



PRESS RELEASE

## **FDA Lifts Clinical Hold on MELANI-01 Study Evaluating Collectis' Product Candidate UCARTCS1 in Multiple Myeloma**

**November 17, 2020 – New York (N.Y.)** – [Collectis](#) (Euronext Growth: ALCLS - Nasdaq: CLLS), a biopharmaceutical company focused on developing immunotherapies based on gene-edited allogeneic CAR T-cells (UCART), today announced that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on the Phase 1 MELANI-01 trial evaluating the UCARTCS1 product candidate for the treatment of patients with relapsed or refractory multiple myeloma (MM).

Collectis worked closely with the FDA over the past months, to address the agency's requests, which include adjustments to the MELANI-01 clinical protocol designed to enhance patient safety.

Collectis continues to work with the clinical site staff and investigators to efficiently obtain the required local approvals to reopen the trial and resume patient enrollment.

"We remain confident in the potential clinical benefit of UCARTCS1 product candidate for patients with relapsed/refractory multiple myeloma, a widely unmet medical need that Collectis will continue to address. The safety of patients enrolled in our clinical trials remains our priority, and we are committed to resuming the clinical development of this promising program," said Carrie Brownstein, MD, Chief Medical Officer, Collectis.

Patient enrollment is ongoing in Collectis' two other proprietary Phase 1 dose escalation trials: AMELI-01 evaluating UCART123 in relapsed and refractory acute myeloid leukemia and BALLI-01 evaluating UCART22 in relapsed and refractory B-cell acute lymphoblastic leukemia.

### **About MELANI-01**

MELANI-01 is a Phase 1 open-label First-In-Human dose escalation clinical study evaluating UCARTCS1 product candidate for the treatment of patients with relapsed or refractory multiple myeloma (MM). UCARTCS1 is an allogeneic, off-the-shelf, gene-edited T-cell product candidate designed for the treatment of CS1/SLAMF7-expressing hematologic malignancies. CS1 (SLAMF7) is highly expressed on MM tumor cells. Learn more about the ongoing clinical trials at [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

### **About Multiple Myeloma (MM)**

Multiple myeloma is a cancer that affects a type of white blood cells called plasma cells that are specialized mature B-cells, which secrete antibodies to combat infections. Multiple

myeloma is characterized by the uncontrolled proliferation of neoplastic plasma cells in the bone marrow, where they overcrowd healthy blood cells. Although MM is a chronic disease and an exact cause has not yet been identified, researchers have made significant progress over the years in managing the disease through better understanding MM's pathophysiology. The progress in finding a cure needs to be continued as The American Cancer Society estimates that 32,270 new cases of MM will be diagnosed, and 12,830 deaths are expected to occur in 2020 in the U.S. alone.

### **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<sup>®</sup>, 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) and multiple myeloma (MM).

Cellectis headquarters are in Paris, France, with additional locations in New York, New York and Raleigh, North Carolina. Cellectis is listed on the Nasdaq Global Market (ticker: CLLS) and on Euronext Growth (ticker: ALCLS). For more information, visit [www.cellectis.com](http://www.cellectis.com).

Follow Cellectis on social media: [@cellectis](#), [LinkedIn](#) and [YouTube](#).

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### **Disclaimer**

This press release contains "forward-looking" statements within the meaning of applicable securities laws, including the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by words such as "could", "estimate", "expect", "intend", "is designed to", "may", "might", "potential", "promising", "remain confident", "should" and "will," or the negative of these and similar expressions. These forward-looking statements, which are based on our management's current expectations and assumptions and on information currently available to management, include statements

about the timing and progress of clinical trials (including with respect to patient enrolment and follow-up), and the timing of our presentation of data. These forward-looking statements are made in light of information currently available to us and are subject to numerous risks and uncertainties, including with respect to the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to the evolving situation. Furthermore, many other important factors, including those factors described in our Annual Report on Form 20-F and the financial report (including the management report) for the year ended December 31, 2019 and subsequent filings Collectis makes with the Securities Exchange Commission from time to time, as well as other known and unknown risks and uncertainties may adversely affect such forward-looking statements and cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

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