News Release

October 29, 2018
JCR Pharmaceuticals Co., Ltd.

Translation

JCR to Initiate Development 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 the initiation of developing JR-031EB, allogeneic bone marrow-derived mesenchymal stem cells, TEMCELL® HS Inj. ("TEMCELL") , for the indication of epidermolysis bullosa.

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. Presently, no effective treatment is available, thus development of a new treatment option has been long awaited for this intractable disease.

JCR has been supporting an Investigator Initiated Trial ("IIT") for EB, with subcutaneously administered TEMCELL, conducted at the Osaka University Hospital since 2016, to which JCR has been supplying TEMCELL as its test drug.

TEMCELL was approved for the indication of acute graft-versus-host disease (acute GVHD) in 2015. Looking ahead, in light of the results obtained from the clinical study, JCR will prepare the application of JR-031EB by the end of FY 2018 for an expanded indication of EB.
JR-031EB was designated as an orphan regenerative medical product by the Ministry of Health, Labour and Welfare for the indication of EB on October 1, 2018.

Furthermore, JCR plans to expand treatment option to intravenous administration.

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

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. EB is designated as an intractable disease by the Ministry of Health, Labour and Welfare. At present, there is basically no treatment for the condition, and care is limited to protecting the ulcerated areas of the skin with medical gauze, petroleum jelly and so forth.

Designation System for Orphan Regenerative Medical Products
This system is designed to provide special support to encourage clinical studies of items designated as Orphan Regenerative Medical Products by the Minister of Health, Labour and Welfare. This is in order to provide treatment options for illnesses with high unmet medical needs but with a relatively small number

of patients requiring medicines.
The designation will enable JCR to preferentially receive guidance and advice from the Ministry of Health, Labour and Welfare, the Pharmaceuticals and Medical Devices Agency, and the National Institutes of Biomedical Innovation, Health and Nutrition and qualify for support measures such as the implementation of priority reviews, the extension of the drug reexamination period, the granting of subsidies for testing and research expenses, and favorable tax treatment. Upon designation, the following designation requirements must be satisfied:

1. The number of patients for the relevant condition in Japan is less than 50,000;
2. There is a compelling medical need for the product;
3. There is a high probability of success for the development of the product.

[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

END
###