asx announcement

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the regenerative medicine company

MESOBLAST PARTNER JCR PHARMACEUTICALS FILES FOR MARKETING APPROVAL OF THE FIRST ALLOGENEIC STEM CELL PRODUCT IN JAPAN

New York, USA, and Melbourne, Australia; 1 October2014: Regenerative medicine company Mesoblast Limited (ASX: MSB; USOTC: MBLTY) today reported that its Japanese partner, JCR Pharmaceuticals Co Ltd (JCR), has filed with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) to receive approval for manufacturing, marketing, and product registration of the allogeneic or "off-the-shelf" Mesenchymal Stem Cell (MSC) product JR-031 for the treatment of acute graft versus host disease (GVHD) in children and adults.

The product registration filing by JCR will be subject to a priority review as JR-031 has been granted orphan drug status. If the filing is successful, JR-031 will be the first allogeneic cell-based product approved in Japan.

Under its agreement with JCR, Mesoblast is entitled to receive milestone payments on JR-031 product regulatory filings, approvals, royalties and other payments at pre-defined thresholds of cumulative net sales. In addition, Mesoblast has the worldwide rights to develop JR-031 for all clinical indications, other than for hematologic malignancies in Japan. JCR has a right of first negotiation to obtain rights to commercialize other MSC-based orphan designations in Japan.

Mesoblast Chief Executive Silviu Itescu said: "We congratulate JCR Pharmaceuticals on achieving this important milestone in Japan. We look forward to a positive outcome which will provide a treatment for children and adults with acute graft versus host disease, a life-threatening condition."

Mesoblast plans a product registration filing with the United States Food and Drug Administration (FDA) for its allogeneic MSC product in children with steroid-refractory acute GVHD in 2016. Additionally, Mesoblast remains on track for commercial launch of its allogeneic MSC product in Canada and New Zealand in 2016 in children with GVHD.

About GVHD

According to the Center for International Blood and Marrow Transplant Research, there are approximately 30,000 allogeneic hematopoietic stem cell transplants (HSCT) globally per year for diseases including hematological cancers. Nearly 50% of these develop acute GVHD. GVHD occurs when immune cells in the donated cell population attack the recipient cells because the recipient cells are seen as 'foreign'. Organs that are mainly affected by the immunological attack are the gastrointestinal tract, skin, and liver. There are no approved therapies for steroid refractory acute GVHD. GlobalData estimates that the GVHD therapeutics market will exceed $400 million by 2018.

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Mesoblast Limited
Mesoblast Limited (ASX: MSB; USOTC: MBLTY) is a world leader in the development of biologic products for the broad field of regenerative medicine. The Company's proprietary adult stem cell technologies include its highly purified, immunoselected Stro-1/Stro-3 positive Mesenchymal Precursor Cells (MPCs), culture-expanded Mesenchymal Stem Cells (MSCs), Dental Pulp Stem Cells (DPSCs), and expanded Hematopoietic Stem Cells (HSCs). Mesoblast's protein technologies are based on factors derived from its proprietary cellular platforms, including Stromal Derived Factor-1 (SDF-1). Mesoblast's allogeneic or 'off-the-shelf' cell-based products are targeting substantial market areas of unmet medical need, including cardiac and metabolic diseases, inflammatory/immune-mediated conditions, oncology, and orthopedic diseases. Lead products under investigation are MSC-100-IV for steroid refractory acute Graft Versus Host Disease, MPC-06-ID for chronic discogenic lower back pain and MPC-150-IM for congestive heart failure, in partnership with Teva Pharmaceutical Industries Ltd. www.mesoblast.com

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