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MESOBLAST ACHIEVES MAJOR MILESTONE COMPLETING PATIENT TREATMENT IN PIVOTAL PHASE 3 TRIAL FOR CHRONIC LOW BACK PAIN

New York, USA: August 16 and Melbourne, Australia: August 17, 2026: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that it has completed patient treatment in the MSB-DR004 pivotal randomized controlled Phase 3 trial of rexlemestrocel-L for chronic low back pain (CLBP) associated with the inflammatory condition of degenerative disc disease. The major milestone was achieved with 350 patients randomized and treated with either an intra-discal injection of rexlemestrocel-L or sham injection. Total patient numbers treated increased from 300 to 350 after strong demand from trial investigators to have their patients enrolled in the innovative program.

The trial's primary endpoint aims to confirm the durable pain reduction at 12 months from a single intra-discal injection of rexlemestrocel-L seen in the earlier MSB-DR003 trial. With 350 treated patients, the trial is well-powered for showing a greater treatment benefit in patients receiving rexlemestrocel-L compared with controls. Secondary endpoints include improvements in function, quality of life, and cessation of pain medication, including opioids.

Silviu Itescu, Chief Executive of Mesoblast, said: "Completing treatment of 350 patients in our pivotal low back pain trial is a momentous milestone for the company as we now count down to the 12-month read-out for what we hope will be the basis of our first blockbuster product."

CLBP caused by inflammation and degenerative disc disease is a serious condition with a prevalence of over 7 million people in the U.S. alone. The indication has potential peak year revenue of >US$10 billion for Mesoblast even with just single digit market penetration.

Rexlemestrocel-L has Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA) for treatment of CLBP due to degenerative disc disease providing eligibility for priority review once the Biologics License Application (BLA) has been filed. Top-line results are expected in mid-CY2027 after the last treated patient has completed 12 months follow-up.

About Rexlemestrocel-L for Chronic Low Back Pain associated with Degenerative Disc Disease
Mesoblast's second generation allogeneic, STRO3-immunoselected, and industrially manufactured stromal cell product candidate rexlemestrocel-L is being evaluated in patients with chronic low back pain (CLBP) due to inflammatory degenerative disc disease (DDD) of less than five years duration. Mesoblast has agreement with FDA on the design of the randomized, placebo-controlled pivotal Phase 3 trial and on the trial's 12-month primary endpoint of pain reduction, previously successfully met in Mesoblast's first Phase 3 trial, as an approvable indication. Key secondary measures include improvement in quality of life and function. A further secondary endpoint will be reduction in opioid use since discogenic back pain accounts for approximately 50% of opioid prescriptions in the U.S.

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 therapies from the Company's proprietary mesenchymal lineage cell therapy technology platform respond to severe inflammation by

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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's Ryoncil® (remestemcel-L-rknd) for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months and older is the first FDA-approved mesenchymal stromal cell (MSC) therapy. Please see the full Prescribing Information at www.ryoncil.com.

Mesoblast is committed to developing additional cell therapies for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Ryoncil® is being developed for additional inflammatory diseases including SR-aGvHD in adults and biologic-resistant inflammatory bowel disease. Rexlemestrocel-L is being developed for heart failure and chronic low back pain. The Company has established commercial partnerships in Japan, Europe and China.

About Mesoblast intellectual property: Mesoblast has a strong and extensive global intellectual property portfolio, with over 1,000 granted patents or patent applications covering mesenchymal stromal cell compositions of matter, methods of manufacturing and indications. These granted patents and patent applications provide commercial protection extending through to at least 2044 in all major markets.

About Mesoblast manufacturing: 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 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, manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's RYONCIL for pediatric SR-aGVHD and any other 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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