asx announcement

mesoblast

FDA ACKNOWLEDGES EFFECTS ON PAIN INTENSITY FAVOR REXLEMESTROCEL-L, CONFIRMS 12-MONTH REDUCTION IN BACK PAIN SUPPORTS PRODUCT EFFICACY

Approval Label May Include Opioid Reduction

New York, USA: January 18 and Melbourne, Australia; January 19, 2026: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided feedback received from the U.S. Food & Drug Administration (FDA) on potential filing of a Biologics License Application (BLA) for its allogeneic cell therapy product rexlemestrocel-L in patients with chronic discogenic low back pain (CLBP). This follows FDA's Type B meeting review of data from Mesoblast's first randomized controlled Phase 3 trial (MSB-DR003) on pain reduction and relationship to decreased use or elimination of opioids for up to three years following a single rexlemestrocel-L administration.

Mesoblast is seeking FDA approval for rexlemestrocel-L based on reduction in CLBP through 12 months. Comparing outcomes between rexlemestrocel-L and placebo from MSB-DR003 trial, FDA acknowledged that the effects on pain intensity appear to favor the active arm. FDA also confirmed that a clinically meaningful reduction in pain intensity in the active arm versus placebo at 12 months can support product efficacy and stated that the robust results on opioid reduction from at least one adequate and well controlled trial could be included in the Clinical Studies section of product labeling.

A second randomized controlled Phase 3 trial, MSB-DR004, is actively recruiting across 40 sites in the U.S., is over 50% enrolled, and is expected to complete the 300-patient enrollment target in the coming three months. CLBP is a major contributory factor to the U.S. opioid crisis, and rexlemestrocel-L has received Regenerative Medicine Advanced Therapy (RMAT) designation from FDA for treatment of CLBP.

Mesoblast Chief Executive Silviu Itescu said: "Rexlemestrocel-L could offer a powerful solution for management of chronic inflammatory back pain with the added potential to contribute to the administration's goals of opioid reduction or cessation."

About Rexlemestrocel-L for Chronic Low Back Pain associated with Degenerative Disc Disease
The 300-patient randomized controlled confirmatory Phase 3 trial of Mesoblast's second generation allogeneic, STRO3-immunoselected, and industrially manufactured stromal cell product candidate rexlemestrocel-L in combination with hyaluronic acid (HA) as delivery agent for injection into the lumbar disc is actively enrolling in patients with chronic low back pain (CLBP) due to inflammatory degenerative disc disease (DDD) of less than five years duration at multiple sites across the U.S.

FDA has previously agreed on the design of this 300-patient randomized, placebo-controlled confirmatory Phase 3 trial, and the 12-month primary endpoint of pain reduction as an approvable indication. This endpoint was successfully met in Mesoblast's first Phase 3 trial. Key secondary measures include improvement in quality of life and function.

A particular focus is on treatment of patients on opioids, since discogenic back pain accounts for approximately 50% of prescription opioid usage in the U.S. In light of the devastating opioid crisis that continues to rage in the U.S., in September 2025 FDA provided new Guidance to Industry on Development of Non-Opioid Agents for Treatment of Chronic Pain.[1]

Significant pain reduction and opioid cessation were observed in Mesoblast's first Phase 3 trial. In Mesoblast's first randomized controlled Phase 3 trial of 404 patients, 168 of whom were taking opioids at baseline, more than 3-fold higher numbers of patients treated with a single intra-discal injection of rexlemestrocel-L + HA were able to cease use of all opioids by 36 months compared with saline-treated controls (p=0.008).

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

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
1114 Avenue of the Americas
4th Floor
New York, NY 10036
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South Tower)
SINGAPORE 138567
T +65 6570 0635
F +65 6570 0176

Track designations, including rolling review and eligibility for priority review on filing of a Biologics License Application (BLA).

About Chronic Low Back Pain
Back pain is the leading cause of disability in Americans under 45 years,[2] with an annual prevalence in the general US adult population of 10-30%.[3] CLBP caused by inflammation and degenerative disc disease (DDD) is a serious condition with a prevalence of over 7 million people in the U.S. alone.[4,5] 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, 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 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. United States Food & Drug Administration. Development of Non-Opioid Analgesics for Chronic Pain Guidance for Industry. Draft Guidance. September 2025
2. 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.
3. 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.
4. Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 – August 2014.
5. 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.

For more information, please contact:

Corporate Communications / Investors
Paul Hughes
T: +61 3 9639 6036

Media – Global
Allison Worldwide
Emma Neal
T: +1 603 545 4843
E: emma.neal@allisonworldwide.com

Media – Australia
BlueDot Media
Steve Dabkowski
T: +61 419 880 486
E: steve@bluedot.net.au