News Release

July 30, 2024
JCR Pharmaceuticals Co., Ltd.

Translation

JCR Pharmaceuticals Announces Discontinuation of TEMCELL®HS Inj. Expanded Indication Development for Neonatal Hypoxic Ischemic Encephalopathy

Hyogo, Japan -- July 30, 2024 -- JCR Pharmaceuticals Co., Ltd. (TSE 4552: Chairman and President Shin Ashida, "JCR") announced today the discontinuation of the expanded indication development of TEMCELL®HS Inj. (generic name: human (allogeneic) bone marrow-derived mesenchymal stem cells) for intravenous use in neonatal hypoxic ischemic encephalopathy (nHIE), under the development code JR-031HIE.

The Phase I/II clinical trial of JR-031HIE was conducted as a parallel-group comparative study. One group received standard hypothermia therapy (hypothermia therapy-alone group), while the other group received both hypothermia therapy and TEMCELL®HS Inj. (Temcell combination group). Treatment efficacy was assessed using the developmental quotient at 18 months of age. The Temcell combination group did not demonstrate a clinically meaningful difference compared to the hypothermia therapy-alone group. After careful consideration of these results, we have decided to discontinue the development of this expanded indication.

TEMCELL®HS Inj. is a therapeutic product for the treatment of a severe complication arising from hematopoietic stem cell transplantation, and it was approved in September 2015 as the first allogeneic regenerative medicine product in Japan.

There is no impact on our consolidated business results for the year ending on March 31, 2025, related to the matter.

About JCR Pharmaceuticals Co., Ltd.
JCR Pharmaceuticals Co., Ltd. (TSE 4552) is a global specialty pharmaceuticals company that is expanding possibilities for people with rare and genetic diseases worldwide. We continue to build upon our 49-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, MPS II (Hunter syndrome), 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, MPS IIIA and B (Sanfilippo syndrome type A and B), 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. For more information, please visit https://www.jcrpharm.co.jp/en/site/en/.

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