



September 19, 2019  
JCR Pharmaceuticals Co., Ltd.

Translation

## **JCR Withdraws Application 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 (TSE 4552; Chairman and President: Shin Ashida; "JCR") announced today that it has withdrawn its application with the Ministry of Health, Labour and Welfare of Japan ("MHLW") for additional marketing approval of TEMCELL® HS Inj.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 ("EB") (development code: JR-031EB).

Following the filing of the application for EB in March 2019, JCR has had extensive discussions with the regulatory agency. However, in the aim to demonstrate the efficacy of TEMCELL for EB with more clarity, JCR decided to withdraw this application for the time being.

JCR will continue discussions with the regulatory agency to pursue the development of JR-031EB.

As a pioneer in cell therapy and regenerative medicine, JCR will continue to steadily pursue its R&D 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, 2020.

### **[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.*

Investors & Media:

JCR Pharmaceuticals Co., Ltd.

Corporate Communications

[ir-info@jcrpharm.co.jp](mailto:ir-info@jcrpharm.co.jp)

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