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MESOBLAST AND JCR PHARMACEUTICALS EXPAND JAPAN LICENSE AGREEMENT TO USE OF MESENCHYMAL STEM CELLS IN NEWBORNS WITH INSUFFICIENT BLOOD FLOW TO THE BRAIN

New York, USA; and Melbourne, Australia; June 11, 2019: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today announced it has expanded its partnership with JCR Pharmaceuticals Co. Ltd. in Japan to the use of mesenchymal stem cells (MSCs) for the treatment of newborns who lack sufficient blood supply and oxygen to the brain, a condition termed neonatal hypoxic ischemic encephalopathy (HIE).

HIE occurs in 2.5 per 1,000 live births[1] and can cause seizures, delayed development of motor skills and cognitive function, and cerebral palsy[2]. In preclinical studies, MSCs have been shown to have a significant positive effect on neurobehavioral outcome following HIE injury[3].

JCR is marketing the allogeneic MSC product TEMCELL®[4] HS Inj. for the treatment of steroid-refractory acute graft versus host disease (aGVHD) in children and adults in Japan. Under the terms of the partnership, Mesoblast receives royalties on TEMCELL product sales for all licensed indications. The license agreement was previously expanded for use in wound healing in patients with Epidermolysis Bullosa (EB), and JCR filed to extend marketing approval of TEMCELL in Japan for this indication in March 2019.

The license agreement has now been further expanded to provide JCR with rights to sell TEMCELL for HIE and to access Mesoblast's broad patent portfolio for this indication. JCR plans to initiate a clinical trial of TEMCELL in newborns with HIE in July 2019 in order to further extend the label in this indication.

Mesoblast has the right to use all safety and efficacy data generated by JCR in Japan to support its development and commercialization plans for its MSC product candidate remestemcel-L in the United States and other major healthcare markets, including for GVHD, wound healing, and now HIE. In the United States there are approximately 6,000 new patients annually with moderate-severe HIE[2] who could potentially benefit from treatment with remestemcel-L.

Mesoblast Chief Executive Dr Silviu Itescu stated: "We are pleased with the strategy by our partner to expand TEMCELL marketing approval for indications beyond aGVHD. This supports our own strategic growth plans for our MSC product candidate remestemcel-L beyond aGVHD in children, including other pediatric indications such as HIE and adult conditions such as aGVHD, chronic GVHD, biologic-refractory Crohn's disease, and osteoarthritis."

Mesoblast recently initiated a rolling Biologics License Application to the U.S Food and Drug Administration for remestemcel-L, its proprietary MSC product candidate, in the treatment of children with aGVHD.

1. Graham EM et al. A systematic review of the role of intra-partum hypoxia-ischemia in the causation of neonatal encephalopathy. Am J Obstetrics and Gynecology 2008:587-595 Lack of sufficient oxygen and blood perfusion to the brain, resulting in brain injury.
2. Lee AC, Kozuki N, Blencowe H, Vos T, Bahalim A, Darmstadt GL, Niermeyer S, Ellis M, Robertson NJ, Cousens S, Lawn JE. Intrapartum-related neonatal encephalopathy incidence and impairment at regional and global levels for 2010 with trends from 1990. Pediatr Res 2013; 74 Suppl 1: 50-72
3. Archambault J, et al. Therapeutic potential of mesenchymal stromal cells for hypoxic ischemic encephalopathy: A systematic review and meta-analysis of preclinical studies. PLoS ONE 2017; 12(12): https://doi.org/10.1371/journal.pone.0189895
4. TEMCELL® HS Inj. is a registered product of JCR Pharmaceuticals Co. Ltd.

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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 technology platform to establish a broad portfolio of late-stage product candidates with three product candidates in Phase 3 trials – acute graft versus host disease, chronic heart failure and chronic low back pain due to degenerative disc disease. Through a proprietary process, Mesoblast selects rare mesenchymal lineage precursor and stem cells from the bone marrow of healthy adults and creates master cell banks, which can be industrially expanded to produce thousands of doses from each donor that meet stringent release criteria, have lot to lot consistency, and can be used off-the-shelf without the need for tissue matching. Mesoblast has facilities in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). www.mesoblast.com

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 in aGVHD; Mesoblast and its collaborators' ability to advance product candidates into, enroll and successfully complete, clinical studies; the timing or likelihood of regulatory filings and approvals for aGVHD; and the pricing and reimbursement of Mesoblast and its collaborators' 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.

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