



Tercica Initiates Phase IIIb Clinical Trial of rhIGF-1 in Short Stature Caused by Primary IGF-1 Deficiency

SOUTH SAN FRANCISCO, Calif., Oct 28, 2004 /PRNewswire-FirstCall via COMTEX/ -- Tercica, Inc., (Nasdaq: TRCA) announced today that it has dosed its first patient in a Phase IIIb clinical study investigating the use of recombinant human insulin-like growth factor-1 (rhIGF-1) as a therapy for children with short stature caused by primary IGF-1 deficiency (Primary IGFD). IGF-1 is the principal hormone necessary for statural growth. Primary IGFD afflicts an estimated 30,000 children evaluated for short stature in the United States.

"For more than 40 years, endocrinologists have been limited to growth hormone treatment for children with short stature," said Daniel E. Hale, M.D., Department of Pediatrics, University of Texas Health Science Center at San Antonio and investigator in the Phase IIIb study. "Now, based on new estimates of the number of children who are resistant to growth hormone and the availability of rhIGF-1 for clinical trials, we plan to evaluate the potential benefit of rhIGF-1 therapy in children with growth failure caused by Primary IGFD."

The randomized, multi-center Phase IIIb study of rhIGF-1 will enroll approximately 160 pre-pubertal children with Primary IGFD whose height and serum IGF-1 levels are more than two standard deviations below normal. The study is designed to evaluate the safety and efficacy of rhIGF-1 in promoting statural growth. The primary endpoint of the study is change in height standard deviation (SD) score over one year. The study is expected to take approximately two years to complete.

"This study, conducted in partnership with pediatric endocrinology investigators from over 30 pediatric endocrine centers, will build upon the positive results from Tercica's Phase III clinical trial of rhIGF-1 in children with more severe IGF-1 deficiency," said John A. Scarlett, MD, President and Chief Executive Officer of Tercica. "If successful, the study results will be the basis of a future regulatory filing."

Earlier this year, Tercica reported positive Phase III study results of the use of rhIGF-1 in Severe Primary IGFD. Results of the clinical study demonstrated a statistically significant increase ($p < 0.001$) in growth rate over an 8-year period in response to therapy, achieving the study's primary endpoint. In addition, an analysis of safety from the study concluded that long-term treatment with rhIGF-1 appeared to be well-tolerated and had an acceptable safety profile.

About Short Stature, Primary IGFD and Severe Primary IGFD

Short stature is medically defined as occurring in approximately 2.5 percent of all children. Children with short stature have a height significantly below the normal range for their age and gender.

Primary IGFD is diagnosed in children who have normal or elevated secretion of endogenous growth hormone and whose height and serum IGF-1 levels are more than two standard deviations below normal. A sub-set of these children, whose height and serum IGF-1 levels are more than three standard deviations below normal, are diagnosed with Severe Primary IGFD. An estimated 6,000 of the 30,000 children with Primary IGFD in the United States have Severe Primary IGFD.

Primary IGFD is typically caused by abnormalities of either the growth hormone receptor or growth hormone signaling pathway. Primary IGFD can lead, in children and adults, to a range of other metabolic disorders affecting long-term health. These metabolic disorders can include lipid abnormalities, decreased bone density, obesity, insulin resistance and cardiovascular disorders.

About Tercica

Tercica, Inc. is a biopharmaceutical company focused on the development and commercialization of rhIGF-1 for the treatment of short stature, diabetes and other endocrine system disorders. For further information on Tercica and Primary IGFD, please visit www.tercica.com.

Except for the historical statements contained herein, this press release contains forward-looking statements including without limitation the statements regarding: (i) Primary IGFD afflicts an estimated 30,000 children evaluated for short stature in the United States; (ii) the study taking approximately two years to complete; (iii) the study results will be the basis of a future regulatory filing; and (iv) an estimated 6,000 of the 30,000 children with Primary IGFD in the United States have Severe Primary IGFD. These forward-looking statements are subject to risks and uncertainties that could cause actual events to differ

materially from those stated. The above forward-looking statements are subject to those risks and uncertainties disclosed from time to time in reports filed by Tercica with the SEC, most importantly Tercica's Form 10-Q for the quarterly period ended June 30, 2004 and the following risks and uncertainties regarding: (1) with respect to (ii) and (iii) above, (a) patient enrollment and retention in the clinical trial; (b) data from the new Phase IIIb clinical trial that shows safety and statistically significant efficacy; (c) the uncertain, lengthy and expensive clinical development and regulatory process; and (d) budget constraints; and (2) with respect to (i) and (iv) above, there may be fewer children than Tercica estimated. We assume no obligation and do not intend to update these forward-looking statements.

SOURCE Tercica, Inc.

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