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the regenerative medicine company

# MESOBLAST'S JAPAN LICENSEE RECEIVES PRICING FOR TEMCELL® HS Inj FOR TREATMENT OF ACUTE GRAFT VERSUS HOST DISEASE

**Melbourne, Australia; and New York, USA; 26 November 2015:** Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today announced that its licensee in Japan, JCR Pharmaceuticals Co. Ltd., has received notification that the Japanese Government's National Health Insurance (NHI) body has formally set the price for the mesenchymal stem cell product TEMCELL® HS Inj., effective from today.

JCR announced that the launch of TEMCELL for the treatment of acute graft versus host disease (aGVHD) after an allogeneic bone marrow transplant (BMT) is anticipated in February 2016. Under its agreement with JCR, Mesoblast is entitled to receive royalties and other payments at pre-defined thresholds of cumulative net sales.

The approved and reimbursed dosing regimen in Japan for TEMCELL is as follows:

- For all patients, eight doses of 2 million cells/kilogram, delivered as an intravenous infusion.
- For patients with persistent symptoms beyond four weeks, a further weekly dose of 2 million cells/kilogram may be given for four additional weeks.

Reimbursement for TEMCELL has been authorized by NHI at ¥868,680 (A$9,767 / US$7,079) per bag of 72 million cells. In Japan, the average adult patient is expected to receive 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 ¥13,898,880 (A$156,000 / US$113,000) or up to ¥20,848,320 (A$234,000 / US$170,000).

## United States

Mesoblast believes it is well positioned to have the first industrially manufactured allogeneic cell-based product approved in the United States, with its product candidate for the treatment of steroid refractory aGHVD in children.

The Company expects to complete recruitment of its open label, 60-patient Phase 3 trial in children with steroid-refractory aGVHD in the fourth quarter of 2016 and to announce top-line interim results of the trial during the third quarter of 2016. This interim analysis may support a Biologics License Application (BLA) regulatory filing by the end of 2016.

In the US, 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. This life-threatening illness is designated as an orphan indication.

According to the Center for International Blood and Marrow Transplant Research, there are approximately 30,000 allogeneic BMTs globally. In the US, there are expected to be 8,900 allogeneic BMTs in 2015, with 25% of all cases in the pediatric population. Of these patients, 50% are expected to 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%. Currently, in the US there are no approved therapies for patients with steroid-refractory aGVHD.

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**About Mesoblast**
Mesoblast Limited (ASX: MSB; Nasdaq: MESO) is a global leader in regenerative medicine. 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 where there are highly unmet medical needs, including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncology/hematology conditions.

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