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FOR IMMEDIATE RELEASE

**OCTAPHARMA RECEIVES FDA APPROVAL FOR OCTAGAM[®]
IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%**

Clinically Documented Efficacy, Safety, and Tolerability in PID

European Market Leader Now Available in U.S.

HERNDON, VIRGINIA, May 24, 2004 – Octapharma AG has received approval from the U.S. Food and Drug Administration (FDA) to market OCTAGAM[®], Immune Globulin Intravenous (Human) 5%, a liquid, ready-to-use, solvent/detergent treated immunoglobulin intravenous (IGIV) product that has been a market leader in Europe for more than 10 years, the company announced today. OCTAGAM, indicated for the treatment of primary immunodeficiency diseases (PID), will be distributed in the United States by Octapharma USA, Inc.

“The approval of OCTAGAM in the United States is a major milestone for Octapharma and extends our commitment to bringing the highest-quality IGIV products to patients around the world,” said Wolfgang Marguerre, chairman, Octapharma AG. “With an unmatched record of safety and reliability in Europe, OCTAGAM represents two decades of intensive investment in technology and process refinement made possible by Octapharma’s exclusive focus on human plasma products. OCTAGAM is also the first of a number of important and innovative plasma-derived therapeutics we hope to introduce in this country over the next several years.”

In replacement therapy for PID, OCTAGAM provides a broad spectrum of IgG antibodies against bacterial and viral pathogens. It is not less than 96 percent pure IgG and provides high functionality because the integrity of the Fc portion of the IgG molecule is maintained. Furthermore, greater than 90 percent of the IgG molecules in OCTAGAM are monomers and dimers, the only molecular forms of

IgG thought to provide therapeutically meaningful activity. The OCTAGAM preparation is physiologically similar to normal plasma in concentration, nativity, osmolality, and distribution of IgG subclasses. It contains no additional stabilizers and is sucrose, fructose, and preservative free.

OCTAGAM is supplied as a ready-to-use liquid and requires no filtration prior to intravenous infusion. Available in 1.0g, 2.5g, 5g or 10g single use bottles, OCTAGAM can be stored at room temperature for up to 18 months (or up to 24 months when refrigerated).

“The clinical data demonstrated the safety and efficacy of OCTAGAM in a multi-site U.S. trial,” said Jonathan Goldsmith, MD, interim president of the Immune Deficiency Foundation (IDF). “Patients with primary immune deficiency diseases are often very involved in their care and recent IDF research reveals that many patients take an active role, with their physicians, in selecting IGIV products based on effectiveness, tolerability, and safety.”

OCTAGAM is the leading IGIV product in Europe. According to the Marketing Research Bureau, which has monitored the plasma products industry since 1974, OCTAGAM held a 22 percent share of the European IGIV market in 2002, the largest of any licensed manufacturer.

OCTAGAM Exceeds New U.S. IGIV Efficacy Standard

The efficacy of OCTAGAM was documented in an open-label, multicenter, U.S. study of 46 patients (including 11 patients <15 years) with primary immunodeficiencies who received a total of 694 infusions over a 12 month period. Conducted under the auspices of the IDF, the study utilized the observed rate of serious infections as the primary efficacy endpoint (the lower the rate, the greater the presumed protection provided by the IGIV product), a new evaluation criterion established by the FDA. In the study, OCTAGAM therapy was associated with 0.1 serious infections per patient per year, which compared favorably with the efficacy standard of 1 serious infection per patient per year set by the FDA for approval of IGIV products.

“In collaboration with the FDA, the IDF worked to design a clinical trial protocol for evaluating new IGIV products in primary immune deficiencies and to attract European manufacturers to pursue licensing in the United States, thereby helping us ensure a reliable supply of high-quality IGIV for our patients,” said Dr. Goldsmith. “Octapharma was the first company to answer this invitation and initiate a clinical trial under the new protocol. The regulatory approval of OCTAGAM is the culmination of this historic collaboration and will benefit tens of thousands of Americans who rely on IGIV to live healthy, productive lives.”

The study, published in the May 2004 issue of the *Journal of Clinical Immunology*, also measured secondary efficacy endpoints involving patient productivity and healthcare utilization. The average number of work or school

days missed, days spent in the hospital, and visits to a physician or emergency room, during the year-long study were very low (5.5 days, 0.4 days, and 2.1 visits, respectively).

OCTAGAM Clinical Safety Profile Supported by European Experience

The majority of adverse reactions documented in the OCTAGAM study were mild to moderate in severity and the product was generally well tolerated. The most commonly reported side effects included headache, nausea, chills, back or chest pain. In general, reported adverse reactions to OCTAGAM in patients with either congenital or acquired immunodeficiencies are similar in kind and frequency to other IGIV products. Various minor reactions, such as headache, chills, backache, chest pain, fever, allergic reactions, arthralgia, dizziness, changes in blood pressure, cutaneous reactions and/or nausea and vomiting may occasionally occur and tend to be related to the rate of infusion.

“Safety data from our pivotal U.S. study was supported by data from non-U.S. clinical trials including 217 patients and data from post-marketing surveillance studies including approximately 4,700 patients,” said Wolfgang Frenzel, M.D., medical director, Octapharma AG. “We were gratified to observe that the safety profile of OCTAGAM established by the U.S. trial mirrors actual European clinical experience with the product over a much larger group of patients and longer time frame.”

Cases of reversible aseptic meningitis and migraine, isolated cases of reversible hemolytic anemia, and reversible increases in liver function tests have been observed with OCTAGAM.

Immediate anaphylactic and hypersensitivity reactions are a remote possibility. Epinephrine should be available for treatment of any acute anaphylactoid reaction.

OCTAGAM carries a class warning about reports associating IGIV products with renal dysfunction, acute renal failure, osmotic nephrosis, and death, particularly in patients predisposed to acute renal failure. While these reports of renal dysfunction and acute renal failure have been associated with the use of many of the licensed IGIV products, those containing sucrose as a stabilizer accounted for a disproportionate share of the total number. OCTAGAM does not contain sucrose.

Viral Safety of OCTAGAM

OCTAGAM is made from pooled human plasma of U.S. origin. Products made from human plasma may contain infectious agents, such as viruses, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses.

Octapharma was the first company to introduce the “gold standard” solvent detergent process in the routine production of plasma derivatives, including Octagam. The Octagam manufacturing process incorporates multiple production steps, including Cohn-Oncley fractionation, treatment with solvent/detergent (S/D) [TnBP+Triton X-100] and a 24 hour pH4 treatment, to provide very high levels of viral reduction and inactivation. *In vitro* studies conducted during the manufacture of OCTAGAM demonstrate that combined these methods provide significant reduction of a wide array of transfusion relevant viral pathogens, including lipid-enveloped viruses such as HIV, hepatitis B & C, West Nile Virus (WNV), and the SARS virus. In nearly 10 years of clinical experience with more than 1,000,000 doses given of OCTAGAM in Europe, no virus transmission has been reported.

Despite these measures, such products can still potentially transmit disease. Because this product is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

About Octapharma

Octapharma AG is a worldwide company dedicated to the production of plasma-derived therapeutic products. Headquartered in Lachen, Switzerland, with offices and plants in more than 21 countries, Octapharma is known world over for the quality, safety, and tolerability of its products, and for standing behind its mission – “for the safe and optimal use of plasma.” More information is available at www.octapharma.com.

Octapharma USA is located in Herndon, Virginia. Ordering information for OCTAGAM is available by calling 1-800-826-6905.

For additional information on OCTAGAM, please see Full Prescribing Information or visit us at www.octapharma.com

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