

asx announcement

SINGLE DOSE OF MESOBLAST'S ALLOGENEIC CELL THERAPY PROVIDES DURABLE PAIN REDUCTION FOR AT LEAST THREE YEARS IN PATIENTS WITH DEGENERATIVE DISC DISEASE

36-Month Results of Phase 3 Trial in Chronic Low Back Pain Presented at 2022 Biotech Showcase

Melbourne, Australia; January 12, and New York, USA; January 11, 2022: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced 36-month follow-up results from the 404-patient Phase 3 trial of its allogeneic cell therapy rexlemestrocel-L (MPC-06-ID) in patients with chronic low back pain (CLBP) associated with degenerative disc disease (DDD). Mesoblast Chief Executive Dr Silviu Itescu presented results from the three-arm trial at the 2022 Biotech Showcase event being held this week, which showed durable reduction in back pain lasting at least three years from a single intra-discal injection of rexlemestrocel-L+hyaluronic acid (HA) carrier.

There is a significant need for a safe, effective, and durable opioid-sparing treatment in patients with CLBP associated with degenerative disc disease. Results presented from this trial showed that:

- Durable reduction in pain through 36 months was greatest in the pre-specified population with CLBP of shorter duration than the study median of 68 months (n=194), suggesting that greatest benefits may be seen when the therapy is administered earlier in the disease process when there is active inflammation and before irreversible fibrosis of the intervertebral disc has occurred
- Pain reduction through 36 months was also seen in the subset of patients using opioids at baseline (n=168) with the rexlemestrocel-L+HA group having substantially greater reduction at all time points compared with saline controls
- Among patients on opioids at baseline, despite instructions to maintain existing therapies throughout the trial, at 36 months 28% who received rexlemestrocel-L + HA were not taking an opioid compared with 8% of saline treated controls (nominal p value 0.0075).

Mesoblast recently received feedback from the US Food & Drug Administration's (FDA) Office of Tissues and Advanced Therapies (OTAT) on the Phase 3 program for CLBP and plans to conduct an additional US Phase 3 trial which may support submissions for potential approval in both the US and EU. Following review of the completed Phase 3 trial data, OTAT agreed with Mesoblast's proposal for pain reduction at 12 months as the primary endpoint of the next trial, with functional improvement and reduction in opioid use as secondary endpoints.

The Biotech Showcase presentation materials have been lodged with the ASX.

About Mesoblast

Mesoblast 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 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 moderate to severe acute respiratory distress syndrome. Rexlemestrocel-L is in development 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

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 forwardlooking 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. Forwardlooking 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 BLA resubmission), 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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