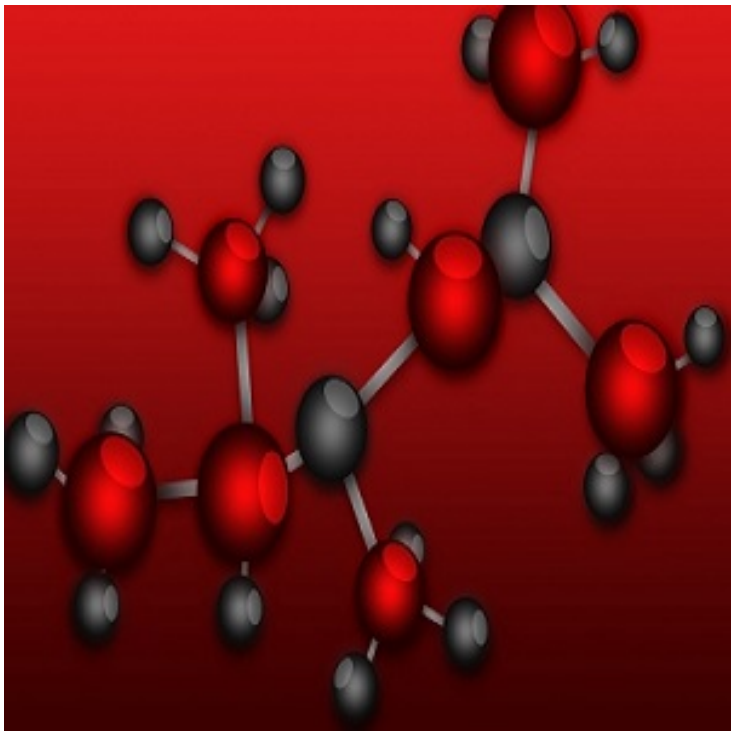
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Mesoblast files for approval of stem cell product in Japan

07 September 2015 | News | By BioSpectrum Bureau

Mesoblast files for approval of stem cell product in Japan



Tokyo: Australia's regenerative medicine company, Mesoblast Limited has announced that its allogeneic mesenchymal stem cell-based regenerative medicine product JR-031 was recommended for approval 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. JR-031 is developed by Mesoblast's Japanese partner JCR Pharmaceuticals Co. Ltd.

JCR indicated that 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 license 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 III 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.