5%. Octapharma now utilizes a commercial absorbent early in the manufacturing process of octagam® 5% that minimizes the presence of Factor XI.

Earlier this year, multiple international regulatory agencies authorized the market return of octagam® 5% and octagam® 10% in worldwide markets.

#### ***About octagam® 5%***

Immune Globulin Intravenous (Human), octagam® 5% liquid, is a solvent/detergent (S/D)-treated, sterile preparation of highly purified immunoglobulin G (IgG) derived from large pools of human plasma. octagam® 5% liquid is a solution for infusion which must be administered intravenously.

octagam® is an immune globulin intravenous (human) 5% liquid indicated for treatment of primary humoral immunodeficiency (PI), such as congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome and severe combined immunodeficiencies.

#### ***About the Octapharma Group***

Headquartered in Lachen, Switzerland, Octapharma AG is one of the largest human protein products manufacturers in the world and has been committed to patient care and medical innovation for over 28 years. Octapharma's core business is the development, production and sale of high quality human protein therapies from both human plasma and human cell-lines, including immune globulin intravenous (IGIV). In the U.S., Octapharma's IGIV product, octagam® (immune globulin intravenous [human] 5%), is used to treat primary immune deficiencies, and Octapharma's Albumin (human)® is indicated for the restoration and maintenance of circulating blood volume. Octapharma's wilate® (Von Willebrand Factor/Coagulation Factor VIII Complex [human]) received orphan drug exclusivity from the U.S.

Food and Drug Administration (FDA) for the treatment of certain types of Von Willebrand Disease (VWD). Octapharma employs over 4,000 people and has biopharmaceutical experience in 80 countries worldwide, including the United States, where Octapharma USA is located in Hoboken, N.J. Octapharma operates two state-of-the-art production sites licensed by the FDA, providing a high level of production flexibility. For more information, please visit [www.octapharma.com](http://www.octapharma.com) or [www.wilateusa.com](http://www.wilateusa.com).

*Forward-looking statements*

This news release contains forward-looking statements, which include known and unknown risks, uncertainties and other factors not under the company's control. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments. These factors include results of current or pending research and development activities and actions by the FDA or other regulatory authorities.