asx announcement

mesoblast

FIRST THREE CHILDREN TO COMMENCE TREATMENT WITH RYONCIL®

UNITED STATES CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) MANDATES RYONCIL® COVERAGE

Melbourne, Australia; March 31 and New York, USA; March 30, 2025: Mesoblast (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that it has entered into the Medicaid National Drug Rebate Agreement (NDRA) with the U.S. Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, for Ryoncil® (remestemcel-L), the first mesenchymal stromal cell (MSC) therapy approved by U.S. Food and Drug Administration (FDA) for any indication. The NDRA agreement with Mesoblast means that the U.S. Government now provides inpatient and outpatient access for a treatment course of Ryoncil® to the approximately 40% of U.S. children covered by Medicaid who have steroid-refractory acute graft versus host disease (SR-aGvHD), the remainder being covered by private insurance. U.S. states have the option to immediately cover Ryoncil®, with mandatory coverage commencing July 1, 2025.

The first three children with SR-aGvHD will receive a course of Ryoncil® commencing this week. Ryoncil® is an allogeneic MSC therapy for treatment of pediatric patients 2 months and older, including adolescents and teenagers, with SR-aGvHD, a condition with high mortality rates. The recommended course of Ryoncil® for pediatric SR-aGvHD is 2×10^6 MSC/kg body weight per intravenous infusion given twice per week for 4 consecutive weeks. Additional information is available on ryoncil.com, where valuable resources for healthcare providers, patients and caregivers can be found.

Mesoblast Chief Executive Dr. Silviu Itescu said: "We are delighted to be commencing treatment with Ryoncil® for children suffering with SR-aGvHD and are proud that the product is available to all children in the U.S. irrespective whether they have private insurance or Medicaid. This is a significant commercial achievement by our team and partners who are driven by an overwhelming desire to help children and their families faced with this devastating disease."

About Mesoblast
Mesoblast (the Company) is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The therapies from the Company's proprietary mesenchymal lineage cell therapy technology platform respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast's RYONCIL® (remestemcel-L) for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months and older is the first FDA approved mesenchymal stromal cell (MSC) therapy. Please see the full Prescribing Information at www.ryoncil.com.

Mesoblast is committed to developing additional cell therapies for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. RYONCIL is being developed for additional inflammatory diseases including SR-aGvHD in adults and biologic-resistant inflammatory bowel disease. Rexlemestrocel-L is being developed for heart failure and chronic low back pain. The Company has established commercial partnerships in Japan, Europe and China.

About Mesoblast intellectual property: Mesoblast has a strong and extensive global intellectual property portfolio, with over 1,000 granted patents or patent applications covering mesenchymal stromal cell compositions of matter, methods of manufacturing and indications. These granted patents and patent applications are expected to provide commercial protection extending through to at least 2041 in major markets.

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About Mesoblast manufacturing: The Company's proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

Mesoblast has locations in Australia, the United States and Singapore 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

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. Forward-looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's RYONCIL for pediatric SR-aGVHD and any other product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; 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.

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