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MESOBLAST AND BMT CTN TO INITIATE PIVOTAL TRIAL OF RYONCIL® AS PART OF FIRST-LINE REGIMEN IN ADULTS WITH SEVERE ACUTE GVHD REFRACTORY TO STEROIDS

Melbourne, Australia; November 21 and New York, USA; November 20, 2025: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today announced that given the high rate of non-responsiveness to therapies in adults with severe acute graft versus host disease (aGvHD) who fail corticosteroids, and the high mortality in these patients, Mesoblast and the United States National Institutes of Health (NIH)-funded Blood and Marrow Transplant Clinical Trials Network (BMT CTN) will collaborate on a pivotal trial of Ryoncil® (remestemcel-L-rknd) as part of first-line regimen in adults with severe aGvHD refractory to corticosteroids (SR-aGvHD). The BMT CTN is a body representing U.S. centers responsible for performing approximately 80% of all U.S. allogeneic BMTs.

Dr John Levine, Chair of the BMT CTN Steering Committee and Professor of Internal Medicine and Pediatrics, Icahn School of Medicine at Mount Sinai, New York said: "We are delighted to be partnering with Mesoblast in this pivotal Phase 3 trial of Ryoncil®. We are aiming to extend the use of this potentially life-saving treatment, already approved by FDA in children and adolescents, to adults with severe SR-aGvHD."

In Grade III/IV SR-aGvHD 44-58% of adults treated with ruxolitinib did not achieve response at Day 28 in two studies that supported FDA approval. In patients who fail ruxolitinib survival remains as low as 20-30% by 100 days.[1-3] Notably, use of Ryoncil® in Mesoblast's Expanded Access program in patients aged 12 and older with SR-aGvHD who failed ruxolitinib or other second-line agents was associated with 76% survival at Day 100.[4]

Mesoblast recently met with FDA to discuss the most appropriate patient population and timing of treatment in a pivotal trial of Ryoncil® for adults with severe SR-aGvHD. In order to give adult patients with severe SR-aGvHD the best chance of survival, patients will be randomized in the trial as early as possible after corticosteroid refractoriness to receive ruxolitinib alone or combined with Ryoncil®. The trial protocol will be provided to FDA in order to initiate enrollment in the first quarter of 2026.

Mesoblast Chief Executive Silviu Itescu said, "We are pleased to be partnering with the BMT CTN to expand the availability of Ryoncil® to adult patients with severe SR-aGvHD given the poor outcome with existing therapies. This clearly remains a major unmet need and a market opportunity 3-4 times larger than the pediatric market."

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-rknd) 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.

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
1114 Avenue of the Americas
4th Floor
New York, NY 10036
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

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 provide commercial protection extending through to at least 2044 in all major markets.

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 X: @Mesoblast

About the Blood and Marrow Transplant Clinical Trials Network (BMT CTN)
The BMT CTN conducts rigorous multi-institutional clinical trials of high scientific merit, focused on improving survival for patients undergoing hematopoietic cell transplantation and/or receiving cellular therapies. The BMT CTN has completed accrual to 52 Phase II and III trials at more than 125 transplant centers and enrolled over 16,600 study participants. BMT CTN is funded by the National Heart, Lung and Blood Institute and the National Cancer Institute, both parts of the National Institutes of Health, and is a collaborative effort of 19 Core Transplant Centers/Consortia, The Center for International Blood and Marrow Transplant Research (CIBMTR), the National Marrow Donor Program (NMDP) and the Emmes Company, LLC, a clinical research organization. CIBMTR is a research collaboration between the NMDP and the Medical College of Wisconsin (MCW). Together, MCW, NMDP and Emmes have been providing research support to the BMT CTN since 2001, as the Network's data and coordinating center. More information about the BMT CTN can be found at www.bmtctn.net

About NMDP®
At NMDP℠, we believe each of us holds the key to curing blood cancers and disorders. As a global nonprofit leader in cell therapy, NMDP creates essential connections between researchers and supporters to inspire action and accelerate innovation to find life-saving cures. With the help of blood stem cell donors from the world's most diverse registry and our extensive network of transplant partners, physicians and caregivers, we're expanding access to treatment so that every patient can receive their life-saving cell therapy. NMDP. Find cures. Save lives. Learn more at nmdp.org.

