News Release

March 8, 2021
JCR Pharmaceuticals Co., Ltd.

Translation

JCR Announces Discontinuation of Development of JR-031EB, Expanded Indication of TEMCELL® HS Inj. for Epidermolysis Bullosa

Mar. 8, 2021 -- JCR Pharmaceuticals Co., Ltd. (TSE 4552; Chairman and President: Shin Ashida; "JCR") announced today that it has decided to discontinue development of JR-031EB, an expanded indication of TEMCELL® HS Inj. ("TEMCELL"), allogeneic bone marrow-derived mesenchymal stem cells administered subcutaneously for epidermolysis bullosa ("EB").

In March 2019, JCR had previously filed for additional marketing approval of JR-031EB based on the results of an investigator initiated trial from 2016. .Thereafter, consultations with PMDA highlighted the necessity to demonstrate the efficacy of TEMCELL for EB more clearly such as implementing complex and long-term clinical trials, in addition to non-clinical trials using a mouse model of the disease. Given that these additional trials require a considerable period of time and resources to prepare and conduct, .JCR has decided to discontinue development of JR-031EB.

As a pioneer in cell therapy and regenerative medicine, JCR will continue to steadily pursue its research and development activities in these fields.

This announcement is expected to have a minor impact on JCR's consolidated financial results for the year ending on March 31, 2021.

Epidermolysis bullosa
Epidermolysis bullosa (EB) is a disease in which minor friction in daily life causes the formation of blisters and skin ulcers resembling thermal burns of the whole body, as a result of the detachment of the outermost layer of the skin from the basement membrane level due to mutations in the genes of the attachment complex proteins expressed in the cutaneous basement membrane zone. There are few newly diagnosed patients in Japan every year (based on available information)

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 45-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), Pompe disease, 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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