asx announcement

mesoblast
the regenerative medicine company

MESOBLAST PARTNER JCR PHARMACEUTICALS RECEIVES RECOMMENDATION FOR APPROVAL OF MESENCHYMAL STEM CELL PRODUCT IN JAPAN

New York, USA, and Melbourne, Australia; 4 September 2015: Mesoblast Limited (ASX: MSB; USOTC: MBLTY) today announced that the allogeneic mesenchymal stem cell-based regenerative medicine product JR-031, developed by Mesoblast's Japanese partner JCR Pharmaceuticals Co. Ltd., was recommended for approval on 2 September at a meeting organized by the Committee on Regenerative Medicine Products and Biological Technology of Pharmaceutical Affairs and Food Sanitation Council of the Japan Ministry of Health, Labour and Welfare. JCR said marketing approval of JR-031 is anticipated in the near future.

JR-031 is a treatment for acute Graft Versus Host Disease (GVHD), a severe complication arising from hematopoietic cell transplants, which JCR has been developing in Japan utilizing technology under a licence from Mesoblast. JCR stated that clinical trials demonstrated the efficacy and safety of JR-031 which led to their filing for a marketing approval in September 2014.

Under its agreement with JCR, Mesoblast is entitled to receive milestone payments on JR-031 product regulatory approvals, as well as royalties and other payments at pre-defined thresholds of cumulative net sales.

Mesoblast is conducting an additional open-label Phase 3 study in the United States of its allogeneic MSC product in approximately 60 children, the results of which are expected to support a Biologics License Application to the United States Food and Drug Administration for pediatric product registration.

Graft Versus Host Disease
In patients who have received a bone marrow transplant, donor cells may attack the person receiving the transplant, causing acute GVHD. According to the Center for International Blood and Marrow Transplant Research, there are approximately 30,000 allogeneic bone marrow transplants globally per year for diseases including hematological cancers. Nearly 50% of all allogeneic bone marrow transplants develop acute GVHD which is associated with the greatest risk of death with mortality rates of up to 90%.

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, 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 cardiovascular conditions, orthopedic disorders, immunologic/inflammatory disorders and oncology/hematology conditions. The lead therapeutic product candidates under investigation include MPC-150-IM for chronic heart failure, MPC-06-ID for chronic discogenic low back pain, MSC-100-IV for acute graft versus host disease, and MPC-300-IV for diabetic nephropathy and biologic refractory rheumatoid arthritis.

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