asx announcement

mesoblast
the regenerative medicine company

UNITED STATES CONGRESS LEGISLATES NEW ACCELERATED APPROVAL PATHWAY FOR REGENERATIVE ADVANCED THERAPIES

New York, USA; and Melbourne, Australia; December 9, 2016: Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today welcomed the passage of a Bill approving the 21st Century Cures Act by the United States Congress which provides an accelerated approval pathway for cell-based medicines designated as regenerative advanced therapies.

Chief Executive Silviu Itescu said that Mesoblast believes a number of its cell therapy product candidates meet the Act's criteria for regenerative advanced therapies based on their intended use to treat, modify, reverse, or cure a serious or life-threatening disease or condition.

"We will work closely with the U.S. Food and Drug Administration on the appropriate regulatory pathways for our product candidates that could meet the Act's criteria for the new regenerative advanced therapy designation.

"We believe our regenerative medicine technology platform may be particularly effective in the most serious segments of major diseases, including the life-threatening complications of chronic advanced heart failure. Over 300 patients have now been enrolled in our Phase 3 trial of MPC-150-IM in chronic advanced heart failure. We look forward to the upcoming interim analysis of the Phase 3 trial's primary endpoint," Dr Itescu added.

Designated regenerative advanced therapies will be eligible for priority review and accelerated approval through, as appropriate, surrogate or intermediate endpoints reasonably likely to predict long term clinical benefit, or reliance upon data obtained from a meaningful number of sites.

For regenerative advanced products receiving accelerated approval, the post approval requirements may include the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records, or the collection of larger confirmatory data sets.

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 diseases, immune-mediated and inflammatory disorders, orthopedic 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

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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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