News Release

March 22, 2019
JCR Pharmaceuticals Co., Ltd.

Translation

JCR Files for Additional Marketing Approval of TEMCELL® HS Inj. (JR-031EB) for the Indication of Epidermolysis Bullosa

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 ("MHLW") for additional marketing approval of TEMCELL® HS Inj. ("TEMCELL"), allogeneic bone marrow-derived mesenchymal stem cells, , for the indication of epidermolysis bullosa (development code: JR-031EB).

Epidermolysis bullosa ("EB") is a serious rare genetic disease in which minor friction causes blisters or erosion of the skin, particularly in parts of the human body susceptible to friction, such as the peripheral limbs and large joints. Therefore, development of a new treatment option has been long awaited for this intractable disease.

An Investigator Initiated Trial with subcutaneously administered JR-031EB conducted at the Osaka University Hospital from 2016, showed promising results. Also, JR-031EB was designated as an orphan regenerative medical product by MHLW for the indication of EB in October 2018. Furthermore, JCR plans to develop intravenous administration of JR-031EB as an expanded treatment option for EB.

As a specialty pharma engaged in the development of pharmaceutical products for rare diseases, JCR will strive to contribute to the treatment of as many patients as possible.

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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