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RYONCIL® COMMERCIAL LAUNCH UPDATE AND PRODUCT PIPELINE

Melbourne, Australia; January 31 and New York, USA; January 30, 2025: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), global leader in allogeneic cellular medicines for inflammatory diseases, today provided an update on the progress of the U.S. commercial launch of Ryoncil® (remestemcel-L) for steroid-refractory acute graft-versus-host disease (SR-aGvHD) in pediatric patients 2 months and older and key upcoming milestones for its late-stage pipeline.

"We are committed to making our FDA approved product Ryoncil® available as quickly as possible to the many children with SR-aGVHD in need of life-saving therapy," said Dr. Silviu Itescu, Chief Executive of Mesoblast. "The team has been working relentlessly on finalizing product availability, including logistics, regulatory documentation, and contractual arrangements to ensure a successful launch of Ryoncil® this quarter."

"The successful financing of US$160 million (A$260 million) this month, which provides the Company with proforma cash on hand of approximately US$200 million (A$322 million), puts us in a strong position to execute the U.S. commercial launch activities of Ryoncil®, to expand the clinical indications of the product, and ensure that commercial manufacturing will meet projected product uptake and demand."

"I look forward to providing an update at half year results on February 27th 9.00am AEDT (February 26th 5.00pm EST)."

INVESTMENT HIGHLIGHTS

Mission

Mesoblast is committed to bring to market innovative off-the-shelf allogeneic cellular medicines to treat serious and life-threatening inflammatory illnesses.

Market Opportunity

- Steroid-refractory acute GvHD >$1 billion annual market potential.
- Heart failure with reduced ejection fraction (HFrEF) >$10 billion addressable market potential.
- Chronic low back pain (CLBP) >$10 billion addressable market potential.
- Additional potential multi-billion-dollar opportunities from existing and future product pipeline based on existing technology platforms.

Product Portfolio

- Ryoncil® the only FDA-approved MSC therapy for any indication; lifesaving for pediatric SR-aGvHD.
- Revascor® has potential for FDA accelerated approval in end-stage HFrEF.
- Rexlemestrocel-L in Phase 3 trial for potential approval in CLBP.
- Additional pipeline therapies targeting unmet medical needs.

Competitive Advantage

- Proven scientific approach, with deep understanding of mechanism of action (MOA).
- Robust and extensive intellectual property.
- Extensive positive clinical trial results across multiple indications.
- Demonstrated ability to meet regulatory requirements of FDA.
- Scalability of manufacturing processes and proprietary next generation technology.

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Financials and Projections

- Strong balance sheet to support Ryoncil® launch and product portfolio.
- Current revenue streams anticipated to expand based on Ryoncil® performance.
- Continued prudent cash management strategy.
- Long-term revenue potential from the existing and future pipeline.

Upcoming Milestones

- Ryoncil® commercial launch planned this quarter.
- Revascor® FDA meeting and subsequent BLA submission.
- Rexlemestrocel-L CLBP Phase 3 completion and BLA submission.
- Expansion into new indications and markets.

PORTFOLIO UPDATE

Ryoncil® (remestemcel-L) U.S. Launch for Steroid-Refractory Acute Graft Versus Host Disease

- On December 18, 2024, Ryoncil® (remestemcel-L) became the first mesenchymal stromal cell (MSC) therapy approved by U.S. FDA for any indication.
- FDA approved Ryoncil® as the first and only therapy for pediatric patients 2 months and older, including adolescents and teenagers, with steroid-refractory acute graft versus host disease (SR-aGvHD), a life-threatening condition with high mortality rates.
- Ryoncil® planned for launch this quarter once Company receives National Drug Codes (NDC) from FDA, enabling subsequent publication of product pricing in the U.S. Price Compendia.
- The U.S. launch of Ryoncil® will be led by Mesoblast's commercial leadership team comprising
    - Marcelo Santoro, Chief Commercial Officer, a seasoned pharmaceutical executive with over three decades of experience successfully leading high-performing teams at Pfizer, Otsuka, and AstraZeneca, with a proven track record of launching innovative therapies, including the creation of multi-billion-dollar brands and the execution of global product launches.
    - Peter McSweeney, MB ChB FRACP, Head of Medical Affairs, is a hematologist and bone-marrow transplant specialist with over 30 years' experience. He has worked at the Fred Hutchinson Cancer Research Center, has been Clinical Director at the University of Colorado's Blood & Marrow Transplant Program, and more recently Director of Cellular Therapy at Colorado Blood Cancer Institute. He has extensive experience in the clinical application and research of allogeneic and autologous transplantation, CAR-T cell therapy, and has many publications in these areas.
    - Commercial and medical affairs functions will be supported by a team of key account managers (KAMs) and medical science liaisons (MSLs), respectively, to provide critical infrastructure for the commercial function and engagement and servicing of treatment centers.
- Commercial launch strategy will initially target those centers with greatest experience using the Ryoncil® product and highest volume, followed by a broader staged rollout. Half of all pediatric transplants are performed at just 15 centers across the U.S. Our commercial team will be heavily engaged in these centers of excellence along with another 30 sites, which together account for almost 80% of pediatric transplants.
- Commercial inventory has been manufactured and a distribution network has been established using Cencora, a leader in specialty pharmaceutical services and distribution. Cencora will leverage its cryogenic logistics capabilities and state-of-the art cryogenic storage infrastructure, to enable the efficient and secure delivery of cryopreserved product to U.S. treatment centers.
- Our patient access hub, *MyMesoblast*™, has been established and will be managed by Cencora to facilitate patient enrollment, shipment & logistics, and will provide support for patients in the inpatient and outpatient setting.
- Mesoblast will have a significant presence, including scientific presentations and exhibitor booth, at the industry's most important meeting, the 2025 Transplantation & Cellular Therapy Meetings (Tandem Meetings) of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for Blood and Marrow Transplant Research (CIBMTR), taking place February 12-15 in Honolulu, HI.

