asx announcement

mesoblast
the regenerative medicine company

MESOBLAST PRESENTS COMMERCIAL PLANS AT 2020 BIOTECH SHOWCASE IN SAN FRANCISCO

Announces Ryoncil™ as Brand Name for First Planned US Product Launch

Melbourne, Australia; January 15 and New York, USA; January 14, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today reported that the United States Food and Drug Administration (US FDA) has agreed to the selection of Ryoncil™ as the commercial name for its lead allogeneic cell therapy remestemcel-L in the treatment of pediatric steroid-refractory acute graft versus host disease (aGVHD). Commercial plans for Ryoncil™ were presented at the 2020 Biotech Showcase being held this week in San Francisco, CA.

Mesoblast Chief Executive Dr Silviu Itescu said: "We begin 2020 with great excitement as we prepare for potential FDA approval and US launch of our lead product candidate Ryoncil™ in pediatric aGVHD, a potentially life-threatening complication of an allogeneic bone marrow transplant. The continued growth in revenues from royalties on sales in Japan of the related product TEMCELL®[1] for aGVHD by our licensee provides important insight for our own US commercial plans. Together with our strategic partners, we are also looking forward to readouts of Phase 3 trials for our blockbuster product candidates in advanced chronic heart failure and chronic low back pain due to degenerative disc disease."

The final module of the rolling Biologics License Application for Ryoncil™ will be filed with the FDA in January, following which the Company will request a priority FDA review of the BLA under the product candidate's existing Fast Track designation. If approved, Ryoncil™ is planned to be launched in the US in 2020.

A webcast of the presentation is available via https://event.webcasts.com/starthere.jsp?ei=1278810&tp_key=f1494febd2 and as an archived webcast for 90 days on the Investors & Media section of the Company's website at www.mesoblast.com.

About Ryoncil™ (remestemcel-L)
Mesoblast's lead product candidate, Ryoncil™, is an investigational therapy comprising culture-expanded mesenchymal stem cells derived from the bone marrow of an unrelated donor. It is administered to patients in a series of intravenous infusions. Ryoncil™ is believed to have immunomodulatory properties to counteract the inflammatory processes that are implicated in aGVHD by down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.

About Mesoblast
Mesoblast Limited (ASX:MSB; Nasdaq:MESO) is a world leader in developing allogeneic (off-the-shelf) cellular medicines. The Company has leveraged its proprietary cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates. Two products have been commercialized in Japan and Europe by its licensees, and it has established commercial partnerships in Europe and China for certain Phase 3 assets. In the United States, Mesoblast has initiated submission of a rolling Biologics License Application to the FDA to seek approval of its product candidate for acute graft versus host disease following a successful Phase 3 trial, and is completing Phase 3 trials for its advanced heart failure and chronic low back pain product candidates. Mesoblast's proprietary manufacturing process yields industrial-scale, frozen, off-the-shelf, cellular medicines based on its mesenchymal lineage cell platform technology. These cell therapies, with defined

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
21 Biopolis Road
#01-22 Nucleos (South Tower)
SINGAPORE 138567
T +65 6570 0635
F +65 6570 0176

pharmaceutical release criteria, are planned to be readily available to patients worldwide. Mesoblast has locations in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). For more information, please see www.mesoblast.com, LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

Mesoblast's Forward-Looking Statements

This announcement 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. Forward-looking statements include, but are not limited to, statements about the timing, progress and results of Mesoblast's preclinical and clinical studies; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies; the timing or likelihood of regulatory filings and approvals; and the pricing and reimbursement of Mesoblast's product candidates, if approved. 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.

Release authorized by the Chief Executive.

1.TEMCELL HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.

For further information, please contact:

Julie Meldrum
Corporate Communications
T: +61 3 9639 6036
E: julie.meldrum@mesoblast.com

Schond Greenway
Investor Relations
T: +1 212 880 2060
E: schond.greenway@mesoblast.com