asx announcement

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the regenerative medicine company

IMPROVED SURVIVAL IN CHILDREN WITH LIFE THREATENING GRAFT VERSUS HOST DISEASE REPORTED AFTER TREATMENT WITH MESOBLAST'S CELL THERAPY

Results Published in *Biology of Blood and Marrow Transplantation* Journal

Melbourne, Australia; 13 November 2013: Regenerative medicine company Mesoblast Limited (ASX:MSB; USOTC: MBLTY) today announced that a peer-reviewed article in the November 2013 issue of the scientific journal *Biology of Blood and Marrow Transplantation* has shown that use of its proprietary culture-expanded Mesenchymal Stem Cell (MSC) product, Prochymal®, resulted in a significant survival benefit among responding pediatric bone marrow transplant recipients with refractory acute Graft versus Host Disease (GvHD). In 75 children with acute severe GvHD, 61% responded to Prochymal® and 76% of these were alive at day 100.

The study, titled "Allogeneic Human Mesenchymal Stem Cell Therapy (remestemcel-L, Prochymal®) as a Rescue Agent for Severe Refractory Acute GvHD in Pediatric Patients", is the largest prospective study of its kind in pediatric patients with severe, multi-line refractory acute GvHD, and can be viewed at http://www.bbmt.org/article/PIIS1083879113005065/fulltext

Acute GvHD arises in approximately 50% of all patients who receive a donor-derived, or allogeneic, hematopoietic stem cell transplant (HSCT). Allogeneic HSCTs from donor bone marrow, cord blood, or peripheral blood are used for the treatment of diseases including hematological malignancies, certain forms of anemia, and immunological deficiencies. GvHD occurs when immune cells in the donated cell population attack recipient organs, such as skin, gastrointestinal tract, and liver, because the recipient cells in these organs are seen as "foreign".

The study comprised 75 children, median age 8 years old, who were treated with Prochymal® in the United Kingdom, Australia, Italy, Finland, New Zealand, Canada and the United States under a United States Food and Drug Administration (FDA) Expanded Access Program (EAP) protocol (Clinicaltrials.gov:NCT00759018).

Of these children, 88% had severe grade C-D disease with inadequate responses to standard of care treatment. Gastrointestinal involvement was seen in 87% and liver involvement in 36%.

Severe, acute Grade C-D GvHD is often refractory to first line therapy, and has a survival of less than 30% at day 100.

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Key findings in the trial were:

- At day 28, 61% of patients were responders to Prochymal® (improvement in at least one grade of organ involvement).
- Responses to Prochymal® were seen across all disease grades and involved organs.
- In 87% of patients, no new therapy for acute GVHD was introduced after Prochymal® therapy.
- Response at day 28 to Prochymal® therapy was a significant predictor of improved survival at day 100.
- Day 100 survival was 76% in Prochymal® responders, compared to 28% in non-responders (p value <0.001, log rank test).
- Excellent safety profile with only 2 reactions reported across more than 500 MSC infusions, and no hematologic or renal toxicity, which is commonly seen with other approaches to prophylaxis against or treatment of acute GvHD.

Mesoblast Chief Executive Silviu Itescu said:"For these children, no other effective therapy exists. Seeing these very encouraging results with respect to response and survival rates following Prochymal® therapy, Mesoblast plans to analyze the existing data set generated under the Expanded Access Program and engage with the regulatory authorities in major jurisdictions as early as possible to discuss product approval options."

About Mesoblast

Mesoblast Limited (ASX:MSB;USOTC:MBLTY) is a world leader in the development of biologic products for the broad field of regenerative medicine. The Company's proprietary technologies include its Mesenchymal Precursor Cell and culture-expanded Mesenchymal Stem Cell technology platforms, Dental Pulp Stem Cells and expanded Hematopoietic Stem Cells. Mesoblast's allogeneic or 'off-the-shelf' regenerative medicine products are being developed for the treatment of conditions with significant unmet medical needs. The lead product candidates use its mesenchymal lineage cells in four major and distinct areas - systemic inflammatory conditions, cardiovascular diseases, orthopedic diseases of the spine and oncology conditions. www.mesoblast.com

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