News Release

August 26, 2020
JCR Pharmaceuticals Co., Ltd.

Translation

Business Expansion in Brazil

JCR Pharmaceuticals Co., Ltd. (TSE 4552; Chairman and President: Shin Ashida; "JCR") announced that it has officially decided to expand our business in Brazil as part of its efforts for the global development of the treatments for lysosomal storage disorders. .

JCR has embraced a vision to be a "research-oriented specialty pharma with global exposure." To realize this vision, JCR has been pursuing global business expansions of its treatments for lysosomal storage disorders, developing such treatments in Brazil, Europe, the U.S as well as in Japan.
In anticipation of the filing of an application for marketing approval for JR-141 for Mucopolysaccharidosis type II (MPS II, Hunter syndrome), a blood-brain-barrier (BBB)-penetrating recombinant iduronate-2-sulfatase, to the Brazilian Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, "ANVISA") scheduled for November of this year, JCR established JCR DO BRASIL FARMACÊUTICOS IMPORTAÇÃO E EXPORTAÇÃO LTDA. ("JCR DO BRASIL") in Brazil as a company to supervise and manage the application process, related sales and other activities. We have also officially decided to conduct a business of selling drugs for the treatment for lysosomal storage disorders based on JCR DO BRASIL.

In recent years, the demand for medical services in Brazil has been increasing due to factors such as the increase in the income of the people as a result of the country's development. The Brazilian healthcare market was ranked seventh in the world in 2018, and is expected to expand to fifth place by 2023 (Japan ranks third in both years). As Brazil is a member of the International Council for Regulatory Harmonization (ICH), as is Japan, Europe, and the U.S., standards and regulatory requirements for the development and approval of new drugs are in place.
We estimate that Brazil has about 300 diagnosed patients with MPS II (Hunter syndrome), of whom about 70% receive treatment. These patients with lysosomal storage disorders are usually treated at a few specialized centers. Based on the above, we have determined that it is strategically reasonable to develop our business in the Brazil as a first step in our global expansion.

JCR DO BRASIL is expected to conduct business activities such as the filing of applications for marketing approval of medications for the treatment of lysosomal storage disorders such as JR-141, post-approval sales activities and drug information services. In addition, JCR DO BRASIL is expected to foster the collaboration with key opinion leaders (KOLs), patient advocacy groups and other partners in Brazil.
In Brazil, a phase 2 clinical trial with JR-141 has already been completed, and plans call for filing an application for marketing approval of JR-141 to ANVISA in November 2020. After the

application, a priority review will be conducted in accordance with the laws and regulations of Brazil, and it is expected that marketing authorization will be granted by the end of 2021 without data from the planed global phase 3 clinical trial.
Moreover, this year, JCR plans to initiate global phase 1/2 clinical trial of JR-171 for MPS I (Hurler syndrome etc.), a BBB-penetrating α-L-iduronidase, in Japan, Brazil and the U.S this year. Setting up JCR DO BRASIL as its new foothold in Brazil, JCR expects that this new subsidiary will facilitate a steady progress in the aforementioned clinical trials without delays.

As a specialty pharma in the rare diseases arena, JCR will accelerate its research and development activities to continue to provide novel treatments for patients around the world.

The planned expansion is expected to have a minor impact on JCR's consolidated financial results for the fiscal year ending March 31, 2021.

[About JCR Pharmaceuticals]

JCR is a specialty pharma company engaged in the research, development, manufacturing and marketing of biopharmaceuticals and regenerative medicine with a focus on rare diseases. Its philosophy, "Contributing towards people's healthcare through pharmaceutical products" drives JCR to create innovative pharmaceutical products as value-added treatment options for the under-served patient populations.

[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 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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