



PRESS RELEASE

## **Collectis Reports Preliminary Results from its Phase 1 BALLI-01 Study of UCART22 in R/R Adult B-ALL at American Society of Hematology (ASH) Annual Meeting**

- Collectis' Proprietary Program UCART22 was Safely Administered in BALLI-01 Phase 1 Study with No Dose-Limiting Toxicity or Evidence of Graft-Vs-Host Disease
- 2 out of 3 Patients at DL1 Achieved CR/CRi and 1 out of 2 Patients at DL2 Achieved a Significant Reduction in Bone Marrow Blasts
- BALLI-01 Currently Enrolling at DL2 with Addition of Alemtuzumab to the FC Lymphodepletion Regimen; Next Data Update Expected in 2021

**December 5, 2020 – 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 preliminary results from Collectis' dose escalation Phase 1 BALLI-01 study of UCART22 product candidate in relapsed/refractory B-cell Acute Lymphoblastic Leukemia (B-ALL) were presented at the American Society of Hematology (ASH) Annual Meeting. This is the first publicly released data from Collectis' BALLI-01 clinical trial.

The BALLI-01 clinical trial presentation released at the ASH Annual Meeting is available on Collectis website: <https://bit.ly/CollectisASH2020>

"We are encouraged by the promising preliminary data obtained from the first two lower dose levels of UCART22 following a standard fludarabine and cyclophosphamide lymphodepletion regimen from the BALLI-01 trial. The anti-leukemia activity observed in these patients with B-ALL who had been previously heavily pre-treated speaks to the validity of CD22 as a target in the CAR T-cell space, and demonstrates the promise of allogeneic cellular therapies to leapfrog the autologous CAR-T products. We have now started enrolling cohorts that include alemtuzumab, an anti-CD52 monoclonal antibody, in the lymphodepletion regimen, as we anticipate this may extend the window of persistence of our TALEN<sup>®</sup> gene-edited allogeneic CAR T-cells," said Carrie Brownstein, MD, Chief Medical Officer, Collectis. "Based on the strong progress of our partnered- and proprietary product candidate portfolio, which was presented at ASH, we are looking forward to presenting additional clinical data in 2021."

## Characteristics

As of the November 2, 2020 data cutoff, 7 patients were enrolled and 5 patients received UCART22 cells. One patient failed screening and one patient was discontinued prior to the administration of UCART22 cells due to an adverse event related to the lymphodepletion.

## Safety

No patient experienced a DLT, ICANS, GvHD, AESI<sup>1</sup>, nor UCART22-related Grade  $\geq 3$  adverse event (AE) nor serious adverse event (SAE). No patient discontinued treatment due to a UCART22-related treatment-emergent adverse event.

## Anti-leukemic Activity

Two patients in Dose Level 1 achieved an objective response of complete remission with incomplete hematologic recovery (CRi) at Day 28, one of which attained a complete remission (CR) at Day 42 and received a transplant after subsequent therapy with inotuzumab. One patient in Dose Level 2 with refractory disease did achieve a noteworthy reduction in bone marrow blasts (60% at screening down to 13% at Day 28) after treatment with UCART22 product candidate and then progressed.

Host lymphocyte reconstitution was observed in all patients within the DLT period (range Day 9-Day 28). Correlative analysis of UCART cell expansion and persistence is ongoing.

UCART22 demonstrated preliminary signs of activity at low dose levels with fludarabine/cyclophosphamide (FC) lymphodepletion regimen, without unexpected nor significant treatment-related toxicities. Host immune recovery was observed early, supporting the addition of alemtuzumab to the FC lymphodepletion regimen which is expected to result in a deeper and more sustained T-cell depletion and thereby promote expansion and persistence of UCART22 cells. Enrollment into the Dose Level 2 cohorts with alemtuzumab is ongoing.

Treatment-emergent adverse events of interest with DL1 and DL2					
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
<b>Graft-versus-host disease (GvHD)</b>	0	0	0	0	0
<b>Cytokine release syndrome (CRS)</b>	2	1	0	0	0
<b>ICANS</b>	0	0	0	0	0
<b>SAEs<sup>2</sup></b>			3	1	1

<sup>1</sup> DLT: Dose Limiting Toxicity; GvHD: Graft versus Host Disease; AESI: adverse event of special interest; ICANS: immune effector cell-associated neurotoxicity syndrome; AE: Adverse Event; SAE: Serious Adverse Event

<sup>2</sup> SAEs that are not related to UCART22 cells

### **About UCART22**

UCART22 is one of Collectis' wholly owned, allogeneic, off-the-shelf gene-edited T-cell product candidates, designed for the treatment of relapsed and refractory B-cell acute lymphoblastic leukemia (R/R B-ALL). Like CD19, CD22 is a cell surface antigen expressed from the pre-B-cell stage of development through mature B-cells. CD22 expression occurs in more than 90% of patients with B-ALL.

### **About Collectis**

Collectis 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, Collectis 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, Collectis 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).

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

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

TALEN<sup>®</sup> is a registered trademark owned by Collectis.

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### **Disclaimer**

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the timing of our presentation of data, the adequacy of our supply of clinical vials, and the sufficiency of cash to fund operations. 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 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.