

Mesoblast and Lonza Enter into Agreement for Commercial Manufacture of Mesoblast's Potential First United States Allogeneic Therapy

Quote from Alberto Santagostino, SVP Head of Cell & Gene Technologies, Lonza:

“Mesoblast is a true trailblazer, leading the way in developing life-changing cell therapies and working hard to soon make them available to large numbers of patients. This agreement builds on the successful partnership and alliance between our two companies over the years. As we also enter new partnerships with early-stage companies on one side, Mesoblast shows the path of success in reaching commercialization on the other. We are committed for the long run with Mesoblast, to continue to grow and deliver cell therapies to all patients in need, together.”

Quote from Dr. Silviu Itescu, Chief Executive, Mesoblast:

“This commercial manufacturing agreement with Lonza for our lead product candidate is designed to ensure that we are in a position to meet projected commercial demand as we plan to roll out the first of our allogeneic cell therapies to people around the world in need of life-saving and disease-modifying products.”

Melbourne, Australia, 17 October 2019, New York, USA & Basel, Switzerland, 16 October 2019 – Mesoblast (ASX:MSB; Nasdaq:MESO) and Lonza (SWX: LONN) announced today that they have entered into an agreement for commercial manufacture of Mesoblast’s lead allogeneic (off-the-shelf) cell therapy product candidate, remestemcel-L for pediatric steroid-refractory acute graft versus host disease (aGVHD). This agreement will facilitate inventory build ahead of the planned United States (US) market launch of remestemcel-L and commercial supply to meet Mesoblast’s long-term market projections.

Mesoblast expects to complete filing of the rolling Biologics License Application (BLA) submission to the US Food and Drug Administration (FDA) by the end of this year. On acceptance of the filing, the product candidate is eligible for FDA priority review under its existing Fast Track designation, providing for an expedited review period. If approved, the US launch of remestemcel-L is expected to occur next year.

The agreement provides for Lonza to expand its Singapore cGMP facilities if required to meet long-term growth and capacity needs for the product. Additionally, it anticipates introduction of new technologies and process improvements which are expected to result in significant increases in yields and efficiencies.

About Lonza

Lonza is an integrated solutions provider that creates value along the Healthcare Continuum[®]. Through our Pharma Biotech & Nutrition segment and our Specialty Ingredients segment businesses, we harness science and technology to serve markets along this continuum. We focus on creating a healthy environment, promoting a healthier lifestyle and preventing illness through consumers' preventive healthcare, as well as improving patient healthcare by supporting our customers to deliver innovative medicines that help treat or even cure severe diseases.

Patients and consumers benefit from our ability to transfer our pharma know-how to the healthcare, hygiene and fast-moving consumer goods environment and to the preservation and protection of the world where we live.

Founded in 1897 in the Swiss Alps, Lonza today is a well-respected global company with more than 100 sites and offices and approximately 15,500 full-time employees worldwide at the end of 2018. The company generated sales of CHF 5.5 billion in 2018 with a CORE EBITDA of CHF 1.5 billion. Further information can be found at www.lonza.com.

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 cell therapy technology platform to establish a broad portfolio of commercial products and late-stage product candidates. Two products have been commercialized in Japan and Europe by its licensees, and it has established commercial partnerships in Europe and China for certain Phase 3 assets. In the United States, Mesoblast has initiated submission of a rolling Biologics License Application to the FDA to seek approval of its product candidate for acute graft versus host disease following a successful Phase 3 trial, and is completing Phase 3 trials for its advanced heart failure and chronic low back pain product candidates. Mesoblast's proprietary manufacturing process yields industrial-scale, frozen, off-the-shelf, cellular medicines based on its mesenchymal lineage cell platform technology. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide. Mesoblast has locations in Melbourne, New York, Singapore and Texas 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

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 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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Additional Information and Disclaimer

Lonza Group Ltd has its headquarters in Basel, Switzerland, and is listed on the SIX Swiss Exchange. It has a secondary listing on the Singapore Exchange Securities Trading Limited (“SGX-ST”). Lonza Group Ltd is not subject to the SGX-ST’s continuing listing requirements but remains subject to Rules 217 and 751 of the SGX-ST Listing Manual.

Certain matters discussed in this news release may constitute forward-looking statements. These statements are based on current expectations and estimates of Lonza Group Ltd, although Lonza Group Ltd can give no assurance that these expectations and estimates will be achieved. Investors are cautioned that all forward-looking statements involve risks and uncertainty and are qualified in their entirety. The actual results may differ materially in the future from the forward-looking statements included in this news release due to various factors. Furthermore, except as otherwise required by law, Lonza Group Ltd disclaims any intention or obligation to update the statements contained in this news release.