Translation

TEMCELL® HS Inj. Receives NHI Reimbursement Price Listing

JCR Pharmaceuticals Co., Ltd. (Headquarters: Ashiya, Hyogo; Chairman and President Shin Ashida) ("JCR") announced today that TEMCELL® HS Inj. ("TEMCELL" hereinafter) was placed on the National Health Insurance reimbursement list as of today. The launch of TEMCELL is anticipated in February 2016.

TEMCELL is a therapeutic product for the treatment of Acute Graft-versus-Host Disease (Acute GVHD), a severe complication arising from hematopoietic stem cell transplant, and it was approved in September 2015 as the first allogeneic regenerative medicine product in Japan.

TEMCELL is isolated and expanded mesenchymal stem cells (MSCs) derived from bone marrow aspirate of a healthy adult donor. Being an off-the-shelf product, we expect TEMCELL to be a new treatment option for patients with Acute GVHD.

To ensure the quality of TEMCELL, a liquid nitrogen-based ultra-low cold chain system was developed jointly with Medipal Holdings, Inc. This system will enable us to ensure stable quality and on-time delivery of TEMCELL to the clinical site even at emergency situations.

We will endeavor to deliver TEMCELL as soon as possible to patients awaiting this therapeutic product. As a specialty pharma, JCR will proactively engage in the research and development of treatment options for patients with rare diseases.

Our consolidated forecasts for this fiscal year ending March 31, 2016 remains unchanged as announced on August 29, 2015.
[About TEMCELL]

- Brand name: TEMCELL® HS Inj.
- Non-proprietary name: Human (allogeneic) bone marrow derived mesenchymal stem cells
- Indication: Acute graft-versus-host disease following hematopoietic stem cell transplant
- Dosage and administration: 2 million cells/ kg body weight per administration. One bag (72 million cells) of TEMCELL is diluted with 18mL of saline and is administered via slow intravenous infusion at 4mL per minute twice weekly at an interval of 3 days or more for 4 weeks. Administration of additional 4 weeks at one infusion weekly is allowed according to the degree of symptoms.
- Approval date: September 18, 2015
- NHI reimbursement price: 868,680 yen per bag

*Licensed in from Osiris Therapeutics Inc. in 2003. In 2013 Osiris assigned all rights related to MSCs to Mesoblast Limited (Australia), and the licensor of the rights granted to JCR had changed to Mesoblast.

[Glossary]

Hematopoietic stem cell transplant
A treatment by transplanting hematopoietic stem cells which are the source of blood production. It is practiced as a radical treatment of leukemia and has various sources such as bone marrow, peripheral blood and cord blood.

Acute Graft-versus-Host Disease (Acute GVHD)
A life-threatening complication associated with hematopoietic stem cell transplant; a disease which immune cells such as lymph corpuscles present in the transplanted hematopoietic stem cells regard the recipient’s body as foreign and attack the recipient cells.

Allogeneic
Cells and tissues used for regenerative medicine product are classified as “autologous” if derived from the patient and “allogeneic” if derived from another person.

[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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