octapharma®

For the safe and optimal use of human proteins

FOR IMMEDIATE RELEASE

FDA Approves Octapharma's cutaquig® 16.5% for Pediatric PI Patients, Providing Flexible Treatment Options

Families, Providers Can Utilize Flexible Infusion Schedule to Meet Patient Needs

PARAMUS, N.J. (December 7, 2021) – Octapharma USA today announced the U.S. Food & Drug Administration (FDA) has approved cutaquig® [Immune globulin, Subcutaneous (Human)-hipp, 16.5% Solution] for the treatment of pediatric patients age 2 and older with primary humoral immunodeficiency (PI). The FDA previously approved cutaquig® for adults with PI.

"The FDA approval provides physicians and families with more treatment options for patients with primary immune disorders, which weaken the immune system and can allow infections and other health issues to occur more easily," said Roger H. Kobayashi, M.D., Clinical Professor UCLA School of Medicine and National Consultant, Immune Deficiency Foundation. "The FDA approval also provides more flexible options by permitting more frequent or less frequent infusions, which can be advantageous based on a patient's pharmacokinetic and clinical response."

Patients and providers have the flexibility to administer cutaquig® at a lower dose more frequently or at a larger dose less frequently if desired. Patients who prefer less frequent injections may have the option of receiving therapy every other week. At the same time, physicians can prescribe daily dosing if patients respond better to more frequent therapy.

"Cutaquig® provides enhanced convenience for a wider group of patients who want to customize therapy with their prescriber to best match patient lifestyle needs," said Octapharma USA President Flemming Nielsen. "Octapharma is committed to providing people with immune disorders the life-saving therapies they need. Both the addition of the pediatric indication and the flexible dosing illustrate our commitment to ensure patients have access to lifesaving products that offer a variety of choices for therapy delivery."

The FDA approval of cutaquig® is based on the results of two clinical trials, which observed 75 PI patients, 37 adults and 38 pediatric patients between ages 2 and 17. The patients received weekly infusions with cutaquig® during a 12-week wash-in/wash-out period followed by a 12-month efficacy period. The main objective of the research was to assess the efficacy of cutaquig® in preventing serious bacterial infections, defined as bacteremia/sepsis, bacterial meningitis, osteomyelitis/septic arthritis, bacterial pneumonia and visceral abscess. No serious bacterial infections were reported.[1]

About PI

Globally, millions of people suffer with primary immunodeficiencies, a group of more than 400 different diseases. Roughly, one in every 10,000 people have PI, but the diseases are even more prevalent in children. Between 70% and 90% of people living with a PI remain undiagnosed.[2]

About cutaquig®

Cutaquig® (Immune Globulin Subcutaneous (Human) - hipp) is a 16.5% immune globulin solution for subcutaneous infusion indicated for treatment of primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older.

WARNING: THROMBOSIS

- Thrombosis may occur with immune globulin products, including cutaquig®. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.

- For patients at risk of thrombosis, administer cutaquig® at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.

Please see full prescribing information for complete boxed warning and other important information at cutaquigus.com.

About the Octapharma Group

Headquartered in Lachen, Switzerland, Octapharma is one of the largest human protein products manufacturers in the world and has been committed to patient care and medical innovation since 1983. Its core business is the development and production of human proteins from human plasma and human cell lines. Octapharma employs more than 10,000 people worldwide to support the treatment of patients in over 115 countries with products across the following therapeutic areas: Hematology (coagulation disorders), Immunotherapy (immune disorders) and Critical Care. The company's American subsidiary, Octapharma USA, is located in Paramus, N.J. Octapharma operates three state-of-the-art production sites licensed by the U.S. Food and Drug Administration (FDA), providing a high level of production flexibility. For more information, please visit octapharmausa.com.

REFERENCES

1 – cutaquig® [Immune globulin, Subcutaneous (Human)-hipp, 16.5% Solution] prescribing information, updated December 1, 2021.
2 – Primary Immunodeficiencies (PID) – Driving Diagnosis for Optimal Care in Europe, European Reference Paper.

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