



PRESS RELEASE

Approval of UCART123 Amendment in AML to Accelerate Clinical Development

Increase of current tested dose levels from 6.25×10^4 /kg to 2.5×10^5 /kg

Treatment interval shortens between patients from 42 days to 28 days, then to 14 days for subsequent patients

MD Anderson Cancer Center added as new clinical site for the AML study

May 22, 2018 – New York (N.Y.) – [Collectis](#) (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 approval of an amendment to the protocol for the Phase 1 clinical trial of Collectis' UCART123 product candidate in patients with acute myeloid leukemia (AML).

The main changes to the protocol include:

- Dose level 1 to be administered increases from 6.25×10^4 to 2.5×10^5 UCART123 cells per kilogram. Dose levels 2 and 3 are now respectively at 6.25×10^5 and 5.05×10^6 . Dose level -1 is now at 1.25×10^5 . The product's safety and tolerability profile allowed Collectis to increase dose levels with a capping at 80kg equivalent.
- The dose limiting toxicities (DLT) observation period decreases from 42 to 28 days post-UCART123 infusion, except for patients with aplastic bone marrow at Day 28 for whom the DLT observation period remains 42 days.
- The time interval between the first and the second patient for UCART123 infusion at each new dose level tested shortens from 42 days to 28 days (42 days in case of aplastic anemia) then to 14 days for subsequent patients.
- A potential second UCART123 infusion is implemented.

In addition, a new AML clinical center has been opened at MD Anderson Cancer Center in Houston, Texas, aiming at increasing the patient enrollment pace. The study is led by Prof. Hagop Kantarjian, MD, Department Chair, Department of Leukemia, Division of Cancer Medicine, and Dr. Naveen Pemmaraju, MD, Assistant Professor, being Principal Investigator.

"This amendment approval for Collectis' UCART123 protocol is an important step in the progression of our study, and opening another clinical site at MD Anderson – one of the world's most premier cancer centers – puts the Company on solid ground to help as many AML patients as possible with this innovative new therapy," said Prof. Stéphane Depil, Senior Vice President, R&D, and Chief Medical Officer at Collectis. "Off-the-shelf

gene editing immunotherapy is continuing to revolutionize the landscape of modern medicine, and we hope that this approach leads to a lifesaving treatment for AML patients in the near future.”

“As Collectis has been working very closely with the concerned parties to review the details of UCART123 study to date, we are eager to hit the ground running with the new protocol in an effort to find a truly effective treatment for AML patients with high unmet medical needs,” added Stéphan Reynier, Chief Regulatory and Compliance Officer at Collectis. “We look forward to obtaining additional data so that we can address such a rare and devastating disease.”

The FDA review period for this protocol amendment has passed and Collectis obtained IRB’s approval.

More information about this trial is available at [ClinicalTrials.gov](https://clinicaltrials.gov).

About UCART123 clinical trial

Our first 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. Collectis received in February 2017 an Investigational New Drug (IND) approval from the U.S. Food and Drug Administration (FDA) to conduct Phase 1 clinical trial with UCART123 in patients with AML. This marks the first allogeneic, “off-the-shelf” gene-edited CAR T-cell product candidate that the FDA has approved for clinical trial.

UCART123 clinical trial in AML is a Phase 1, open label dose-escalation and dose-expansion study to evaluate the safety, expansion, persistence and clinical activity of UCART123 (allogeneic engineered T-cells expressing anti-CD123 chimeric antigen receptor), administered in patients with relapsed/refractory AML, and patients with newly diagnosed high-risk AML.

The clinical research is coordinated by principal investigator Prof. Gail J. Roboz, MD, at Weill Cornell, Professor of Medicine at Weill Cornell Medicine and Director of the Clinical and Translational Leukemia Programs at Weill Cornell Medicine and NewYork-Presbyterian.

AML is a devastating clonal hematopoietic stem cell neoplasm that is characterized by uncontrolled proliferation and accumulation of leukemic blasts in bone marrow, peripheral blood and, occasionally, in other tissues. These cells disrupt normal hematopoiesis and rapidly cause bone marrow failure and death. In the U.S. alone, there are in 2017 an estimated 21,000 new AML cases per year, with 10,000 estimated deaths per year.¹

About Collectis

Collectis is a clinical-stage biopharmaceutical company focused on developing a new generation of cancer immunotherapies based on gene-edited T-cells (UCART). By capitalizing on its 18 years of expertise in gene editing – built on its flagship TALEN® technology and pioneering electroporation system PulseAgile – Collectis uses the power of the immune system to target and eradicate cancer cells.

Using its life-science-focused, pioneering genome engineering technologies, Collectis’ goal is to create innovative products in multiple fields and with various target markets.

¹ National Cancer Institute (NCI), <https://seer.cancer.gov>

Collectis is listed on the Nasdaq market (ticker: CLLS) and on Euronext Growth (ticker: ALCLS). To find out more about us, visit our website: www.collectis.com

Talking about gene editing? We do it. TALEN® is a registered trademark owned by Collectis.

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