Octapharma Aims to Expand U.S. Immune Globulin Therapy Portfolio

Swiss Biopharmaceutical Company Submits FDA License Application for octagam(R) 10%

LACHEN, SWITZERLAND and HOBOKEN, N.J., Sept. 23 /PRNewswire/ -- **Octapharma AG** recently submitted its Biological License Application for **octagam(R) 10%** (human normal intravenous immunoglobulin, liquid) to the **U.S. Food and Drug Administration** (FDA) with the goal of expanding the biopharmaceutical company's U.S. immune globulin therapy portfolio by early 2010. The application was submitted for the treatment of Idiopathic Thrombocytopenic Purpura (ITP), a blood-clotting disorder that can result in excessive bruising and bleeding.

"We are extremely pleased with the BLA submission for octagam 10% and look forward to advancing Octapharma's firm commitment to providing immune globulin therapy in the U.S. marketplace," said Octapharma USA President **Flemming Nielsen**. "The expected introduction of octagam 10% will provide yet another immune globulin intravenous (IGIV) product option for patients that further builds on the success already achieved with the octagam product line both globally and in the U.S."

In 2004, Octapharma, one of the largest plasma products manufacturers in the world, gained U.S. approval from the FDA for its IGIV product, **octagam(R)** (immune globulin intravenous [human] 5%). The therapy, which treats disorders of the immune system, has already gained over 10% of the U.S. market despite entrenched competition.

"No market is more important to Octapharma than the U.S.," said Nielsen. "Octapharma has been committed to patient care and medical innovation since its founding over 25 years ago and our vision of providing patients with the safest, highest quality products available is stronger than ever. We look forward to a rapid expansion of our U.S. product portfolio. Octapharma is committed to providing life saving products as well as ensuring reliable supply and fair pricing."

Octapharma also recently submitted an Investigational New Drug (IND) application for a next generation IGIV product for the treatment of ITP and chronic inflammatory demyelinating polyneuropathy (CIDP), a neurological disorder that progressively impairs leg and arm function.

The IND for this next generation IGIV is just one part of Octapharma's extensive global Research and Development program. Octapharma also is evaluating the efficacy of immune globulin as a treatment in new and existing conditions. Octagam is currently being investigated in clinical trials studying the efficacy of treatment for CIDP, ITP, multiple sclerosis, Alzheimer's disease and primary immune deficiency. In February, Octapharma started phase II clinical trials following FDA review of its IND for octagam 10% in mild-to-moderate Alzheimer's disease.

Octapharma AG

Headquartered in Lachen, Switzerland, Octapharma is the third largest plasma products manufacturer in the world and has been committed to patient care and medical innovation for over 25 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(R)** (immune globulin intravenous [human] 5%), is used to treat disorders of the immune system, and Octapharma's **Albumin** (Human) is indicated for the restoration and maintenance of circulating blood volume. Octapharma employs over 3,000 people and has biopharmaceutical experience in 80 countries worldwide, including the United States, where **Octapharma USA** is headquartered in Hoboken, N.J. Octapharma operates two state-of-the-art production sites licensed by the **U.S. Food and Drug Administration**, providing the highest level of production flexibility and minimizing product shortages. For more information, please visit **www.octapharma.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.

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