

Jerini Submits New Drug Application for Icatibant in the Treatment of HAE to the FDA and Requests Priority Review

BERLIN, Oct. 29, 2007 (PRIME NEWSWIRE) -- Jerini AG (FSE:JI4) announced today the submission of its electronic New Drug Application (NDA) for Icatibant in the treatment of hereditary angioedema (HAE) to the U.S. Food and Drug Administration (FDA) as well as the company's request for priority review. Jerini has received technical clearance of its eCTD (Electronic Common Technical Document) from the agency, which ensures that the documentation meets the agency's technical standards. The FDA has up to 60 days to determine whether the application is complete and meets the regulatory requirements for filing. Priority review designation, which shortens the regulatory review period from ten to six months, will also be decided by the agency in this timeframe.

"The NDA submission is a major milestone for Jerini. This important regulatory step in the U.S. along with Icatibant's already accepted European filing demonstrates our commitment to bring this novel treatment to HAE patients in both the U.S. and Europe," said Jens Schneider-Mergener, CEO of Jerini."

About Icatibant

Icatibant, a synthetic peptidomimetic, works by blocking the B2 receptor as an antagonist to the peptide hormone bradykinin. Bradykinin has been shown to be elevated in HAE patients and responsible for edema formation during HAE attacks. Icatibant has been granted orphan drug status for the treatment of angioedema by the U.S. Food and Drug Administration (FDA) and the European Medicines Evaluation Agency (EMA), potentially securing upon approval, market exclusivity for seven and ten years, respectively. In addition, the FDA has granted fast-track designation to Icatibant in the indication HAE.

About HAE

HAE is a debilitating and potentially life-threatening genetic disease characterized by unpredictable recurring swelling attacks of the hands, feet, face, larynx, and abdomen. It is estimated that approximately 10,000 patients in the United States and Europe have been diagnosed with HAE. HAE attacks affecting the hands, face, and feet can be disfiguring, while attacks in the gastrointestinal tract result in severe pain caused by swelling of the intestinal wall. Attacks that affect the larynx are life-threatening because swelling of the larynx constricts the upper airways and can lead to death by suffocation. The prevalence of HAE is estimated between one in 50,000 and one in 10,000 individuals, and it is estimated that between 15,000 and 75,000 people are affected with HAE in the European Union and the United States.

About Jerini

Jerini is a pharmaceutical company based in Berlin, Germany, focusing on the discovery, development, and commercialization of novel peptide-based drugs. The company pursues disease indications that have limited or no treatment options and has built a drug pipeline composed of its own programs, as well as others in collaboration with established partners. Jerini has completed Phase III clinical trials of Icatibant in the subcutaneous treatment of hereditary angioedema (HAE). The company's marketing authorization application has been accepted for review by the European Medicines Evaluation Agency (EMA) and granted accelerated assessment by the agency, shortening the regulatory review period from 210 to 150 calendar days. Jerini plans to complete its U.S. submission to the Food and Drug Administration (FDA) in the fourth quarter of 2007. Based on its technology platform, Jerini has also established several in-house development programs, which address indications within the therapeutic areas of ophthalmology, oncology, and inflammatory disease.

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