asx announcement



MESOBLAST HIGHLIGHTS 2019 KEY PRIORITIES FOR ITS LEADING CELLULAR MEDICINES PIPELINE AT BIOTECH SHOWCASE IN SAN FRANCISCO

New York, USA; January 7, 2019 and Melbourne, Australia; January 8, 2019: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), world leader in the development and commercialization of cellular medicines, today reported on commercial and development plans for its lead cellular therapies to Biotech Showcase 2019 being held this week in San Francisco, CA.

Mesoblast Chief Executive Dr Silviu Itescu said: "We enter calendar 2019 building upon the successful advancement of our late-stage pipeline where we successfully completed a Phase 3 trial in steroidrefractory acute graft versus host disease (aGVHD) which has near-term commercial potential in the United States (U.S.), and another product candidate having achieved clinical outcomes in line with the U.S. Food and Drug Administration (FDA) guidance for a registrable clinical indication for market authorization, and two additional Phase 3 assets with blockbuster potential. With the momentum of these marquee therapies, we are preparing for multiple milestones and inflection points across these product candidates in the coming year."

Dr Itescu told meeting attendees that in 2019 Mesoblast plans to work diligently with the FDA to submit a rolling Biologics License Application for use of remestemcel-L in treating aGVHD in children, and will execute on the product candidate's market access and commercialization strategy.

The meeting attendees were also told that 2019 will be a pivotal year for the Company's heart failure product candidate Revascor. Mesoblast will meet with the FDA in the first half of 2019 to discuss a potential approval pathway for Revascor in patients with end-stage heart failure and a left ventricular assist device. This follows the clinically meaningful outcomes of reduction in major gastrointestinal bleeding and related hospitalizations achieved in the 159-patient U.S. National Institutes of Healthfunded trial in these patients. In addition, Dr Itescu provided the key takeaways on the Phase 3 trial of Revascor for patients with advanced heart failure which has completed recruitment of approximately 570 patients.

A webcast of the presentation will be available via https://event.webcasts.com/starthere.jsp?ei=1226368&tp_key=1f4916da2 and as an archived webcast for 90 days on the Investors & Media section of the Company's website at www.mesoblast.com

About Mesoblast

Mesoblast Limited (ASX:MSB; Nasdaq:MESO) has leveraged its proprietary technology platform to establish a broad portfolio of late-stage allogeneic (off-the-shelf) product candidates with three product candidates in Phase 3 trials – acute graft versus host disease, chronic heart failure and chronic low back pain due to degenerative disc disease. Through a proprietary process, Mesoblast selects rare mesenchymal lineage precursor and stem cells from the bone marrow of healthy adults and creates master cell banks, which can be industrially expanded to produce thousands of doses from each donor that meet stringent release criteria, have lot to lot consistency, and can be used off-theshelf without the need for tissue matching. Mesoblast has facilities in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdag (MESO). www.mesoblast.com

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 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 quarantee 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 timing, progress and results of Mesoblast's preclinical and clinical studies; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies; the timing or likelihood of regulatory filings and approvals; 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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