asx announcement

mesoblast
the regenerative medicine company

MESOBLAST PRESENTS CORPORATE UPDATES AT GLOBAL HEALTHCARE CONFERENCES

New York, USA; and Melbourne, Australia; September 25, 2017: Mesoblast Limited (ASX:MSB; Nasdaq: MESO) today announced that the company will this week present corporate updates at the annual Cantor Fitzgerald Global Healthcare Conference and the Ladenburg Thalmann Healthcare Conference, both being held in New York City, New York.

The Company presentations will focus on the Phase 3 clinical trials of its lead product candidates in acute graft versus host disease (aGVHD), chronic low back pain due to disc degeneration (CLBP), and chronic heart failure (CHF), and on potential regulatory strategies to achieve accelerated approval pathways for these product candidates based on the serious and life-threatening nature of the diseases and the cumulative clinical results obtained to date using the Company's proprietary mesenchymal lineage cell technology platforms.

The Company has significant upcoming milestones in regard to these Phase 3 assets, has strengthened its financial position post the recently completed institutional and retail entitlement offers, and continues to be in active discussions with several potential strategic partners, including Mallinckrodt Pharmaceuticals plc.

Mesoblast's lead product candidate for treatment of steroid-refractory acute aGVHD is **MSC-100-IV**, and this product candidate has been granted a Fast Track designation by the United States Food and Drug Administration (FDA). MSC-100-IV has been used extensively under an Expanded Access Program with very encouraging results on both overall response and survival. The open-label Phase 3 trial in up to 60 children successfully met a pre-specified interim futility analysis of the primary endpoint in November 2016, and the trial is expected to have top-line data readout in 2H CY17.

Mesoblast's lead product candidate for treatment of chronic low back pain due to disc degeneration is **MPC-06-ID.** The 360-patient Phase 3 trial is aiming to confirm the durable reduction in pain and improvement in function seen in the prior 100-patient Phase 2 trial, and is comparing a single intra-disc injection of MPC-06-ID or placebo (2:1 randomization). Additional objectives of the trial are to evaluate the potential of an intra-disc injection of MPC-06-ID to prevent or reduce the use of opioids in these patients, a major focus of the 21st Century Cures Act given the opioid epidemic. The Phase 3 trial is expected to complete enrollment in Q4 CY17.

Mesoblast's lead product candidate for chronic heart failure is **MPC-150-IM,** currently being evaluated in two complementary Phase 2b/3 trials for the treatment of patients with either end-stage or advanced heart failure. In these trials, the same product dose and formulation is delivered by either direct epicardial injection surgically or by catheter-based endomyocardial injection.

In patients with end-stage heart failure, 1-year mortality approaches 50% on maximal medical therapy alone. In the 159-patient Phase 2b trial, MPC-150-IM or placebo (2:1 randomized) is injected directly into the epicardium of damaged heart muscle, with a primary objective to strengthen the heart muscle sufficiently that it can temporarily support the circulation without assistance from a left ventricular assist device (LVAD). The primary end-point will be measured at 6 months, with top-line results expected in Q1 CY2018.

In the Phase 3 trial of up to 600 patients with moderate to severe heart failure, MPC-150-IM or placebo (1:1 randomized) is injected by catheter into the endomyocardium. In April 2017, the pre-specified interim futility analysis of the trial's efficacy endpoint of reducing recurrent hospitalizations was successful in the first 270 patients, and over 400 patients have been randomized to date. Enrollment is expected to complete in 2H CY18 and the results from this Phase 3 trial in advanced heart failure will be used to complement the results from the Phase 2b trial in end-stage heart failure.

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About Mesoblast
Mesoblast Limited (ASX:MSB; Nasdaq:MESO) is a global leader in developing innovative cell-based medicines. The Company has leveraged its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells, to establish a broad portfolio of late-stage product candidates. Mesoblast's allogeneic, 'off-the-shelf' cell product candidates target advanced stages of diseases with high, unmet medical needs including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncologic/hematologic conditions.

Forward-Looking Statements
This announcement 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 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.

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