MESOBLAST'S ALLOGENEIC, "OFF-THE-SHELF", STEM CELLS ARE SAFE AND EFFECTIVE FOR CERVICAL SPINE FUSION

Unique clinical and commercial advantages in global competitive landscape

Key Points

- Mesoblast's allogeneic cells are safe and effective for fusion of the cervical spine
- In view of FDA safety concerns for use of BMP in cervical fusion, Mesoblast's product may have unique clinical and commercial advantages
- Potential for accelerated timeline to product market approval given limited alternative treatment options
- New high-margin market opportunity

Melbourne, Australia; 21 August 2008: Australian regenerative medicine company Mesoblast Limited (ASX: MSB; USOTC: MBLTY), today announced that its allogeneic, or "off-the-shelf", cell therapy product was safe and highly effective in preclinical trials for interbody fusion of the cervical spine in the neck.

These results provide Mesoblast with a major clinical and commercial opportunity in light of the recent notification by the United States Food and Drug Administration (FDA)1 alerting healthcare practitioners to reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine.

In July 2008, the FDA issued a formal public health notification concerning life-threatening complications associated with use of rhBMP for cervical fusion, including swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. The notification stated that "since the safety and effectiveness of rhBMP for treatment of cervical spine conditions has not been demonstrated, and in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies".

Given the limited treatment options available for patients in need of cervical fusion, Mesoblast believes that this clinical indication may provide an accelerated path to regulatory market approval of its product. Consequently, the company will actively pursue formal regulatory discussions regarding initiation of a Pivotal/Phase 3 clinical trial protocol for use of its proprietary cells for cervical fusion.

Fusion of the cervical spine accounts for up to 40% of all spinal fusion procedures, a growing market expected to exceed 500,000 annual procedures in the United States alone by 2010. Mesoblast is currently in Phase 2 clinical trials for fusion of the lumbar spine, and based on these new results will extend its market opportunity to cover the entire spectrum of spinal fusion. Subject to FDA approval, Mesoblast's product will eliminate the need for autograft (patient's own bone transplanted from the pelvis), which requires a second operation and is often associated with severe pain at the graft site.

Mesoblast initiated trials at Monash University in Australia to determine the safety and efficacy profile of its allogeneic stem cell therapy in cervical fusion. Twenty-four ewes underwent anterior removal of the cervical intervertebral disc at the C3/4 level, and were randomised to one of four treatment arms: autograft, bone graft substitute (Medtronic Mastergraft granules), and allogeneic Mesoblast cells at doses of 5 or 10 million cells implanted in an FDA-approved interbody cage. The trial was completed at 3 months.

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Significantly, no cell-related adverse events were noted at any time throughout the study. Groups receiving either dose of Mesoblast's allogeneic cells had earlier and more robust fusion than the other groups. By CT scan at 3 months, 9/12 (75%) cell-treated animals had continuous interbody bony bridging compared with only 1/6 autograft and 2/6 with bone graft substitute (p=0.019 and p=0.043 respectively). Functional x-rays at 3 months showed that cell-treated subjects had significantly reduced flexion/extension at the C3/4 level compared with the other groups (p=0.007), indicating significantly superior fusion outcomes.

"In view of the FDA notification concerning life threatening complications of rhBMP in cervical fusion, we are encouraged that the profile of our allogeneic cells in the cervical interbody space may translate into a safe and effective clinical alternative," said Mesoblast Executive Director Professor Silviu Itescu.

"In addition, the very low dose of allogeneic cells that were effective in the interbody procedure to obtain cervical fusion makes this target market a very attractive and high-margin new commercial opportunity for Mesoblast," he added.

1. FDA. July, 2008 http://www.fda.gov/cdrh/safety/070108-rhbmp.html

About Mesoblast

Mesoblast Limited (ASX:MSB; USOTC:MBLTY) is committed to the development of novel treatments for orthopaedic conditions, including the rapid commercialisation of a unique adult stem cell technology aimed at the regeneration and repair of bone and cartilage. Our focus is to progress through clinical trials and international regulatory processes necessary to commercialise the technology in as short a timeframe as possible. Mesoblast has the worldwide exclusive rights for a series of patents and technologies that have been developed over more than 10 years and which relate to the identification, extraction and culture of adult Mesenchymal Precursor Cells (MPCs). The Company has also acquired 39% of Angioblast Systems Inc., an American company developing the platform MPC technology for the treatment of cardiovascular diseases including repair and regeneration of blood vessels and heart muscle. Mesoblast and Angioblast are jointly funding and progressing the core technology. Mesoblast's strategy is to maximise shareholder value through both corporate partnerships and the rapid and successful completion of clinical milestones.

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