About the Medical College of Wisconsin (MCW)
With a history dating back to 1893, the MCW is dedicated to leadership and excellence in education, patient care, research, and community engagement. More than 1,500 students are enrolled in MCW's medical school and graduate school programs in Milwaukee, Green Bay, and Central Wisconsin. MCW's School of Pharmacy opened in 2017. A major national research center, MCW is the largest research institution in the Milwaukee metro area and second largest in Wisconsin. In the last 10 years, faculty received more than $1.5 billion in external support for research, teaching, training, and related purposes. This total includes highly competitive research and training awards from the National Institutes of Health (NIH). Annually, MCW faculty direct or collaborate on more than 3,100 research studies, including clinical trials. Additionally, more than 1,800 physicians provide care in virtually every specialty of medicine for more than 2.8 million patients annually. It has a long history in hematopoietic transplantation and cellular therapy, including operating an outcomes registry of transplantation and cellular therapy outcomes and facilitating related research since 1972.

About CIBMTR®
CIBMTR® (Center for International Blood and Marrow Transplant Research®) is a nonprofit research collaboration between NMDP℠, in Minneapolis, and the Medical College of Wisconsin (MCW), in Milwaukee. CIBMTR collaborates with the global scientific community to increase survival and enrich quality of life for patients. CIBMTR facilitates critical observational and interventional research through scientific and statistical expertise, a large network of centers, and a unique database of long-term clinical data for more than 680,000 people who have received hematopoietic cell transplantation and other cellular therapies. Learn more at cibmtr.org. It is funded by the National Cancer Institute, the National Heart, Lung and Blood Institute and the National Institute for Allergy and Infectious Disease, the Health Resources and Services Administration, the Office of Naval Research, industry sponsors, MCW, and NMDP.

About Emmes
Emmes Group, a specialty, technology and AI enabled contract research organization (CRO), is advancing and modernizing clinical research to improve patient outcomes. Founded as Emmes more than 47 years ago, we became a trusted clinical research partner to the U.S. government. Today, Emmes Group is a global full-service CRO operating in 72 countries worldwide collaborating with government agencies, public-private partnerships, and biopharma innovators. Now wholly owned by New Mountain Capital, we are transforming the future of clinical research and bringing life-changing treatments closer to patients. Where human intelligence meets artificial intelligence. Learn more at www.theemmesgroup.com.

References / Footnotes

1. Jagasia M, et al. Ruxolitinib for the treatment of steroid-refractory acute GVHD (REACH1): a multicenter, open-label phase 2 trial. *Blood.* 2020 May 14; 135(20): 1739–1749
2. Abedin S, et al. Ruxolitinib resistance or intolerance in steroid-refractory acute graft versus-host disease — a real-world outcomes analysis. *British Journal of Haematology*, 2021;195:429–43
3. Zeiser R, et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease. *N Engl J Med* 2020;382:1800-1810
4. Kurtzberg J, et al. Ryoncil (Remestemcel-L) for Third-Line Treatment of SR-aGvHD in Adolescents and Adults [Poster presentation]. 2025 Transplantation & Cellular Therapy Tandem Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for Blood and Marrow Transplant Research (CIBMTR).

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.

For more information, please contact:

Corporate Communications / Investors
Paul Hughes
T: +61 3 9639 6036

Media – Global
Allison Worldwide
Emma Neal
T: +1 603 545 4843
E: emma.neal@allisonworldwide.com

Media – Australia
BlueDot Media
Steve Dabkowski
T: +61 419 880 486
E: steve@bluedot.net.au