Ryoncil® Label Extension in Pediatric & Adult Inflammatory Diseases

- Mesoblast is developing a comprehensive clinical, regulatory and commercial strategy to build a pediatric inflammatory disease franchise using Ryoncil® to target diseases of high unmet need given the extensive safety profile of the product in children, the unique mechanism of action of Ryoncil®, and the limited options available for these inflammatory conditions.
- For adult patients, Mesoblast is collaborating with Blood and Marrow Transplant Clinical Trials Network (BMT CTN) in the United States, a body that is funded by the National Institutes of Health (NIH) and is responsible for approximately 80% of all US allogeneic BMTs, to conduct a pivotal trial in adults with SR-aGVHD.
- Survival in adults with SR-aGVHD who have failed at least one additional agent, such as ruxolitinib, remains as low as 20-30% by 100 days.[1,2] In contrast, 100-day survival was 73% after Ryoncil® treatment was used under expanded access in 25 adults with SR-aGVHD who failed to respond to at least one additional agent, such as ruxolitinib.

Revascor® (rexlemestrocel-L) for Chronic Heart Failure with Reduced Ejection Fraction (HFrEF) and Persistent Inflammation

- In 2024 FDA informed Mesoblast that it supports an accelerated approval pathway for REVASCOR, Mesoblast's second generation allogeneic, STRO3-immunoselected, and industrially manufactured stromal cell therapy, in patients with end-stage ischemic HFrEF kept alive with a left ventricular assist device (LVAD).
- Accelerated approval to market REVASCOR, if received, will require Mesoblast to commit to a post-approval confirmatory study in NYHA Class II/III HFrEF patients which could result in full approval in the broader HFrEF population.
- In November 2024 a publication in the prestigious peer-reviewed European Journal of Heart Failure (EJHF) reported that a single intramyocardial injection of REVASCOR results in improved survival in high-risk NYHA Class II/III patients with ischemic heart failure and inflammation.[3] This identifies the HFrEF population that is responsive to REVASCOR and will be the target of a confirmatory trial after accelerated approval, if received.
- Under its Regenerative Medicine Advanced Therapy (RMAT) designation Mesoblast intends to meet with FDA to discuss data presentation, timing and FDA expectations for an accelerated approval filing in these patients.

Revascor® for Pediatric Congenital Heart Disease - Hypoplastic Left Heart Syndrome

- U.S. FDA granted REVASCOR a RMAT designation following submission of results from the randomized controlled trial in children with hypoplastic left heart syndrome (HLHS), a potentially life-threatening congenital heart condition.
- Earlier in 2024, FDA granted REVASCOR both Rare Pediatric Disease Designation (RPDD) and Orphan-Drug Designation (ODD) for treatment of children with HLHS.
- RMAT designations aim to expedite the development of regenerative medicine therapies intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the therapy has the potential to address unmet medical needs for the disease or condition. An RMAT designation for rexlemestrocel-L provides all the benefits of Breakthrough and Fast Track designations, including rolling review and eligibility for priority review on filing of a Biologics License Application (BLA).
- On FDA approval of a BLA for REVASCOR for the treatment of HLHS, if received, Mesoblast may be eligible to receive a Priority Review Voucher (PRV) that can be redeemed for any subsequent marketing application or may be sold or transferred to a third party.

Rexlemestrocel-L for Chronic Low Back Pain associated with Degenerative Disc Disease – Phase 3 Program

- The confirmatory Phase 3 trial of Mesoblast's second generation allogeneic, STRO3-immunoselected, and industrially manufactured stromal cell product candidate rexlemestrocel-L in patients with chronic low back pain (CLBP) due to inflammatory degenerative disc disease (DDD) of less than five years duration has commenced enrollment and treatment at multiple sites across the U.S.
- The capital raise concluded this month will facilitate expansion of sites enrolling in the trial and acceleration of patient accrual.

- FDA has previously agreed on the design of this 300-patient randomized, placebo-controlled confirmatory Phase 3 trial, and the 12-month primary endpoint of pain reduction as an approvable indication.
- This endpoint was successfully met in Mesoblast's first Phase 3 trial. Key secondary measures include improvement in quality of life and function.
- A particular focus is on treatment of patients on opioids, since discogenic back pain accounts for approximately 50% of prescription opioid usage in the US. Significant pain reduction and opioid cessation were observed in Mesoblast's first Phase 3 trial.
- FDA has designated rexlemestrocel-L a RMAT for the treatment of chronic low back pain.

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.

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

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. Perin EC. Et al. Mesenchymal precursor cells reduce mortality and major morbidity in ischaemic heart failure with inflammation: DREAM-HF. *Eur J Heart Fail* 2024. https://doi.org/10.1002/ejhf.3522

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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