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PATIENT ENROLLMENT COMMENCED IN PIVOTAL PHASE 3 TRIAL OF REXLEMESTROCEL-L FOR CHRONIC LOW BACK PAIN

Melbourne, Australia; July 22 and New York, USA; July 21, 2024: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, announced today that the confirmatory Phase 3 trial of its allogeneic, immunoselected, and industrially manufactured stromal cell product rexlemestrocel-L in patients with chronic low back pain (CLBP) due to inflammatory degenerative disc disease of less than five years duration has commenced enrollment at multiple sites across the United States.

The United States Food and Drug Administration (FDA) has previously confirmed alignment with Mesoblast on the design of the 300-patient randomized, placebo-controlled trial and the 12-month primary endpoint of pain reduction as an approvable indication. Key secondary measures include improvement in quality of life, function, and reduced opioid usage.

FDA has designated rexlemestrocel-L a Regenerative Medicine Advanced Therapy (RMAT) for the treatment of chronic low back pain. RMAT designation provides all the benefits of Breakthrough and Fast Track designations, including rolling review and eligibility for priority review on filing of a Biologics License Application (BLA).

"This therapy has the potential to be groundbreaking and life changing for the low back pain population," said Dr. Alan Miller, MD, trial investigator at Coastal Health Specialty Care in Jacksonville, Florida.

Mesoblast Chief Medical Officer Dr. Eric Rose said "We are very excited to be actively enrolling our pivotal trial of rexlemestrocel-L across multiple sites and look forward to confirming the durable pain reduction previously observed in the first Phase 3 trial. There is a significant need for a safe, effective, and durable treatment in patients with CLBP and degenerative disc disease, in particular one that reduces or eliminates opioid use."

About Chronic Low Back Pain

Back pain is the leading cause of disability in Americans under 45 years,[1] with an annual prevalence in the general US adult population of 10-30%.[2] CLBP caused by inflammation and degenerative disc disease (DDD) is a serious condition with a prevalence of over 7 million people in the US alone.[3,4] CLBP due to DDD is a leading cause of disability, and is associated with impaired quality of life, severe limitations in ability to perform activities of daily living, reduced ability to work, and negative impacts on mental health. CLBP accounts for approximately 50% of prescription opioid usage in the US,[4] making the condition a significant contributor to the opioid epidemic.

About Mesoblast

Mesoblast (the Company) is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2041 in all major markets. The Company's proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

Mesoblast is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease, and biologic-resistant inflammatory bowel disease. Rexlemestrocel-L is being developed for advanced chronic heart failure and chronic low back pain. Two products have been commercialized in Japan and Europe by Mesoblast's licensees, and the Company has established commercial partnerships in Europe and China for certain Phase 3 assets.

Mesoblast has locations in Australia, the United States and Singapore and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). For more information, please see www.mesoblast.com, LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

References / Footnotes

1. American Academy of Pain Medicine - Get the Facts on Pain. The American Academy of Pain Medicine. http://www.painmed.org/patientcenter/facts-on-pain/ Accessed on June 28, 2017.
2. Urits I, Burshtein A, Sharma M, et al. Low Back Pain, a Comprehensive Review: Pathophysiology, Diagnosis, and Treatment. Current Pain and Headache Reports. 2019;23(3):1-10. doi:10.1007/s11916-019-0757-1.
3. Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 – August 2014.
4. Decision Resources: Chronic Pain December 2015.

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. Forward-looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals (including any future decision that the FDA may make on the BLA for remestemcel-L for pediatric patients with SR-aGVHD), manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. 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.

Release authorized by the Chief Executive.

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