asx announcement

mesoblast
the regenerative medicine company

FIRST ALLOGENEIC CELL THERAPY PRODUCT LAUNCHED IN JAPAN BY MESOBLAST LICENSEE

Melbourne, Australia; and New York, USA; 24 February 2016: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) announced that its licensee in Japan, JCR Pharmaceuticals Co. Ltd., today launched its mesenchymal stem cell product TEMCELL® HS Inj., for the treatment of acute graft versus host disease (aGVHD) in children and adults in Japan. TEMCELL is the first allogeneic cell therapy to be fully approved in Japan.

The Japanese Government's National Health Insurance set reimbursement for TEMCELL at ¥868,680 (approximately US$7,700) per bag of 72 million cells. In Japan, the average adult patient is expected to receive at least 16 or up to 24 bags of 72 million cells. On this basis, Mesoblast expects a treatment course of TEMCELL in an adult Japanese patient to be reimbursed at a minimum of ¥13,898,880 (approximately US$123,000) or up to ¥20,848,320 (approximately US$185,000).

Under its agreement with JCR, Mesoblast is entitled to receive royalties and other payments at predefined thresholds of cumulative net sales.

In the world's largest healthcare market, the United States, there are currently no approved therapies for patients with acute steroid-refractory GVHD, and off-label options have demonstrated mixed efficacy with high toxicity.

To support filing of a biologic license application (BLA) to the United States Food and Drug Administration for regulatory approval, Mesoblast is conducting a 60-patient, open label Phase 3 trial using MSC-100-IV as front-line therapy in children with steroid-refractory aGVHD. After filing a BLA for pediatric approval of MSC-100-IV, Mesoblast plans to conduct a further trial to support a product approval of its cell therapy in adults with gastrointestinal or liver aGVHD, the patient groups who have the highest mortality risk.

In the United States, pricing reimbursement methodology is expected to consider the burden of illness associated with steroid-refractory aGVHD as well as health utilization costs, and may result in a higher price than in Japan.

About Graft Versus Host Disease
Mesoblast is developing MSC-100-IV for the treatment of aGVHD following an allogeneic bone marrow transplant (BMT). In patients who have received a BMT, donor cells may attack the recipient (the person receiving the transplant), causing aGVHD, resulting in activation of pro-inflammatory T-cells and tissue damage in the skin, gut and liver which is often fatal.

According to the Center for International Blood and Marrow Transplant Research, there are approximately 30,000 allogeneic BMTs globally per year for diseases including hematological cancers, with 25% of all cases in the pediatric population. Nearly 50% of all allogeneic BMT patients develop aGVHD. Liver or gastrointestinal involvement occur in up to 40% of all patients with aGVHD and are associated with the greatest risk of death, with mortality rates of up to 85%.

About Mesoblast
Mesoblast Limited (ASX: MSB; Nasdaq:MESO) is a global leader in developing innovative cell-based medicines. The Company has leveraged its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells, to establish a broad portfolio of late-stage product candidates. Mesoblast's allogeneic, 'off-the-shelf' cell product candidates target advanced stages of diseases with high, unmet medical needs including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncologic/hematologic conditions.

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Forward-Looking Statements
This press release includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. You should read this press release together with our risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

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