

## **Jerini Announces Positive Results from Two Phase III Trials of Icatibant for the Treatment of Hereditary Angioedema**

BERLIN, Sept. 21, 2006 (PRIMEZONE) -- Jerini AG (FSE:JI4) announced today the results of its two pivotal Phase III trials (FAST-1 and FAST-2) for the subcutaneous treatment of hereditary angioedema (HAE). In the FAST-2 study, the primary endpoint was reached, showing a significant reduction in the time to onset of symptom relief. While FAST-1 results were clinically relevant, the primary endpoint was not reached. A supportive analysis combining both studies showed a significant reduction in the time to onset of symptom relief. Secondary endpoints, such as patient and physician reported time to first improvement of symptoms, and the time to almost complete relief of symptoms showed highly significant results in favor of Icatibant. Based on the clinically relevant and consistent results of the two trials, the company intends to apply as planned for expedited reviews by the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) starting submission at year-end 2006, with potential launch in 2007.

In FAST-2, a study comparing Icatibant against tranexamic acid, 74 patients were randomized in Europe and Israel. The primary endpoint, as measured by a visual analog scale (VAS), was met with a median time to onset of symptom relief of 2.0 hours for Icatibant versus 12.0 hours for tranexamic acid ( $p$  less than 0.001). Secondary endpoints entered in the analysis also showed statistically significant differences in favor of Icatibant. Time to onset of relief of key symptoms, as measured by a preset reduction in the VAS, was highly significant for skin swelling ( $p$  less than 0.001), skin pain ( $p = 0.002$ ) and abdominal pain ( $p = 0.028$ ).

Another clinically relevant time point, at which patients showed almost complete symptom relief as measured by VAS, was 0.4 days for Icatibant versus 1.5 days for tranexamic acid ( $p$  less than 0.001). The efficacy of Icatibant is highlighted further by the time point at which patients first reported improvement of symptoms. Median times were 0.8 hours for Icatibant versus 7.9 hours for tranexamic acid ( $p$  less than 0.001). Icatibant showed an excellent safety profile in this study.

In FAST 1, a study comparing Icatibant against placebo, 56 patients were randomized in the United States, Canada, Australia, and Argentina. The primary endpoint of median time to onset of symptom relief was 2.5 hours for Icatibant versus 4.6 hours for placebo. Although clinically relevant, this difference did not reach statistical significance ( $p = 0.131$ ) due to an unexpectedly high response to placebo in patients with abdominal pain as measured by VAS. In two subgroup analyses, the primary endpoint was met ( $p = 0.025$  and  $p = 0.024$ ), and further analyses are ongoing. Time to onset of relief of key symptoms, as measured by VAS, showed a statistically significant reduction for skin swelling ( $p = 0.032$ ), skin pain ( $p = 0.007$ ), and almost statistical significance for abdominal pain ( $p = 0.056$ ). The clinically relevant time point, at which patients showed almost complete symptom relief, as measured by VAS, was 0.4 days for Icatibant versus 1.5 days for placebo ( $p = 0.035$ ). The efficacy of Icatibant is highlighted further by the time point at which patients first reported improvement of symptoms. Median times were 0.8 hours for Icatibant versus 16.9 hours for placebo ( $p$  less than 0.001). Icatibant showed an excellent safety profile in this study.

The median time in both studies at which patients receiving Icatibant first reported improvement of symptoms was consistent with Jerini's Phase II study results.

Further evidence of Icatibant's efficacy is shown in the combined analysis of FAST-1 and FAST-2. In this analysis, a significant reduction in the time to onset of symptom relief was reached ( $p$  less than 0.001), as were all secondary endpoints entered into the combined analysis. The data from both studies are highly consistent, further supporting Icatibant's excellent efficacy in the treatment of HAE.

In the treatment of life-threatening laryngeal attacks, Icatibant has shown a clinically relevant reduction in the time to symptom relief. In the controlled phase treating 11 patients, the median time to first improvement of symptoms was 1.0 hours (FAST-2) and 0.6 hours (FAST-1) as reported by patient, and 0.7 hours (FAST-2) and 0.8 hours (FAST-1) as assessed by the physician. In the Open Label Extension (OLE) phase, 19 additional laryngeal attacks were successfully treated.

In both OLE phases, patients received Icatibant for the treatment of subsequent attacks. The time point at which patients first reported improvement of their symptoms was consistent with the outcome of the controlled phases of both studies, thus demonstrating maintenance of Icatibant's clinical efficacy with repeated exposures over time. Patients received Icatibant for up to 38 attacks in the OLE phase. The total number of attacks treated in the OLE phases was 231. Patient satisfaction in the OLE phases was assessed after six months, and over 90% of patients stated that they would continue using this medication after completion of study.

