asx announcement

mesoblast
the regenerative medicine company

# MESOBLAST PROVIDES UPDATE ON GLOBAL HEART FAILURE PROGRAM

**Key points:**

- Mesoblast regains worldwide rights to cardiovascular field for its cell therapy platform
- Lead product candidate in cardiovascular portfolio is MPC-150-IM for heart failure, with multibillion dollar blockbuster potential and no financial consideration to Teva Pharmaceutical Industries Ltd
- Independent Data Monitoring Committee recommended continuation of the 600-patient heart failure trial without modification after clinical data review of first 175 patients
- Mesoblast aims to complete the Phase 3 heart failure trial, almost 40% recruited, within eighteen months
- To meet the program's remaining funding requirements, Mesoblast has been offered an equity finance facility
- FDA approval has been obtained to incorporate into the heart failure program a widely-used second catheter delivery system which is likely to result in accelerated recruitment and provide a commercial distribution channel
- Japan conditional approval pathway provides potential early revenue opportunity
- Mesoblast now has unencumbered rights to partner with a leading cardiovascular company with a commitment to heart failure product commercialization

**New York, USA; and Melbourne, Australia; 14 June 2016:** Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today announced that it has regained full worldwide rights and full strategic flexibility to exploit its mesenchymal precursor cell (MPC) technology platform for the cardiovascular field. The lead asset in this cardiovascular portfolio is Mesoblast's Phase 3 product candidate MPC-150-IM for advanced chronic heart failure, which has the potential to be a multibillion dollar blockbuster for Mesoblast, with no financial consideration to Teva.

In April the Data Monitoring Committee of the 600-patient Phase 3 trial for this product candidate recommended that the trial continue without any modification after having reviewed efficacy and safety data for the first 175 patients. The trial is now close to 40% recruited, and is scheduled for completion within eighteen months. Mesoblast has been offered an equity finance facility which can be used by the company to meet the program's funding requirements.

Mesoblast Chief Executive Dr Silviu Itescu said, "We are delighted to regain full control of this very valuable asset in our portfolio, and to have been offered a finance facility we can draw on to meet the funding requirements for the program. The growing body of clinical evidence validates our strong conviction in the potential of our product candidate MPC-150-IM to change the way that advanced heart failure is treated. We thank our partner Teva for having brought our Phase 3 heart failure program to this advanced stage of development, and acknowledge their decision is based on strategic reasons aligned to their core therapeutic areas of focus. Mesoblast now has unencumbered rights to partner with a leading cardiovascular company with a commitment to heart failure product commercialization."

In addition, Mesoblast announced that the United States Food and Drug Administration (FDA) has approved the use of a second navigational catheter system in Mesoblast's Phase 3 program for advanced heart failure. Over 2,000 of these FDA-approved systems are currently in use across the United States for the treatment of atrial fibrillation, and their use in Mesoblast's program is likely to result in accelerated Phase 3 trial recruitment and potentially a simplified distribution process through existing commercial channels once the product is approved.


**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

The Phase 3 trial has enrolled over 230 patients out of a total of 600 patients with advanced heart failure, with the primary endpoint agreed to with the FDA for product registration being recurrent heart failure-related hospitalizations or deaths (Heart Failure-Related Major Adverse Cardiovascular Events, HF-MACE). In the completed Phase 2 trial, patients treated with MPC-150-IM had no HF-MACE over 36 months of follow-up, compared with 11 recurrent HF-MACE events in the control group ($p<0.001$, log rank test). In patients with advanced heart failure as defined by baseline Left Ventricular Systolic Volume >100ml, who closely resemble the patients being recruited in the Phase 3 trial, 71% of controls had at least one HF-MACE event vs 0 of those who received a single injection of MPC-150-IM ($p<0.001$).

Mesoblast's heart failure Phase 3 asset represents a prime partnering opportunity with leading cardiovascular companies committed to commercializing heart failure products globally. While the United States and Europe are leading markets for our product candidate, Japan presents a nearer-term commercial opportunity in light of the Pharmaceuticals and Medical Devices Agency's (PMDA) new regulatory framework for cell therapy that enables early conditional approval and reimbursement of cell therapy products based on Phase 2 trial results.

In addition to the ongoing Phase 3 trial in patients with advanced heart failure, a second trial of MPC-150-IM in 120 patients with end-stage heart failure and an implantable left ventricular assist device is almost 60% recruited, and is being fully funded by the National Institutes of Health. The trial's results are expected in the second half of 2017 and will be used to support the marketing approval application for the product candidate.

Dr. Emerson Perin, Director of Clinical Research for Cardiovascular Medicine and Medical Director Stem Cell Center, Texas Heart Institute, and a co-Principal Investigator on the Phase 3 heart failure trial, said "The trial has progressed extremely well and has been given a green light for continued enrolment by the Data Monitoring Committee. I have a deep sense that this is extremely important and meaningful work and have dedicated my career towards it."

**Conference Call and Webcast Details**

Mesoblast will provide a corporate update beginning at 9:00 am Australian Eastern Standard Time on Tuesday, June 14 / 7:00 pm Eastern Daylight Time on Monday, June 13, 2016.

*To access the call, please dial:*

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| Australia Toll Free | 1 800 558 698 |
| Australia Alternate | 1 800 809 971 |
| United States | 1 855 881 1339 |
| United Kingdom | 0800 051 8245 |
| Singapore | 800 101 2785 |
| Hong Kong ` | 800 966 806 |
| International | +61 2 9007 3187 |

The conference identification code is 257646.

The audio call can be accessed via:

http://boardroom.media/broadcast/?refid=&eid=57589faf4c64e59e61dc747e

**About Chronic Heart Failure (CHF)**
CHF is characterized by an enlarged heart and insufficient blood flow to the organs and extremities of the body. The condition is progressive and can be caused by many factors that put an excess demand on the heart muscle such as high blood pressure, faulty valves, infections or congenital heart problems. The American Heart Association reports 5.7 million adults in the United States with diagnosed CHF, or about 2% of the adult population, with 925,000 new cases diagnosed each year. New York Heart Association Class II / III CHF patients with low ejection fraction continue to be at high risk of repeated hospitalizations and mortality, despite standard of care pharmacological treatments. CHF prevalence is expected to increase by 46% by 2030, affecting more than 8 million Americans. The estimated annualized cost for CHF is approximately $32 billion, and is projected to grow to $77 billion by 2030.

**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 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. 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:*

Michael Schuster
Investor Relations
Mesoblast Limited
T: +1 212 880-2060
E: michael.schuster@mesoblast.com

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