



## **FDA Approves Tercica's Increlex for Short Stature Caused by Severe Primary IGF-1 Deficiency**

### **- Targeted Replacement Therapy for Growth Failure in Children With Low Blood Levels of the Hormone IGF-1 - Conference Call to be Held at 8:30 a.m. EDT Today**

BRISBANE, Calif., Aug 31, 2005 /PRNewswire-FirstCall via COMTEX/ -- Tercica, Inc. (Nasdaq: TRCA) announced today that the U.S. Food and Drug Administration (FDA) has approved Increlex(TM) (mecasermin [rDNA origin] injection) for the long-term treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to growth hormone. The FDA also designated Increlex as an orphan drug for severe Primary IGFD.

Insulin-like growth factor-1, or 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. Severe Primary IGFD is a growth hormone-resistant state characterized by abnormally low blood IGF-1 levels in the presence of normal or elevated growth hormone, which afflicts approximately 6,000 children in the U.S.

"We believe that no child should suffer from a preventable or treatable disorder," said Mary Andrews, Chairman and Founder of the MAGIC Foundation, a non-profit organization that supports the families of children with growth problems. "With today's FDA approval, we are happy to know that there is a new treatment option for children suffering from short stature caused by severe Primary IGFD."

"We are pleased Increlex was approved within the six-month priority review timeline, making Increlex the only therapy indicated to treat children with severe Primary IGFD," said John A. Scarlett, M.D., President and Chief Executive Officer of Tercica. "Today, Increlex becomes Tercica's first commercial drug and represents the first major innovation in the treatment of short stature since recombinant growth hormone was approved 20 years ago -- an advance that we believe will change the way physicians diagnose and treat patients with growth failure due to severe Primary IGFD."

"For more than 30 years, growth hormone has been the only treatment option endocrinologists have had for children with short stature due to hormonal deficiency," said Philippe Backeljauw, M.D., Division of Endocrinology, Cincinnati Children's Hospital and a co-investigator in the Phase III trial conducted for Increlex. "The availability of Increlex will enable physicians to offer a more specific treatment for children whose growth failure is linked to abnormally low blood IGF-1 levels."

The active ingredient of Increlex is identical to the natural hormone, IGF-1, which the body produces in response to stimulation by growth hormone. Without adequate IGF-1, children cannot achieve height within the normal range. Tercica acquired exclusive rights to develop, commercialize and manufacture Increlex from Genentech, Inc.

Ross Clark, Ph.D., Founder and Chief Technical Officer of Tercica, said, "This product approval is the culmination of more than two decades of research and development at Genentech. We would like to acknowledge the collective efforts of our clinical investigators, our collaborators, and our partner Genentech. Their contributions have helped bring this new drug to pediatric endocrinologists and to the children and families affected by this disorder."

#### About Severe Primary IGFD

Children with severe Primary IGFD have height and serum IGF-1 levels that are more than three standard deviations below normal. They are not growth hormone deficient, and, because they are resistant to the effects of growth hormone, they cannot be expected to respond adequately to growth hormone therapy. In both children and adults, severe Primary IGFD can lead to a range of other metabolic disorders including lipid abnormalities, decreased bone density, obesity and insulin resistance.

"IGF-1 has proven to be the most critical factor in the growth of children," said Ron Rosenfeld, M.D., Senior Vice President of Medical Affairs, Lucille Packard Foundation for Children's Health and Professor of Pediatrics, Stanford University. "For many years, we believed that growth was largely regulated by the production of growth hormone from the pituitary gland. We now know that while growth hormone is critical, it is IGF-1 that is the primary mediator of growth."

#### About the Increlex Trials

The FDA's approval of Increlex is based on clinical trial data from 71 patients. Data reported at the 2004 Annual Meeting of the Endocrine Society demonstrated a statistically significant increase ( $p < 0.001$ ) in growth rate over an eight-year period in response to therapy. Compared to pre-treatment growth patterns, on average, children gained an additional inch per year for each year of therapy over the course of eight years. In addition, an analysis of safety concluded that long-term treatment with Increlex appears to be well tolerated and has an acceptable safety profile. The most common 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.

#### Conference Call and Webcast Information

John A. Scarlett, M.D., the Company's President and Chief Executive Officer and other members of Tercica's senior management team will host a conference call today at 8:30 a.m. Eastern Daylight Time. To access the live teleconference, dial 1-800-988-0482 (U.S.) or 1-210-839-8116 (international), and reference the pass code "Tercica." The webcast can be accessed at [www.tercica.com](http://www.tercica.com). A replay of the webcast and teleconference will be available approximately one hour after the conclusion of the call for 10 business days. To access the replay, please call 1-888-568-0874 (U.S.) or 1-402-998-1553 (international).

#### 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), has been approved for the treatment of severe Primary IGFD. For further information on Tercica, please visit [www.tercica.com](http://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: (a) Increlex will change the way physicians diagnose and treat patients with growth failure due to severe Primary IGFD; (b) Severe Primary IGFD afflicts approximately 6,000 children; and (c) the availability of Increlex will enable physicians to offer a more specific treatment for children with adequate amounts of growth hormone. 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: (1) 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 August 4, 2005; (2) regarding (a) and (c), physicians may be slow or not choose to prescribe Increlex instead of growth hormone, which many physicians currently prescribe for Primary IGFD, and/or reimbursers may not agree to pay for Increlex; (3) regarding (b), there may be fewer children than Tercica estimates; and (4) if Tercica's results do not meet analysts' forecasts and expectations, its stock price could decline. These statements are based on information as the date of this press release. Tercica assumes no obligation to update any forward-looking statements and the Company assumes no obligation to update any forward-looking statement.

#### SOURCE Tercica, Inc.

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