"We are very pleased with the results of these trials, which confirm the outstanding potential of Icatibant for the treatment of hereditary angioedema," stated Jens Schneider-Mergener, CEO of Jerini. "We are looking forward to presenting these data to the FDA and EMEA and will continue with our plans to begin submission for regulatory approval in December 2006. HAE patients are in need of a reliable treatment allowing them to manage their disease themselves, and we will move forward in our efforts to bring Icatibant to patients as quickly as possible."

#### Conference Call Details

Jerini will host an audio webcast and conference call, including an open question and answer session, on Friday, September 22nd, 2006, to discuss the results of its two Phase III trials.

Date: September 22, 2006

Time: 11:00 p.m. CET Telephone Access:

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+44 (0)20 7806 1955 UK

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Please dial-in 10 minutes prior to start of the conference call. To View the Presentation Online:

To view the presentation with audio, go to the Jerini website ([www.jerini.com](http://www.jerini.com)) and follow the instructions for accessing the live audio webcast. The replay of the webcast will be available online ([www.jerini.com](http://www.jerini.com)), 2 hours after the end of the conference call, through December 22, 2006.

#### About FAST-1 and FAST-2 Studies

The FAST-1 and FAST-2 studies were randomized, controlled, multi-center trials that screened 425 patients. FAST-1 enrolled patients in the US, Canada, Argentina, and Australia, whereas FAST-2 enrolled patients in Europe and Israel.

The patients enrolled in FAST-1 were randomized to receive either a single subcutaneous dose of 30mg Icatibant or placebo. Patients enrolled in FAST-2 were randomized and received either a single subcutaneous dose of 30mg Icatibant or tranexamic acid. Tranexamic acid is an anti-fibrinolytic agent that is used in some European countries for the treatment of HAE and was proposed by the EMEA as a comparator. Subsequent to the completion of randomization, patients were referred to an Open Label Extension (OLE) phase.

The primary endpoint was time to onset of symptom relief as measured by a visual analog scale (VAS) by the patient. Onset of symptom relief was defined as a preset reduction on the VAS for key symptoms: abdominal pain, skin pain and skin swelling. A statistically significant difference between Icatibant and the comparator or placebo had to be reached. VAS is a measure of symptom severity and has been validated and accepted by regulatory authorities as an instrument for documenting Patient Reported Outcome (PRO). Secondary endpoints were assessed by VAS, symptom scores, and Clinical Global Impression (CGI), as reported by patient and/or physician. Thus, the clinically relevant treatment effects of Icatibant were assessed by three independent measures.

#### Icatibant Safety Profile

Icatibant has shown an excellent safety profile in previous and ongoing trials sponsored by Jerini and sanofi-aventis, and has been administered, to date, in over 1,300 subjects. This safety profile was confirmed in the FAST-1 and the FAST-2 studies. No drug-related serious adverse events occurred. The most frequent adverse events were injection site reactions such as erythema, swelling, and occasional itching and pain. These symptoms were transient and resolved spontaneously.

#### 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 US Food and Drug Administration (FDA) and the European Medicines 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. Icatibant's subcutaneous administration, along with its excellent safety profile demonstrated in clinical studies to date and one-year-stability at room temperature, all offer key benefits to HAE patients. Jerini and its US partner Kos Pharmaceuticals, Inc., plan to market Icatibant in a pre-filled syringe that patients could self-administer at the onset of an HAE attack, enabling them to live a safe and independent life.

#### About HAE

HAE is a debilitating and potentially life-threatening genetic disease characterized by unpredictable recurring swelling attacks in 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 in 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 there could be between 15,000 and 75,000 people affected with HAE in the European Union and the United States.

#### About Jerini AG

Jerini AG is a pharmaceutical company based in Berlin, Germany focusing on the discovery and development of peptide-based drugs. Having recognized the potential of peptides as

natural starting molecules for drug discovery, the company has developed state-of-the-art technologies to identify and transform peptides into drugs. Based on its technology platform, Jerini has established several in-house development programs, which address indications within ophthalmology, oncology, and inflammatory therapeutic areas. The most advanced of these programs targets age-related macular degeneration (AMD), the leading cause of vision loss and blindness in people over the age of 55 in developed countries, and is scheduled to begin clinical testing the first half of 2007.

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