

MESOBLAST PHASE 3 CELL THERAPY TRIAL FOR CHRONIC LOW BACK PAIN COMPLETES ENROLLMENT

New York, USA; and Melbourne, Australia; March 29, 2018: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today announced that enrollment has completed in the Phase 3 trial evaluating a single intra-discal injection of its proprietary allogeneic mesenchymal precursor cell (MPC) product candidate MPC-06-ID in patients with chronic low back pain due to degenerative disc disease.

MPC-06-ID is being evaluated to determine whether it can alleviate pain and improve function in patients who do not receive adequate relief from current standard of care therapies such as non-steroidal anti-inflammatory drugs, epidural steroid injections or opioids.

The 2:1 randomized, placebo-controlled Phase 3 trial (NCT02412735) enrolled 404 patients across 48 centers in the United States and Australia. Following completion of the planned enrollment of 360 patients, all additional patients still in screening at that point were allowed to complete enrollment.

The Phase 3 trial's primary endpoint is in line with written guidance from the United States Food and Drug Administration (FDA) in support of product registration, and specifies

- use of a composite measurement showing significant clinical improvement in pain and function at both 12 and 24 months
- pre-specified thresholds for determining significant improvement in pain (50% decrease in Visual Analog Score) and function (15-point improvement in Oswestry Disability Index)
- patients who undergo additional interventions at the treated level are considered treatment failures.

Phase 2 results in 100 patients showed that a single intra-discal injection of MPC-06-ID alleviated pain and improved function for up to three years in patients whose symptoms were not adequately treated with current standard of care therapies.

Mesoblast Chief Executive Dr Silviu Itescu said, "There is an urgent need to provide an effective treatment for patients suffering from chronic low back pain due to degenerative disc disease, a population which today accounts for 50% of prescription opioid usage. If the Phase 3 results demonstrate durable improvement in pain and function, MPC-06-ID has the potential to make a major difference in patients with this serious medical condition."

About Chronic Low Back Pain (CLBP) Caused By Degenerative Disc Disease

Over 33 million¹ patients in the U.S. alone suffer from CLBP with approximately 22%² caused by degenerative disc disease. The patient population suffering from chronic low back pain due to intervertebral disease is estimated at more than 3.2 million patients in the U.S. alone³. Total costs of low back pain in the U.S. are estimated at between US\$100 billion and US\$200 billion annually with two thirds of these costs attributed to patients' decreased wages and productivity.⁴

All approved therapies for progressive, severe and debilitating pain due to degenerating intervertebral discs treat the symptoms of the disease, but are not disease-modifying and thus do not address the underlying cause of the disease.

Limited treatment options exist for patients who have failed conservative treatment such as physical therapy, anti-inflammatory agents or analgesics as well as other measures including opioids and

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

epidural steroid injections. In the United States, approximately 50% of opioid prescriptions are for chronic low back pain^{5,6,7,8}.

When disc degeneration has progressed to a point that pain and loss of function can no longer be managed by conservative means, major invasive surgery is the only remaining option. Even with surgical intervention such as spinal fusion or artificial disc replacement, between 30-46% of patients are considered treatment failures.⁹

1. Decision Resources: Chronic Pain December 2015.
2. Verrillis P, Nowesenitz G, Barnard A. (2015) Prevalence and Characteristics of Discogenic Pain in Tertiary Practice: 223 Consecutive Cases Utilizing Lumbar Discography. *Pain Med.* Aug; 16(8): 1490-9
3. Mesoblast internal estimate from primary market research conducted by Navigant and LEK.
4. Katz JN. Lumbar disc disorders and low-back pain: socioeconomic factors and consequences. *J Bone Joint Surg Am.* 2006;88 (suppl 2):21–24
5. Abdel Shaheed C et al. Efficacy, Tolerability, and Dose-Dependent Effects of Opioid Analgesics for Low Back Pain: A Systematic Review and Meta-analysis. *JAMA Internal Medicine* . American Medical Association; 2016 Jul;176(7):958-68.
6. Pain Management Study: Chronic Pain, December 2013. Decision Resources
7. Hudson TJ et al. Epidemiology of Regular Prescribed Opioid Use: Results from a National, Population-Based Survey. *Journal of Pain and Symptom Management.* Elsevier; 2008 Sep;36(3):280-288.
8. Sullivan MD et al. Regular use of prescribed opioids: Association with common psychiatric disorders. *Pain.* Wolters Kluwer; 2005 Dec 15;119(1-3):95-103.
9. Chan C, Peng P. Failed back surgery syndrome. *Pain Med* 2011;12:577–606.

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

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

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

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