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mesoblast
the regenerative medicine company

MESOBLAST UPDATES MARKET ON REGISTRATION PLANS FOR GVHD CELL PRODUCT IN JAPAN

Melbourne, Australia; 28 October 2013: Regenerative medicine company Mesoblast Limited (ASX:MSB; USOTC:MBLTY) today updated the market on product registration plans in Japan for its proprietary culture-expanded Mesenchymal Stem Cells (MSCs) in the treatment of steroid-refractory graft-versus-host disease (GvHD).

Under a collaborative agreement, JCR Pharmaceuticals Co. Ltd. has exclusive rights in Japan to manufacture, develop and market Mesoblast's culture-expanded MSCs in connection with the use of hematopoietic stem cells derived from peripheral blood, cord blood or bone marrow in the treatment of hematological malignancies. JCR is developing and marketing the culture-expanded MSC product JR-031 for the treatment of steroid-refractory GvHD in children and adults following bone marrow transplantation.

In an announcement to the Tokyo Securities Exchange on 24 October, JCR President and CEO Shin Ashida said the company intends to file for product regulatory approval in Japan for JR-031 during the fiscal year ending March 2014. If the filing is successful, JR-031 would be the first allogeneic cell-based product approved in Japan.

JCR will bear all costs associated with bringing culture-expanded MSC products to market in Japan for hematological malignancies, and will manufacture and sell the products. JCR is required to make milestone payments to Mesoblast on both product regulatory filing and approvals, certain payments to Mesoblast for pre-determined thresholds of cumulative net sales, as well as royalties.

Acute GvHD is a potentially life threatening complication that arises in approximately 50% of all patients who receive an unrelated-donor bone marrow transplant. There are more than 3,500 unrelated-donor bone marrow transplants performed in Japan each year.

Mr Ashida said JCR was looking to enhance its collaboration with Mesoblast. “We look forward to proactively building a relationship with Mesoblast with a view to potential expansion of the partnership,” he said.

Mesoblast Chief Executive Silviu Itescu said: “We are very pleased with our new partnership with JCR. The planned regulatory filing by JCR facilitates the first commercial launch of our mesenchymal lineage products in Japan, the world’s second largest healthcare market.”

About JCR Pharmaceuticals Co., Ltd. (JCR)

JCR (TSE 2nd Section, Code: 4552) is a Japanese pharmaceutical company specialized in the research, development, manufacture and sales of biotherapeutics. Founded in 1975, the company under its philosophy, “Contributing towards people’s healthcare through pharmaceutical products” is engaged in the creation of biotherapeutics utilizing its cultivation technology and biotechnology platform. JCR’s R&D focus in the rare diseases represents its commitment to deliver value-added treatment options for the under-served patient community. At present JCR’s core products consist of two biotherapeutics, recombinant human growth hormone and erythropoiesis-stimulating agent. Several products for treatment of lysosomal storage diseases and cell-based products are in JCR’s R&D pipeline.

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About Mesoblast

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 technologies include its Mesenchymal Precursor Cell and culture-expanded Mesenchymal Stem Cell technology platforms, Dental Pulp Stem Cells, and expanded Hematopoietic Stem Cells. Mesoblast's allogeneic or 'off-the-shelf' regenerative medicine products focus on repair of damaged tissues and modulation of inflammatory responses in conditions with significant unmet medical needs. The lead product candidates use its mesenchymal lineage platforms in four major and distinct areas - systemic inflammatory conditions, cardiovascular diseases, orthopedic diseases of the spine and oncology conditions. www.mesoblast.com

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