asx announcement

mesoblast
the regenerative medicine company

MESOBLAST LICENSEE FILES FOR MARKETING APPROVAL TO TREAT EPIDERMOLYSIS BULLOSA

New York, USA; and Melbourne, Australia; Monday March 25, 2019: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today announced its licensee in Japan, JCR Pharmaceuticals Co. Ltd., has filed to extend marketing approval of TEMCELL®[1] HS Inj. for use in patients with Epidermolysis Bullosa (EB). TEMCELL is already approved for the treatment of acute graft versus host disease (aGVHD), and was the first allogeneic cellular medicine to receive full regulatory approval in Japan.

The parties have amended their License Agreement in order for JCR to access Mesoblast's mesenchymal stem cell (MSC) wound healing patents to enable it to develop and commercialize TEMCELL for EB. Mesoblast will receive royalties on TEMCELL product sales for EB.

JCR has received Orphan Designation for TEMCELL in the treatment of EB based on promising results from an investigator-initiated trial at Osaka University Hospital where TEMCELL was subcutaneously administered. JCR also intends to seek a label extension for TEMCELL in Japan for intravenous delivery of TEMCELL.

Mesoblast will have access to clinical data generated by JCR in Japan to support development and commercialization of its MSC product candidate remestemcel-L in markets outside Japan for EB and other wound healing applications. Mesoblast plans to file for United States FDA regulatory approval of remestemcel-L shortly for the treatment of aGVHD.

There are many genetic and symptomatic variants of EB, with all sharing the prominent symptom of extremely fragile skin that blisters and tears from minor friction or trauma. Internal organs and bodily systems can also be seriously affected by the disease. EB is always painful, often pervasive and debilitating, and is in some cases lethal before the age of 30. The international branch of the Dystrophic Epidermolysis Bullosa Research Association (DEBRA International) reports that there are approximately 25,000 people with EB in the United States. Currently, there are no effective treatments available[2].

References

1. TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.
2. https://www.debra.org/itwonthurttowatch

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 allogeneic (off-the-shelf) 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).
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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; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies; the timing or likelihood of regulatory filings and approvals; 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.

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