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MEDIA & INVESTOR RELEASE

Novartis secures exclusive rights for potential acute respiratory distress syndrome cell therapy

- *Novartis enters into exclusive worldwide license with Mesoblast to develop, commercialize and manufacture remestemcel-L for treatment of acute respiratory distress syndrome (ARDS) and other indications*

- *Addition of remestemcel-L could expand Novartis respiratory portfolio by adding potential first-in-class ARDS therapy using innovative cell-based technology with platform potential*

- *Deal includes $50 million upfront cash payment and equity/share subscription, plus performance-based milestones and royalties for access to a cell-therapy based platform with worldwide rights to a range of potential indications*

Basel, November 19, 2020 — Novartis announced today that it entered into an exclusive worldwide license and collaboration agreement with Mesoblast to develop, commercialize and manufacture remestemcel-L for the treatment of acute respiratory distress syndrome (ARDS), including that associated with COVID-19. ARDS is an area of significant unmet need, with an approximate 40% mortality rate with current standard of care, which includes prolonged ICU treatment and mechanical ventilation.[1,2] As the potential first ARDS therapy, remestemcel-L will use mesenchymal stromal cells (MSCs), a cell-based platform technology, 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 III study.[3] Novartis intends to initiate a Phase III study in non-COVID-19-related ARDS after the anticipated closing of the license agreement and successful completion and outcome of the current study.

“We believe that Novartis is uniquely placed to advance this important potential new therapy,” said John Tsai, M.D., Head of Global Drug Development and Chief Medical Officer for Novartis. “Novartis is committed to, and has demonstrated success with, cell-based therapies and transforming care for a spectrum of respiratory diseases. This makes remestemcel-L an important addition to our pipeline. It has the potential to be the first treatment for the most critically ill ARDS patients, and it provides us with an opportunity to apply years of specialized experience directly to the work of saving lives.”

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.

In March, an open label compassionate use program was conducted, which included 12 patients with COVID-19-related ARDS, who were being supported with mechanical ventilation. Remestemcel-L treatment was associated with an 83% survival rate.[4] Based on those results, remestemcel-L is being studied in this population in an ongoing 300-patient Phase III study, conducted in collaboration with the Cardiothoracic Surgical Network, which is anticipated to be completed in early 2021.[3] After the anticipated closing of the license agreement and successful completion and outcome of this ongoing study, Novartis and Mesoblast will work together to develop appropriate critical quality attributes that meet U.S. Food and Drug Administration requirements for remestemcel-L in advance of initiation of the Phase III study in non-COVID-19-related ARDS.

Under the license agreement, Novartis will acquire the exclusive worldwide rights to develop, commercialize and manufacture remestemcel-L for ARDS, and will obtain access to an innovative cell-therapy platform with a range of potential applications in severe respiratory conditions and beyond. Novartis will make a $25 million upfront payment and invest $25 million in Mesoblast equity with additional payments and royalties due on achievement of agreed development, regulatory and commercial milestones. In addition, Novartis will provide certain support to enable commercial manufacturing scale-up. Novartis has the option, if exercised, to distribute remestemcel-L for graft versus host disease (GVHD) (outside Japan). Both parties have rights to co-fund development and commercialization for other non-respiratory indications. 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 remestemcel-L
Remestemcel-L, is an investigational therapy comprising of culture-expanded mesenchymal stromal cells derived from the bone marrow of an unrelated donor.[5] 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.[5] In the Phase III study in COVID-19-related ARDS, remestemcel-L is administered as two infusions of $2x10^6$ MSC/kg given three to four days apart.[3] The administration of remestemcel-L for the treatment of all-cause ARDS could be the subject of further exploration.

About mesenchymal stromal cells
Mesenchymal stromal cells (MSCs) are isolated from bone marrow, adipose tissue and other sources that can be expanded in culture to larger quantities.[6] In preclinical studies MSCs have been suggested to transiently accumulate in the pulmonary circulation and have potent immunomodulatory functions.[7] They express receptors for multiple chemokine, cytokine and growth factor receptors and in inflammatory conditions secrete immunomodulatory mediators that have broad-acting effects to promote resolution of inflammation and tissue repair.[8] MSCs have been infused into well over 1,000 patients, including young children, without serious adverse events to date, testifying to the general safety of this therapeutic approach.[9]

About acute respiratory distress syndrome
Acute respiratory distress syndrome (ARDS) is a clinical syndrome that represents a final common pathway for lung injury caused by a variety of factors including bacterial and viral infection (including COVID-19).[2] It is characterized by life threatening hypoxemia and bilateral pulmonary infiltrates without evidence of cardiac failure.[10] Mortality often exceeds 40%.[2] Aside from appropriate ventilator and fluid management, no therapies have been shown to consistently improve survival in randomized clinical trials.[8,11]

Disclaimer
This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “may,” “could,” “anticipated,”

"believe," "committed," "investigational," "pipeline," "to develop," "intends," "to initiate," "anticipated," "advances," "bringing forward," "to lead," "development," "ongoing," "to address," "intends," "to enable," or similar terms, or by express or implied discussions regarding potential marketing approvals or labeling for remestemcel-L, or regarding potential future revenues from remestemcel-L; or regarding the worldwide license and collaboration agreement to develop, commercialize and manufacture remestemcel-L. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the transaction described in this press release will be completed in the expected time frame, or at all. Neither is there any guarantee that the expected benefits and synergies from such transaction will be achieved in the expected timeframe, or at all. Nor can there be any guarantee that remestemcel-L will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that remestemcel-L will be commercially successful in the future. In particular, our expectations regarding the transaction described in this press release and remestemcel-L could be affected by, among other things, the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and satisfaction of certain other closing conditions; the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 110,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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