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the regenerative medicine company

FDA GRANTS FAST TRACK DESIGNATION FOR MESOBLAST'S CELL THERAPY IN CHILDREN WITH ACUTE GRAFT VERSUS HOST DISEASE

Melbourne, Australia; and New York, USA, March 7, 2017: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today announced that the United States Food and Drug Administration (FDA) has granted a Fast Track designation for the use of its cell therapy, MSC-100-IV, to achieve improved overall response rate in children with steroid refractory acute Graft Versus Host Disease (aGVHD).

Fast Track designation has the potential to shorten the time to FDA approval of MSC-100-IV for this indication through priority review (shortened FDA review process from 10 to 6 months) and a streamlined rolling review process (completed sections of the Biologics License Application, BLA, can be submitted for FDA review as they become available, instead of waiting for all to be completed). The product candidate's existing Orphan Indication designation may additionally lead to potential commercial benefits following FDA approval.

Mesoblast's application for Fast Track status was supported by the clinical data in 241 pediatric patients with steroid refractory aGVHD who were treated on a single expanded access protocol (EAP) with MSC-100-IV. Overall response rate at Day 28 in this group was 65%, and day 100 survival was significantly improved in children who achieved an overall response at day 28 (82% vs. 39%, log rank p-value <0.0001).

The clinical results from the EAP were also used by Mesoblast in earlier discussions with the FDA that initially established the current accelerated development pathway for MSC-100-IV as front-line therapy in children with steroid-refractory aGVHD. Based on these discussions, Mesoblast believes that a single successful open-label Phase 3 trial will be sufficient for conditional FDA approval.

In November 2016, Mesoblast reported that the ongoing 60-patient open label Phase 3 registration trial of MSC-100-IV in children with steroid refractory aGVHD was successful in a pre-specified interim futility analysis using the trial's primary endpoint of Day 28 overall responses. The futility threshold was established using a Bayesian analysis method which determined the likelihood of obtaining a statistically significant treatment effect at study completion based on the data observed at this interim time point. Enrollment in this Phase 3 trial is expected to complete mid-2017 with a top-line read out in 2H CY 2017.

In December 2016, Mesoblast entered into exclusive negotiations with Mallinckrodt Pharmaceuticals for a commercial and development partnership to develop product candidates for pediatric and adult aGVHD, outside of Japan and China. MSC-100-IV is marketed as TEMCELL HS Inj.® for acute GVHD in children and adults in Japan by Mesoblast's licensee, JCR Pharmaceuticals.

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.

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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.

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