asx announcement

mesoblast
the regenerative medicine company

FINAL PATIENT DOSED IN MESOBLAST PHASE 3 TRIAL OF REVASCOR CELL THERAPY FOR ADVANCED HEART FAILURE

New York, USA; and Melbourne, Australia; February 19, 2019: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), a world leader in development and commercialization of cellular medicines, announced today that the last patient has now been dosed in the Phase 3 events-driven trial of its allogeneic cell therapy product candidate Revascor for advanced chronic heart failure. The 566-patient trial will complete when sufficient primary endpoint events have accrued, which is likely to be within 12 months.

Results from a prior Phase 2 trial identified the patients most likely to benefit from Revascor as being those at high risk of recurrent hospitalization events and death. These results guided the trial design and selection criteria for enrollment of high-risk patients in the current Phase 3 trial in order to maximize the probability that the Phase 3 results would confirm the Phase 2 results.

Consequently, the Company is confident that the total number of randomized patients enrolled in the Phase 3 trial is sufficient to show whether Revascor is superior to placebo in the trial's primary endpoint of reduction in heart failure-related hospital admissions, and in the key secondary endpoint of reduction in cardiac deaths. In April 2017, the Phase 3 trial was successful in a pre-specified futility analysis of the primary efficacy endpoint in the first 270 patients.

Mesoblast's cardiovascular partner in China, Tasly Pharmaceutical Group, is planning to meet with the National Medical Products Administration (NMPA) of China, formerly known as the China Food and Drug Administration, in the first quarter 2019 to discuss the regulatory approval pathway for Revascor in China. The objective is to initiate a Phase 3 trial of Revascor in China using similar clinical endpoints and targeting a similar patient population of advanced heart failure patients at high risk of recurrent heart failure-related hospitalization and death. Tasly and Mesoblast will leverage each other's clinical trial results in China, the United States and other territories to support their respective regulatory submissions.

About Heart Failure

There are over 8 million patients with heart failure in the United States alone. Up to 20 percent progress to advanced heart failure refractory to all existing medicines, categorized as New York Heart Association Class III or IV disease. These patients represent a major unmet medical need due to their high rates of recurrent hospitalization, progression to end-stage disease, and high mortality[1].

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-the-shelf 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 Nasdaq (MESO). www.mesoblast.com

1.AHA's 2017 Heart Disease and Stroke Statistics Update

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
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668
T +65 6570 0635
F +65 6570 0176

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 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.

For further information, please contact:

Julie Meldrum
Corporate Communications
T: +61 3 9639 6036
E: julie.meldrum@mesoblast.com

Schond Greenway
Investor Relations
T: +1 212 880 2060
E: schond.greenway@mesoblast.com