News Release

September 28, 2018
JCR Pharmaceuticals Co., Ltd.

Translation

JCR Files for Marketing Approval for JR-131,
a Long-Acting Erythropoiesis-Stimulating Agent

JCR Pharmaceuticals Co., Ltd. (TSE: 4552, Chairman and President: Shin Ashida, "JCR") announced today that it has filed an application with the Ministry of Health, Labour and Welfare of Japan for marketing approval for JR-131, a proposed biosimilar to darbepoetin alfa, a long-acting erythropoiesis-stimulating agent for the treatment of renal anemia.

JCR and Kissei Pharmaceutical Co., Ltd. have been conducting the development of JR-131 since the two companies entered into a collaborative research and development agreement for JR-131 in September 2013. The Phase III study initiated in August 2016 established the equivalence in efficacy and safety compared with darbepoetin, along with the similarity in the safety profile.

JCR will continue to provide new treatment options by leveraging its strong expertise in biopharmaceutical manufacturing of global quality standards with the sales results of the first biosimilar in Japan, "Epoetin alfa BS Injection [JCR]" launched in 2010. Through these efforts, JCR will strive to contribute to the treatment available to the broader patient population.

This filing for marketing approval is expected to have a minor impact on JCR's consolidated financial results for the year ending March 31, 2019.

[About JCR Pharmaceuticals]
JCR is a specialty pharma engaged in the research, development, manufacture 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 community.

[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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