



Tercica Submits Marketing Authorization Application for Increlex in the European Union

BRISBANE, Calif., Dec 07, 2005 (BUSINESS WIRE) -- Tercica, Inc. (Nasdaq:TRCA) announced today that it has submitted a Marketing Authorization Application (MAA) to the European Agency for Evaluation of Medicinal Products (EMA) for approval to market Increlex(TM) (mecasermin (rDNA origin) injection) in the European Union (EU) for the long-term treatment of growth failure in children with severe primary insulin-like growth factor-1 (IGF-1) deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

Increlex was approved for this indication by the U.S. Food and Drug Administration (FDA) on August 30, 2005 and has received orphan drug exclusivity in the U.S. for this indication. The product also has received European orphan drug designation for growth hormone insensitivity syndrome (GHIS), which the FDA has determined to be equivalent to Primary IGFD and GH gene deletion.

The review of the MAA will be coordinated by the EMA under the centralized licensing procedure, which, if resulting in approval, provides one marketing authorization for all 25 member states of the EU. The MAA filing is supported by data from clinical trials evaluating the safety and efficacy of Increlex in children with severe Primary IGFD. Upon acceptance of the MAA submission, the application will be evaluated on a timetable that would lead to an opinion in approximately seven months, plus any time needed by Tercica to reply to regulatory authority questions.

"We believe that in the EU approximately 6,000 children are affected by severe Primary IGFD, making the EU market for Increlex similar in size to the estimated U.S. market size," said John A. Scarlett, M.D., President and Chief Executive Officer of Tercica. "This filing represents a significant step toward our goal of making Increlex available globally to children with severe Primary IGFD."

Tercica plans to broaden the initial indication of use for Increlex in the U.S. and the EU with supplemental applications, pending positive results of ongoing clinical trials evaluating Increlex in children with Primary IGFD. Primary IGFD is characterized by height and IGF-1 levels that are two standard deviations below the mean, in spite of normal or elevated growth hormone levels. Tercica estimates that approximately 30,000 children in the EU are affected by Primary IGFD, which is similar to the estimated U.S. market size.

About IGF-1 and severe Primary IGFD

The active ingredient of Increlex is identical to the natural hormone IGF-1, which the body normally produces in response to stimulation by GH. IGF-1 is the direct mediator of growth hormone's effect on statural growth and must be present in order for children's bones, cartilage and organs to grow normally. Without adequate IGF-1, children cannot achieve a height within the normal range.

Children with severe Primary IGFD have a height that is three standard deviations or more below the mean, they are IGF-1 deficient but are not GH deficient and, because they are resistant to the effects of GH, they cannot be expected to respond adequately to approved doses of GH. Severe Primary IGFD can lead to a range of other metabolic disorders including lipid abnormalities, decreased bone density, obesity and insulin resistance.

The MAA filing for Increlex was based on clinical trial data from 76 patients who were treated for an average of 4.4 years. Height velocity increased from 2.8 cm/yr to 8.0 cm/yr in the first year of treatment (p less than 0.0001). Statistically significant increases in height velocity were seen over six years. An analysis of safety showed that long-term treatment with Increlex has an acceptable safety profile and appears to be well tolerated. The most common drug-related adverse events were hypoglycemia, lipohypertrophy and tonsillar hypertrophy. Side effects were generally mild to moderate in nature, and no patients withdrew from the study as a result of them.

About Tercica

Tercica, Inc. is a biopharmaceutical company focused on the development and commercialization of products to improve endocrine health. The company's first product, Increlex(TM), or recombinant human insulin-like growth factor-1 (rhIGF-1), is approved by the FDA for the treatment of severe Primary IGFD. For further information on Tercica, please visit www.tercica.com.

Safe Harbor Statement

Except for the historical statements contained herein, this press release contains forward-looking statements including, without limitation, the statements that Tercica believes that: (1) its MAA will take approximately seven months to be evaluated, plus any time needed by Tercica to reply to regulatory authority questions; (2) approximately 30,000 children in the EU are affected by Primary IGFD and approximately 6,000 children in the EU are affected by severe Primary IGFD; and (3) it plans to broaden the initial indication of use for Increlex in the U.S and the EU with supplemental applications, pending positive results of ongoing clinical trials evaluating Increlex in children with Primary IGFD. Because Tercica's forward-looking statements are subject to risks and uncertainties, there are important factors that could cause actual results to differ materially from those in the forward-looking statements. These factors include, without limitation, those risks and uncertainties disclosed from time to time in reports filed by Tercica with the SEC, most recently Tercica's Form 10-Q filed on November 4, 2005 and other factors regarding (1) the timetable for EMEA review of Tercica's MAA may be longer than approximated, and the MAA may not be approved by the EMEA; (2) there may be fewer children in the U.S. and the EU with severe Primary IGFD or with Primary IGFD than Tercica estimates; and (3) results from ongoing clinical trials may not be sufficient to submit supplemental applications. These statements are based on information as of the date of this press release. Tercica assumes no obligation to update any forward-looking statements.

SOURCE: Tercica, Inc.

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