

MESOBLAST CELL THERAPY SHOWS DISEASE MODIFYING EFFECTS ON KNEE OSTEOARTHRITIS

Clinical Results Presented at 2016 Osteoarthritis Research Society International Congress

Melbourne, Australia; and New York, USA; 1 April 2016: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today announced that results from its Phase 2a trial in patients with post-traumatic knee injury to the anterior cruciate ligament (ACL) showed that a single intra-articular injection of its mesenchymal precursor cell (MPC) product candidate, MPC-75-IA, resulted in improvement in pain, function, cartilage thickness, and joint structure over 24 months.

The study results were selected for oral presentation at the 2016 Osteoarthritis Research Society International (OARSI) World Congress in Amsterdam, The Netherlands, and presented on 31 March by Professor Flavia Cicuttini, Head Musculoskeletal Unit, Department of Epidemiology and Preventive Medicine School of Public Health and Preventive Medicine at Monash University, Australia.

Professor Cicuttini said: "These very exciting results suggest that Mesoblast's cells may be disease modifying and potentially slow or halt the natural history of osteoarthritis."

The double-blind, placebo-controlled trial randomized (2:1) 17 patients aged 18-40 years old who had undergone ACL knee reconstruction surgery 4-6 weeks earlier to receive either a single intra-articular injection of 75 million allogeneic MPCs plus hyaluronic acid (HA) or HA alone. Pain, function and quality of life parameters were measured over 24 months using the composite of Knee Injury and Osteoarthritis Outcomes Scores (KOOS) and the Short Form Health Survey (SF-36, a 36-item, patient-reported survey of patient health). Joint space width reflecting cartilage thickness was measured by X-ray, and structural changes in the joint were measured by magnetic resonance imaging (MRI).

Key findings:

- The trial met its primary safety and secondary efficacy endpoints
- There were no cell-related serious adverse events over the duration of the trial
- The MPC+HA group showed greater improvement in KOOS scores for symptoms and pain relative to the HA group at week 78 (p=0.034; p=0.026) and 104 (p=0.041; p=0.018), respectively
- The SF-36 bodily pain score demonstrated greater pain reduction for the MPC+HA group than the HA group at weeks 26 (p=0.019), 52 (p=0.050) and 104 (p=0.032), respectively
- By X-ray, the HA group had reduced joint space width at weeks 78 and 104 compared with the MPC+HA group (p=0.027 and p=0.069, respectively) consistent with reduced cartilage thickness
- By MRI, the MPC+HA group showed less tibial bone expansion over 26 weeks than the HA group (0.5% vs 4.0%, p=0.02) and a trend towards less tibial bone expansion over 52 and 104 weeks (both p=0.09)
- The MPC+HA group showed a trend towards less medial tibial volume loss over 26 weeks (0.7% vs -4.0%, p=0.10).

Key conclusions:

- The clinical results are consistent with the protective and pro-regenerative effects of Mesoblast's allogeneic MPCs on joint cartilage seen previously in ovine models of both post-traumatic knee injury and established osteoarthritis
- The results suggest that allogeneic MPCs may have disease-modifying effects on osteoarthritis, potentially halting the adverse structural changes in this common condition
- The results support further study of the effects of allogeneic MPCs on cartilage preservation and longer-term osteoarthritis outcomes in patients at high risk of disease progression or with established disease.

Professor Cicuttini added: "These results are remarkable in that we were able to demonstrate significant improvements in patient symptoms and joint structure. We look forward to conducting a larger Phase 2/3 trial to confirm the observed significant long-term benefits in pain, function, and quality of life."

About Post-Traumatic Osteoarthritis

Osteoarthritis (OA) is a common and debilitating disease that affects approximately 27 million people in the USA, resulting in annual medical care expenditures of \$185.5 billion. Post-traumatic osteoarthritis (PTOA) of the knee, hip and ankle accounts for approximately 5.6 million cases of OA in the USA.

There are approximately 200,000 ACL reconstruction procedures performed annually in the USA, with more than 70% of ACL procedures in patients under the age of 65 years. Despite corrective surgery, as many as 80% of knees post-ACL injury will progress to radiographic and symptomatic OA after 5 to 15 years. In addition, approximately 1 million meniscal reconstruction procedures are performed annually in the USA, with similar rates of subsequent progression to knee OA.

While ACL reconstruction is considered to be a cost-effective treatment strategy, in the USA there is still a significant cost of \$2.78 billion attributable to the long-term development of OA. An innovative therapy that demonstrates disease modifying effects on OA development or progression could deliver estimated annual societal cost savings of \$1.1 billion.

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.

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

For further information, please contact:
Julie Meldrum
Global Head of Corporate Communications
Mesoblast Limited
T: +61 3 9639 6036
E: julie.meldrum@mesoblast.com

Mesoblast Limited
ABN 68 109 431 870
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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