First Patient Dosed with Cellectis’ New Allogeneic UCART123 Product Candidate for Relapsed/Refractory Acute Myeloid Leukemia

AMELI-01 Clinical Trial Uses New UCART123 Construct With Optimized Production Process & New IND Number

First Patient Dosed at MD Anderson Cancer Center

January 15, 2020 – New York (N.Y.) – Cellectis (Euronext Growth: ALCLS - Nasdaq: CLLS), a clinical-stage biopharmaceutical company focused on developing immunotherapies based on gene-edited allogeneic CAR T-cells (UCART), announced today the first patient dosing in AMELI-01, the Phase 1 dose escalation clinical trial evaluating a new UCART123 product candidate in relapsed/refractory acute myeloid leukemia (AML). This trial, sponsored by Cellectis, is part of an Investigational New Drug (IND) from the US Food and Drug Administration for a new UCART123 construct and an optimized production process, and will evaluate the safety, expansion, persistence and clinical activity of the product candidate in patients with relapsed/refractory AML. AMELI-01 replaces the first US clinical trial assessing the UCART123 product candidate.

“Cellectis invented and has pioneered the allogeneic approach for many years,” said Dr. André Choulika, Chairman and CEO, Cellectis. “Being a leader of the space, it’s important for us to consistently improve our technology and manufacturing expertise to remain at the forefront. With this new IND, we are delivering on our promise of continual innovation in order to advance the efforts of our clinical trials. We hope that with this optimized production process, our UCART123 product candidate will be well equipped to help people living with AML.”

This clinical trial is led by Gail J. Roboz, M.D., Professor of Medicine at Weill Cornell Medicine and New York-Presbyterian (New York, USA), in collaboration with Naveen Pemmaraju, M.D., Associate Professor, Department of Leukemia, Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center (Texas, USA), David Sallman, M.D., Assistant Member in the Malignant Hematology Department at H. Lee Moffitt Cancer Center (Florida, USA), and Daniel DeAngelo, M.D., Ph.D., Institute Physician and Director of Clinical and Translational Research of Adult Leukemia at Dana Farber Cancer Institute (Massachusetts, USA).

About UCART123
Our wholly controlled product candidate, UCART123, is a gene-edited T-cell investigational drug that targets CD123, an antigen expressed at the surface of leukemic cells in AML. In July 2019, the US Food and Drug Administration (FDA) accepted an Investigational New Drug (IND) for Cellectis to conduct a Phase 1 clinical trial with an optimized version of the UCART123 product candidate in patients living with AML. This IND includes a new UCART123 construct and an optimized production process, and replaces our previous IND on UCART123.
About Cellectis
Cellectis is developing the first of its kind allogeneic approach for CAR-T immunotherapies in oncology, pioneering the concept of off-the-shelf and ready-to-use gene-edited CAR T-cells to treat cancer patients. As a clinical-stage biopharmaceutical company with over 20 years of expertise in gene editing, Cellectis is developing life-changing product candidates utilizing TALEN®, its gene editing technology, and PulseAgile, its pioneering electroporation system to harness the power of the immune system in order to target and eradicate cancer cells.

As part of its commitment to a cure, Cellectis remains dedicated to its goal of providing life-saving UCART product candidates to address unmet needs for multiple cancers including acute myeloid leukemia (AML), B-cell acute lymphoblastic leukemia (B-ALL), multiple myeloma (MM), Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL).


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TALEN® is a registered trademark owned by Cellectis.

For further information, please contact:

Media contacts:
Jennifer Moore, VP of Communications, 917-580-1088, media@cellectis.com
Caitlin Kasunich, KCSA Strategic Communications, 212-896-1241, ckasunich@kcsa.com

IR contact:
Simon Harnest, VP of Corporate Strategy and Finance, 646-385-9008, simon.harnest@cellectis.com

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