



June 26, 2023
JCR Pharmaceuticals Co., Ltd.

Translation

JCR receives an Approval for Expanded Indication of Growject® in Short Stature due to SHOX-Deficiency

June 26, 2023-- JCR Pharmaceuticals Co., Ltd. (TSE 4552; Chairman and President: Shin Ashida; “JCR”) announced that JCR has received an approval from the Ministry of Health, Labour and Welfare of Japan today for an expanded indication of Growject® S.C. Injection 6mg and Growject® S.C. Injection 12mg (INN : somatropin) , a recombinant human growth hormone product, for the treatment of short stature caused by alterations of the Short Stature Homeobox-containing Gene (*SHOX*).

SHOX deficiency is a congenital disorder caused by micro deletions, duplications, or mutations that result in loss of function of a growth-gene *SHOX* presents on the sex chromosomes.

The disease presents with growth failure due to an underlying genetic alteration. Growject® is the first approved growth hormone for the treatment of short stature due to SHOX deficiency in Japan.

Growject® is approved in Japan and prescribed for the treatment of short stature due to pediatric growth hormone deficiency, Turner syndrome, small for gestational age, and for adult growth hormone deficiency. Short stature due to SHOX deficiency becomes the fifth indication approved.

Currently, JCR is developing a long-acting growth hormone product for the treatment of short stature due to pediatric growth hormone deficiency. Furthermore, JCR aims to improving the quality of life (QOL) of patients, by developing a patient-friendly delivery device such as GROWJECTOR® L, a motorized injector, and providing added value services for daily growth hormone treatment such as the Melon Nikki™, a dedicated smartphone app for growth hormone medication management.

JCR will continue to contribute to the growth hormone arena by providing a stable supply of high-quality pharmaceuticals and striving to provide various treatment options to meet the needs of the patients with growth disorders.

The impact of this matter on our consolidated financial results for the current fiscal year (ending March 31, 2024) has already been incorporated into our plan at the beginning of the fiscal year.

About JCR Pharmaceuticals Co., Ltd.

JCR Pharmaceuticals Co., Ltd. (TSE 4552) is a global specialty pharmaceuticals company that is

redefining expectations and expanding possibilities for people with rare and genetic diseases worldwide. We continue to build upon our 48-year legacy in Japan while expanding our global footprint into the US, 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, 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 (Hunter syndrome), MPS III A and B (Sanfilippo syndrome type A and B), and more. JCR strives to expand the possibilities for patients while accelerating medical advancement at a global level. Our core values – reliability, confidence, and persistence – benefit all our stakeholders, including employees, partners, and patients. Together we soar. For more information, please visit <https://www.jcrpharm.co.jp/en/site/en/>.

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.

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