



June 10, 2019
JCR Pharmaceuticals Co., Ltd.

Translation

**JCR Announces Completion of Phase 1/2 Clinical Trial Notification
of TEMCELL® HS Inj. (JR-031HIE)
for the Indication of Neonatal Hypoxic Ischemic Encephalopathy
-Phase 1/2 clinical trial to commence in July 2019-**

JCR Pharmaceuticals Co., Ltd. (TSE 4552; Chairman and President: Shin Ashida; "JCR") announced today the successful completion of the Phase 1/2 clinical trial notification for JR-031HIE, TEMCELL® HS Inj. (TEMCELL) allogeneic bone marrow-derived mesenchymal stem cells for the treatment of hypoxic ischemic encephalopathy in neonates (HIE) via intravenous administration, to the Pharmaceuticals and Medical Devices Agency (PMDA), along with due regulatory inquiries. JCR plans to initiate this trial in July 2019.

HIE is a condition where there is an insufficient supply of oxygen to the brain of a newborn due to reduced cerebral blood flow either in the womb or during delivery. This can lead to neurological disorders affecting the brain, including delayed acquisition of motor skills or neurodevelopment, and cerebral palsy. More effective therapies for HIE are needed because the efficacy of current treatments cannot be confirmed in around half of cases.

TEMCELL was approved for the indication of acute graft-versus-host disease in 2015. As detailed in an earlier release, JCR filed an application for manufacturing and marketing approval of subcutaneously administered TEMCELL for the expanded indication of epidermolysis bullosa (EB) in March 2019 (development code JR-031EB). HIE is the third indication under the expanded license agreement with Mesoblast Limited.

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

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