asx announcement

mesoblast
the regenerative medicine company

JAPANESE LEGISLATION TAKES EFFECT FOR EXPEDITED APPROVALS OF REGENERATIVE MEDICAL PRODUCTS

New York, USA, and Melbourne, Australia; 25 November, 2014: Mesoblast Limited (ASX: MSB, USOTC: MBLTY) provided an update to the market on the Pharmaceuticals, Medical Devices and Other Therapeutic Products Act (PMD Act) which takes effect today in Japan. This Act establishes a framework for expedited approval in Japan for regenerative medical products.

Mesoblast Chief Executive Silviu Itescu said that the Company intends to seek expedited conditional approvals in Japan for its cell therapy product candidates by capitalizing on its clinical data generated to date, its strong intellectual property, and its manufacturing know how.

Key takeaways of the PMD Act for Mesoblast are:

- Conditional product approvals will be based on existing Phase 2 trial results demonstrating probable efficacy and safety with bridging studies in Japanese patients
- Conditional approvals will allow sales of each product candidate for up to 7 years
- Conditionally approved products will be covered by health insurance
- Conditional approvals will cover allogeneic cell therapy product candidates manufactured under GMP outside of Japan; and
- Full approval is expected to require further confirmation of safety and efficacy in a larger population.

The PMD Act will enable Mesoblast to make its cell therapy product candidates available sooner to patients with unmet medical needs, and to achieve nearer term revenues in Japan ahead of other major jurisdictions.

In order to achieve its corporate objectives in Japan, Mesoblast

- has completed prioritization of lead product candidates based on assessment of commercial opportunity and feasibility in Japan
- will leverage existing Phase 2 clinical trial results for Tier 1 and Tier 2 product candidates
- has engaged with product development and commercialization experts in Japan
- has initiated dialog with the Japanese regulatory authority, the Pharmaceuticals and Medical Devices Agency (PMDA); and
- is in active discussions with existing and potential commercialization partners for its product candidates in Japan.

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668
T +65 6570 0635
F +65 6570 0176

Mesoblast Limited
Mesoblast Limited (ASX: MSB; USOTC: MBLTY) 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 (MLCs), to establish a broad portfolio of late stage product candidates. Mesoblast's allogeneic or 'off-the-shelf' cell product candidates target significantly advanced stages of diseases where there are highly unmet medical needs, including orthopedic disorders, cardiovascular disorders, immunologic/inflammatory disorders and oncology /hematology conditions. Lead product candidates under investigation include MPC-06-ID for chronic discogenic low back pain, MPC-150-IM for chronic congestive heart failure, in partnership with Teva Pharmaceutical Industries Ltd., and MSC-100-IV for acute graft versus host disease (aGVHD).

For further information, please contact:

Julie Meldrum
Global Head of Corporate Communications
Mesoblast Limited
T: +61 (0) 3 9639 6036
E: julie.meldrum@mesoblast.com