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mesoblast

MESOBLAST ENTERS GLOBAL COLLABORATION FOR DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION OF REMESTEMCEL-L

Initial Focus on Acute Respiratory Distress Syndrome, including COVID-19

Melbourne, Australia; November 20, and New York, USA; November 19, 2020: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), today announced that it has entered into an exclusive worldwide license and collaboration agreement with Novartis for the development, manufacture and commercialization of Mesoblast's mesenchymal stromal cell (MSC) product remestemcel-L, with an initial focus on the development of the treatment of acute respiratory distress syndrome (ARDS), including that associated with COVID-19.

Mesoblast Chief Executive Dr Silviu Itescu stated: "Our collaboration with Novartis will help ensure that remestemcel-L could become available to the many patients suffering from ARDS, the principal cause of mortality in COVID-19 infection. This agreement is in line with our corporate strategy to collaborate and partner with world-leading major pharma companies in order to maximize market access for our innovative cellular medicines."

The demonstrated ability of Novartis to rapidly move from clinical to commercial scale with cell-based therapies will play a role in the successful development and potential commercialization of remestemcel-L, as will the nearly two decades of experience Novartis has in delivering first-in-class products that address areas of unmet respiratory need.

ARDS is an area of significant unmet need, with a high mortality rate despite current standard of care, which includes prolonged ICU treatment and mechanical ventilation. As the potential first ARDS therapy, remestemcel-L will be evaluated to treat this deadly condition and improve outcomes. Remestemcel-L is currently being studied in COVID-19-related ARDS in an ongoing 300-patient Phase 3 study, where even with maximal existing therapies, mortality is estimated to be even higher. Novartis intends to initiate a Phase 3 study in non-COVID-19-related ARDS after the anticipated closing of the license agreement and successful completion and outcome of the current study.

Key transaction terms:

- Novartis will make a US$50 million upfront payment including US$25 million in equity.
- From the initiation of a Phase 3 trial in all-cause ARDS, Novartis will fully fund global clinical development for all-cause ARDS and potentially other respiratory indications.
- Mesoblast may receive a total of US$505 million pending achievement of pre-commercialization milestones for ARDS indications.
- Mesoblast may receive additional payments post-commercialization of up to US$750 million based on achieving certain sales milestones and tiered double-digit royalties on product sales.
- Mesoblast will retain full rights and economics for remestemcel-L for graft versus host disease (GVHD), and Novartis has an option to, if exercised, become the commercial distributor outside of Japan.
- For most non-respiratory indications, the parties may co-fund development and commercialization on a 50:50 profit-share basis.
- Mesoblast will be responsible for clinical and commercial manufacturing and Novartis will purchase commercial product under agreed pricing terms. Novartis will reimburse Mesoblast up to US$50 million on the achievement of certain milestones related to the successful

implementation of its next-generation manufacturing processes using its proprietary media and three-dimensional bioreactors aimed at delivering substantial manufacturing efficiencies. Novartis will be responsible for any capital expenditure required to meet increased capacity requirements for manufacture of remestemcel-L.

The closing of the license agreement is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and certain other conditions.

About Mesenchymal Stromal Cells (MSCs)
MSCs have immunomodulatory properties which may facilitate their effective use in life-threatening conditions associated with systemic inflammation. Key inherent characteristics of MSCs are their capacity for significant expansion in culture and their relative lack of immunogenicity. These properties facilitate their use as allogeneic or "off-the-shelf" therapeutics with specific release criteria and batch-to-batch reproducibility.

About Remestemcel-L
Remestemcel-L is an investigational therapy comprising culture-expanded MSCs derived from the bone marrow of an unrelated donor. Remestemcel-L is thought to have immunomodulatory properties to counteract the cytokine storms that are implicated in various inflammatory conditions 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. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid-refractory acute graft versus host disease (SR-aGVHD) and moderate to severe acute respiratory distress syndrome.

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 mesenchymal lineage cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates. Mesoblast has a strong and extensive global intellectual property (IP) portfolio with protection extending through to at least 2040 in all major markets. 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.

Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid-refractory acute graft versus host disease and moderate to severe acute respiratory distress syndrome. Mesoblast is completing Phase 3 trials for its product candidates for advanced heart failure and chronic low back pain. Two products have been commercialized in Japan and Europe by Mesoblast's licensees, and the Company has established commercial partnerships in Europe and China for certain Phase 3 assets.

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

Conference Call
There will be a webcast today beginning at 9.00am AEDT (Friday, November 20); 5.00pm EST (Thursday, November 19, 2020). It can be accessed via https://webcast.boardroom.media/mesoblast-limited/20201119/NaN5fb59c68f297810019932232

The archived webcast will be available on the Investor page of the Company's website: www.mesoblast.com

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 potential milestone and royalty payments that may be received pursuant to the agreement with Novartis, 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 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 Board.

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