Life is Rare

April 13, 2026
JCR Pharmaceuticals Co., Ltd.

JCR Pharmaceuticals Initiates Phase III Dose Comparison Study of GROWJECT™ S.C. Injection 12mg in Japan

Hyogo, Japan – April 13, 2026 – JCR Pharmaceuticals Co., Ltd. (TSE 4552; "JCR"), a global specialty biopharmaceutical company dedicated to developing therapies for rare and genetic diseases, today announced that the first participant has been dosed in a Phase III dose comparison study of GROWJECT™ S.C. injection 12mg (somatropin, a recombinant therapy) in pediatric patients with growth hormone deficiency short stature in Japan.

In Japan, standard treatment for pediatric growth hormone deficiency short stature includes daily subcutaneous administration of recombinant human growth hormone (HGH) at 0.175 mg/kg/week, as well as once-weekly long-acting recombinant HGH products. Outside of Japan, dose adjustment according to patient response is permitted for daily HGH products, and in the United States, pediatric patients with growth hormone deficiency short stature may receive adjusted doses (0.175–0.3 mg/kg/week).[1]

To help improve final adult height and quality of life (QoL) in Japan by narrowing the gap with international dosing practices, JCR has initiated development of a dosing regimen that allows dose adjustment in Japan.

This study will compare the efficacy and safety of continuous administration of the study drug at 0.3 mg/kg/week versus 0.175 mg/kg/week in pediatric patients with growth hormone deficiency short stature, while also evaluating the superiority of the higher-dose regimen. Details of the study are available through the Japan Registry of Clinical Trials (jRCT): (JR-401G-301 Study: jRCT2051250213).

"I am pleased to see progress in therapies for children," said Dr. Kenichi Kashimada, Head, Division of Endocrinology and Metabolism, National Center for Child Health and Development. "Through this study, treatment with daily HGH products will be reexamined against international dosing standards rather than the conventional standard dose used in Japan. I hope this will lead to new treatment strategies and help improve final adult height and QoL for pediatric patients with growth hormone deficiency short stature. Going forward, safe and sustainable treatment approaches tailored to each patient are needed."

JCR remains committed to contributing to the field of growth hormone therapy by maintaining a stable supply of high-quality pharmaceuticals and providing a broad range of treatment options for growth disorders to better meet the needs of patients.

About Growject™
Growject™ is an injectable preparation containing recombinant human growth hormone, first launched in Japan by JCR in 1995. The dosage is administered subcutaneously six to seven times per week, adjusted according to the indicated condition.

About JCR Pharmaceuticals Co., Ltd.
JCR Pharmaceuticals Co., Ltd. (TSE 4552) is a global specialty pharmaceutical company that develops treatments that go beyond rare diseases to solve the world's most complex healthcare challenges. We continue to build upon our 50-year legacy in Japan while expanding our global footprint into the U.S., Europe, and Latin America. We improve patients' lives by applying our scientific expertise and unique technologies to research, develop, and deliver next-generation therapies. Our approved products in Japan include therapies for the treatment of growth disorder, MPS II (Hunter syndrome), Fabry disease, acute graft-versus host disease, and renal anemia.

Our investigational products in development worldwide are aimed at treating rare diseases including MPS I (Hurler, Hurler-Scheie and Scheie syndrome), MPS II, MPS IIIA and B (Sanfilippo syndrome type A and B), and more. Our core values – Putting people first, Forging our own path, Always advancing, and Committed to excellence – mean that the work we do benefits all our stakeholders, including partners, patients and employees. We strive to expand the possibilities for patients while accelerating medical advancement at a global level. For more information, please visit JCR's global website: https://jcrpharm.com/

Cautionary Statement Regarding Forward-Looking Statements

This document contains forward-looking statements that are subject to known and unknown risks and uncertainties, many of which are outside our control. Forward-looking statements often contain words such as "believe," "estimate," "anticipate," "intend," "plan," "will," "would," "target" and similar references to future periods. All forward-looking statements regarding our plans, outlook, strategy and future business, financial performance and financial condition are based on judgments derived from the information available to us at this time. Factors or events that could cause our actual results to be materially different from those expressed in our forward-looking statements include, but are not limited to, a deterioration of economic conditions, a change in the legal or governmental system, a delay in launching a new product, impact on competitors' pricing and product strategies, a decline in marketing capabilities relating to our products, manufacturing difficulties or delays, an infringement of our intellectual property rights, an adverse court decision in a significant lawsuit and regulatory actions. This document involves information on pharmaceutical products (including those under development). However, it is not intended for advertising or providing medical advice. Furthermore, it is intended to provide information on our company and businesses and not to solicit investment in securities we issue. Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the factors that could cause actual results to differ materially, even if new information becomes available in the future.

Reference

1. Tanaka T. Changes, limitations, and prospects of adult height in GH treatment for Japanese GHD patients. Clin Pediatr Endocrinol. 2022;31(4):211-24.

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