



PRESS RELEASE

Collectis Reports Clinical Hold Placed on MELANI-01 Study

July 6, 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 MELANI-01 trial has been placed on clinical hold by the U.S. Food and Drug Administration (FDA).

This clinical hold which impacts one of the three Collectis product candidates currently in clinical studies, was initiated following the submission of a safety report regarding one patient enrolled in the MELANI-01 study at dose level two (DL2), with relapsed and refractory multiple myeloma. This patient, who had been treated unsuccessfully, prior to enrollment with numerous lines of prior therapy, including autologous CAR T-cells, experienced a fatal treatment-emergent adverse event of cardiac arrest. Clinical evaluation of the case remains ongoing and additional details as to the immediate and underlying causes of this event are being collected.

Of note, prior to the clinical hold being issued by the FDA, Collectis had decided to expand enrollment at DL1, which may be the appropriate dose for further evaluation in the expansion portion of the trial and potentially the recommended Phase 2 dose based on an assessment of the preliminary clinical and translational data. The Company had begun executing updates to the clinical protocol to reflect this as well as to monitor and mitigate for additional potential risks given its novel mechanism of action.

“We share the FDA’s commitment to patient safety and are working collaboratively with the agency and the investigators to resolve this clinical hold,” said Carrie Brownstein, MD, Chief Medical Officer, Collectis. “The safety of patients enrolled in our clinical trials is our utmost priority and we at Collectis remain committed to safely resuming the clinical development of UCART product candidate targeting CS1 for patients with multiple myeloma and unmet medical need.”

Collectis is working closely with the FDA to address the agency’s requests including changes to the MELANI-01 clinical protocol designed to enhance patient safety, and expect to submit requested information including an amended protocol in due course.

Patient enrollment is ongoing in our 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 UCARTCS1A product candidate for the treatment of patients with relapsed or refractory multiple myeloma (MM). UCARTCS1A 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.

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 32,110 new cases of MM will be diagnosed, and 12,960 deaths are expected to occur in 2019 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[®], 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.

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

TALEN[®] is a registered trademark owned by Cellectis.

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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. These forward-looking statements include statements regarding Collectis’ responses to the FDA requests, the timing of clinical protocol amendments and the resolution of the FDA clinical hold. These forward-looking statements are based on management’s current expectations and assumptions and on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties and other factors (including, without limitation, the results of the ongoing clinical evaluation) that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Further information on the risk factors that may affect company business and financial performance is included in Collectis’ 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. 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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