asx announcement

mesoblast
the regenerative medicine company

IMPROVED SURVIVAL IN CHILDREN WITH GRAFT VERSUS HOST DISEASE WHO RESPOND TO MESOBLAST'S CELL THERAPY

Results of 160 patients presented at American Society for Blood and Marrow Transplantation Meeting

New York, USA, and Melbourne, Australia; 16 February 2015: Results of 160 pediatric patients treated with Mesoblast's proprietary allogeneic Tier 1 product candidate MSC-100-IV for severe steroid-resistant acute Graft Versus Host Disease (aGVHD) were presented at the 2015 American Society for Blood and Marrow Transplantation meeting in San Diego on 14 February.

Lead investigator, Dr Joanne Kurtzberg**,** said the data from the initial 160 children enrolled in Mesoblast's Expanded Access Program (EAP) Protocol 275 study continue to show a clear and meaningful survival benefit among responding pediatric bone marrow transplant recipients.

"The enrolled patients represent a very challenging population with severe graft versus host disease that was non-responsive to treatments, including steroids and for many of these children, multiple immunosuppressive agents, so we believe these results are very promising. These are very sick patients who have developed this life-threatening complication of stem cell transplantation," stated Dr Kurtzberg, who is the Jerome Harris Distinguished Professor of Pediatrics and Director of the Pediatric Blood and Marrow Transplant Program at Duke University Medical Center.

Key points from the presentation were:

- These are patients who failed steroid therapy and most failed multiple additional treatments. 81% of patients were severe, grades C and D (28 and 53%, respectively), and represent the poorest prognosis patients with reported survival probabilities of 5-20%.
- Overall response (defined as partial + complete response) at day +28 was 64%, and this response correlated with statistically significant improved survival compared to non-responders at day +100 after an MSC-100-IV infusion (81% versus 39 %, p=0.0001).
- The Day 28 overall responses by grade were 74% for grade B, 66% for grade C, and 59% for grade D. Overall responses by organ involvement at day +28 were 62% for GI, 77% for skin, and 53% for liver.
- Approximately 80% of Grade B/C patients and over 50% of Grade D patients survived to Day 100.
- MSC-100-IV continues to be well tolerated with minimal clinically significant toxicities.

This large EAP data set continues to provide support for the benefit of MSC 100-IV for the treatment of aGVHD in children.

A single arm, open-label Phase 3 registration trial to support product approval by the United States Food and Drug Administration, which will include approximately 60 pediatric patients with aGVHD, is in progress.

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Mesoblast Limited
Mesoblast Limited (ASX: MSB; USOTC: MBLTY) is a global leader in regenerative medicine. The Company has leveraged its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells (MLCs), to establish a broad portfolio of late stage product candidates. Mesoblast's allogeneic or 'off-the-shelf' cell product candidates target significantly advanced stages of diseases where there are highly unmet medical needs, including cardiovascular conditions, orthopedic disorders, immunologic/inflammatory disorders and oncology/hematology conditions. The lead therapeutic product candidates under investigation include MPC-150-IM for chronic congestive heart failure, in partnership with Teva Pharmaceutical Industries Ltd., MPC-06-ID for chronic discogenic low back pain, MSC-100-IV for acute graft versus host disease, and MPC-300-IV for biologic refractory rheumatoid arthritis and diabetic nephropathy.

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