Gamida Cell and Lonza Establish Commercial Manufacturing Agreement for Omidubicel

June 19, 2019

BASEL, Switzerland & BOSTON--(BUSINESS WIRE)--Jun. 19, 2019-- Gamida Cell Ltd. (Nasdaq: GMDA), a leading cellular and immune therapeutics company, and Lonza (SWX: LONN), an integrated healthcare solutions provider, today announced that the companies have entered into a strategic manufacturing agreement. The agreement provides for the future commercial production after potential FDA approval of omidubicel, Gamida Cell's investigational advanced cell therapy currently in clinical development designed to enhance the life-saving benefits of hematopoietic stem cell (bone marrow) transplant. An international, randomized Phase 3 study of omidubicel in patients with hematologic malignancies is currently ongoing, and omidubicel has not yet been approved for marketing in the United States or any other jurisdiction.

This agreement follows a successful multi-year clinical manufacturing relationship and provides Gamida Cell with a path to commercial supply of omidubicel. Under this multi-year agreement, Lonza will construct and dedicate production suites at its Geleen, NL site, for the anticipated commercial launch. Additionally, the agreement enables Gamida Cell to increase the number of dedicated production suites over time to ensure commercial supply. Gamida Cell also has the option of expanding further into Lonza's global cell and gene therapy manufacturing network.

"Gamida Cell and Lonza have had a strong relationship for the clinical supply of omidubicel, and we are pleased to extend our relationship as we prepare to potentially bring omidubicel to patients in a commercial setting after potential FDA approval," stated Julian Adams, chief executive officer of Gamida Cell. "The ability to reliably provide an advanced cellular therapy to patients is critical, and this agreement provides Gamida Cell with access to a top-tier manufacturing site for the long-term commercial supply of omidubicel after potential FDA approval. Additionally, this agreement enables the supply of commercial product as we plan for the build out of Gamida Cell's own commercial-scale cGMP manufacturing facility to augment production."

"This agreement is an example of our long-term manufacturing partnership capabilities and efforts to drive the industrialization of the cell therapy industry. Our cell therapy experience and expertise will enable us to best support Gamida Cell at this important phase in the development of omidubicel," said Alberto Santagostino, SVP, head of cell & gene technologies at Lonza. "We seek to partner with such innovative companies who are pioneering important new treatment options to patients and look forward to enabling Gamida Cell to deliver omidubicel at a commercial scale after potential FDA approval."

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 Gamida Cell

Gamida Cell is a clinical-stage biopharmaceutical company committed to developing advanced cell therapies with the potential to cure blood cancers and rare, serious hematologic diseases. We are leveraging our proprietary nicotinamide-based, or NAM-based, cell expansion technology to develop product candidates designed to address the limitations of cell therapies. For additional information, please visit www.gamida-cell.com.

About Omidubicel

Omidubicel (formerly known as NiCord®), the company's lead clinical program, is an advanced cell therapy under development as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant solution for patients with hematologic malignancies (blood cancers). Omidubicel is the first bone marrow transplant product to receive Breakthrough Therapy Designation from the U.S. Food and Drug Administration and has also received Orphan Drug Designation in the U.S. and EU. In a Phase 1/2 clinical study, omidubicel demonstrated rapid and durable time to engraftment and was generally well-tolerated.[1] A Phase 3 study evaluating omidubicel in patients with leukemia and lymphoma is ongoing in the U.S., Europe and Asia.[2] Omidubicel is also being evaluated in a Phase 1/2 clinical study in patients with severe aplastic anemia.[3] The aplastic anemia investigational new drug application is currently filed with the FDA under the brand name CordIn®, which is the same investigational development candidate as omidubicel. For more information on clinical trials of omidubicel, please visit www.clinicaltrials.gov.

Omidubicel is an investigational therapy, and its safety and efficacy has not been evaluated by the U.S. Food and Drug Administration or any other health authority.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including with respect to potential FDA approval of omidubicel and the commercial production thereof, which statements are subject to a number of risks,

uncertainties and assumptions, including, but not limited to the scope, progress, expansion and results of Gamida Cell's clinical trials, FDA review of the data generated thereby and Gamida Cell's ability to commercialize omidubicel following any potential FDA approval. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of Gamida Cell's public filing on Form 20-F, filed with the SEC on February 25, 2019, and other filings that Gamida Cell makes with the SEC from time to time (which are available at http://www.sec.gov), the events and circumstances discussed in such forward-looking statements may not occur, and Gamida Cell's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this press release and are based on information available to Gamida Cell as of the date of this release.

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[1] Horwitz M.E., Wease S., Blackwell B., Valcarcel D. et al. Phase I/II study of stem-cell transplantation using a single cord blood unit expanded ex vivo with nicotinamide. *J Clin Oncol.* 2019 Feb 10;37(5):367-374.

[2] ClinicalTrials.gov identifier NCT02730299.

[3] ClinicalTrials.gov identifier NCT03173937.

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Source: Gamida Cell Ltd.

Lonza:
Dirk Oehlers
Investor Relations Officer
Lonza Group Ltd
Tel +41 61 316 8540
dirk.oehlers@lonza.com

Dr. Sanna Fowler
Head of Public Relations
Lonza Pharma & Biotech
Tel +41 61 316 8929
sanna.fowler@lonza.com

Constance Ward
Head External Communications
Lonza Group Ltd
Tel +41 61 316 8840
constance.ward@lonza.com

Gamida Cell:
Jaren Irene Madden
jaren@gamida-cell.com
1-617-286-6264

Krystle Gibbs *(media)*
krystle@tenbridgecommunications.com
508-479-6358