



MESOBLAST'S FULL 24-MONTH TRIAL RESULTS FOR CHRONIC LOW BACK PAIN PRESENTED AT SPINE INTERVENTION SOCIETY ANNUAL MEETING, RECEIVE AWARD FOR BEST BASIC SCIENCE

Results Show Sustained Improvement In Pain And Function Over 24 Months Following A Single Intra-Disc Cell Injection

Melbourne, Australia; and New York, USA; 1 August 2016: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today announced that the 24-month results from the 100-patient, four-arm, randomized, placebo-controlled Phase 2 trial of its chronic low back pain (CLBP) product candidate MPC-06-ID were presented at the 24th Annual Scientific Meeting of the Spine Intervention Society (SIS) held in New Orleans 27-30 July, and received the 2016 Best Basic Science Abstract award at the meeting.

The trial results were selected following peer review for a podium presentation entitled "A Randomized, Controlled Trial Evaluating the Safety and Effectiveness of Immunoselected, Allogeneic, Mesenchymal Precursor Cells for Treatment of Chronic Low Back Pain".

Lead investigator and trial presenter Dr Michael J. DePalma, President and Medical Director of Virginia iSpine Physicians, stated: "The long term results from this study indicate that a single injection of Mesoblast's allogeneic Mesenchymal Precursor Cells (MPCs) into the disc of patients with moderate to severe CLBP due to degenerative disc disease was well tolerated and provided substantial improvement in pain and function over 24 months compared with control therapies."

Key trial results were:

- The procedure and treatment were well tolerated, without any significant differences in safety between cell-treated patients and controls.
- The 6 million MPC dose, currently used in the ongoing Phase 3 trial, resulted in the greatest proportion of patients meeting the Phase 3 primary endpoint of Overall Treatment Success (the composite of both pain and functional responder status) through 24 months.
- A significantly greater proportion of subjects who received 6 million MPCs achieved the pain responder criteria at both 12 and 24 months (50% pain reduction from baseline, as measured using a visual analog scale, with no intervention) than saline-treated controls (50.0% vs 12.5%, p=0.020); pain responder criteria were met by 36.0% of patients who received 18 million MPCs and by 23% who received hyaluronic acid.
- A significantly greater proportion of subjects who received 6 million MPCs achieved the functional responder criteria at both 12 and 24 months (15 point functional improvement from baseline, as measured by the Oswestry disability index, with no intervention) than saline-treated controls (46.2% vs 12.5%, p=0.042); functional responder criteria were met by 53.9% of patients who received 18 million MPCs (p=0.01 vs saline) and by 29.4% who received hyaluronic acid.
- Overall Treatment Success at 12 months was achieved by 50% of patients in the 6 million MPC group compared with 18.8% in the saline group (p=0.056); 77% of MPC-treated patients who achieved Overall Treatment Success at 12 months maintained this at 24 months (p=0.09 vs saline).
- Overall Treatment Success at both 12 and 24 months was achieved by 38.5% of the 6 million MPC group, 34.6% of the 18 million MPC group, 17.7% of the hyaluronic acid group, and 12.5% of the saline group.

Dr DePalma added: "If findings from the ongoing Phase 3 trial are comparable, Mesoblast's MPCs could become a valuable treatment for a significant number of people suffering with chronic low back pain who currently have no other viable option."

Mesoblast Limited ABN 68 109 431 870 www.mesoblast.com Corporate Headquarters Level 38 55 Collins Street Melbourne 3000 Victoria Australia

т +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

т +65 6570 0635 **F** +65 6570 0176 Mesoblast's ongoing Phase 3 trial is recruiting 360 patients across 30 sites in the United States and Australia, randomized 2:1 to receive either 6 million MPCs or saline control. The trial's primary endpoint of Overall Treatment Success (using a composite of 50% improvement in lower back pain and 15 point improvement in function at both 12 and 24 months) is an acceptable endpoint for product approval, as per guidance from the United States Food and Drug Administration (FDA). Subject to further discussions with the FDA, Mesoblast anticipates being able to provide interim data from the trial in early 2017.

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

Approximately 5.7 million patients in the U.S. alone suffer from CLBP caused by degenerative disc disease, of which 4.0 million patients have moderate to severe disease. After failure of conservative measures (medication, injections, physical therapy, etc.), there is no treatment that prevents progression of disc degeneration, reduces pain and improves function over a sustained period of 6 to 12 months. 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 such as spinal fusion is the only remaining option.

All 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. Surgical intervention is not always successful in addressing the patient's pain and functional deficit. Surgeons estimate that between 50% to 70% of patients ultimately fail back surgery, with failure defined as either not achieving at least a 50% reduction of symptoms within four months or experiencing new-onset pain and spasm. Total costs of low back pain are estimated to be between US\$100 billion and US\$200 billion annually with two thirds of attributed to patients' decreased wages and productivity.

As a result, we believe that the most significant unmet need and commercial opportunity in the treatment of CLBP is a therapy that has the ability to reverse, halt or slow the progression of the disease. MPC-06-ID is being developed to target the population of patients suffering from moderate to severe CLBP due to moderately degenerated discs. The target patient population has exhausted conservative treatment options, may have failed epidural steroid injections to alleviate pain and has no treatment option other than invasive and costly surgical interventions.

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, whether as a result of new information, future developments or otherwise.

Mesoblast Limited ABN 68 109 431 870 www.mesoblast.com Corporate Headquarters Level 38 55 Collins Street Melbourne 3000 Victoria Australia

т +61 3 9639 6036 г +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

т +65 6570 0635 **F** +65 6570 0176 For further information, please contact: Julie Meldrum **Corporate Communications** Mesoblast Limited T: +61 3 9639 6036 E: julie.meldrum@mesoblast.com

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Corporate Headquarters Level 38 55 Collins Street Melbourne 3000 Victoria Australia

т +61 3 9639 6036 г +61 3 9639 6030

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τ +1 212 880 2060 **F** +1 212 880 2061

Asia

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т +65 6570 0635 г +65 6570 0176