
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES
EXCHANGE ACT OF 1934**

Date of Report: June 9, 2023

Commission File Number: 001-36891

**Collectis S.A.
(Exact Name of registrant as specified in its charter)**

**8, rue de la Croix Jarry
75013 Paris, France
+33 1 81 69 16 00
(Address of principal executive office)**

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F Form 40-F

EXHIBIT INDEX

Exhibit Title

99.1 [Press Release dated June 9, 2023](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Collectis S.A.
(Registrant)

Date: June 9, 2023

/s/ André Choulika
André Choulika
Chief Executive Officer

Collectis Presents Updated Clinical and Translational Data on BALLI-01 at the European Hematology Association (EHA) 2023

NEW YORK, June 09, 2023 (GLOBE NEWSWIRE) -- Collectis (the “Company”) (Euronext Growth: ALCLS - NASDAQ: CLLS), a clinical-stage biotechnology company using its pioneering gene-editing platform to develop life-saving cell and gene therapies, presented today updated clinical and translational data on its clinical trial BALLI-01 (evaluating UCART22) at the European Hematology Association (EHA) 2023. The data presented support the preliminary safety and efficacy of UCART22 in a heavily pretreated relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-ALL) population.

“These clinical data are very positive for patients with r/r B-ALL who have failed multiple lines of treatment options including chemotherapy, CD19 directed CAR T-cell therapy and allogeneic stem cell transplant and encourage further enrollment into the BALLI-01 clinical study” said Nicolas Boissel, M.D., Ph.D., Head of Hematology Adolescent and Young Adult Unit at Hôpital Saint-Louis, Paris, France.

The poster presentation at EHA highlights the following data:

BALLI-01 is a Phase 1/2a open-label study, evaluating the safety and clinical activity of UCART22 in patients with relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B-ALL).

The poster presentation reviewed clinical and translational data from patients who received UCART22 after lymphodepletion (LD) with fludarabine and cyclophosphamide (FC) (F : 30 mg/m² × 3d, C : 1.0 g/m² × 3d) or fludarabine, cyclophosphamide and alemtuzumab (FCA) (F: 30 mg/m² × 3d, C : 0.5g/m² × 3d, A : 20 mg/d × 3d) in patients with r/r B-ALL.

Compared to the clinical update on BALLI-01 at ASH 2021, the poster presents data from six additional patients who received UCART22 at dose level 3 (DL3), 5 x 10⁶ cells/kg, as of the December 31, 2022 data cutoff.

Preliminary safety data

UCART22 administered after FC or FCA LD regimen was well tolerated. No dose limiting toxicities (DLTs) nor immune effector cell-associated neurotoxicity syndrome (ICANS) were observed; 61% of patients reported cytokine release syndrome (CRS) (Grade 1 [N=9] or Grade 2 [N=2]). One serious adverse event of special interest (AESI) of Grade 2 graft-versus-host disease (GvHD) (skin) was reported in the setting of reactivation of prior allogeneic hematopoietic stem cell transplantation (HSCT) donor stem cells. Serious adverse events (SAEs) (G≥3) reported in 72% of patients included infections (39%) and febrile neutropenia (28%), and all were not related to UCART22.

Preliminary efficacy data

Responses were assessed beginning on Day 28.

Up to FC/FCA-Intermediate Dose Level 2 (DL2i): 3 complete remissions with incomplete count recovery (CRi) and 1 morphologic leukemia-free state (MLFS) were observed and previously reported at the American Society of Hematology (ASH) 2021 conference.

For FCA-Dose Level 3 (DL3), 50% of the six patients responded:

- 1 patient who failed 4 prior lines, including multiagent chemotherapy, blinatumomab, inotuzumab, autologous CAR19, and allogeneic HSCT, achieved a minimal residual disease (MRD) negative complete response (CR) lasting over 90 days after UCART22 infusion as of the December 31, 2022 data cutoff.
- 1 patient who failed 4 prior lines, including multiagent chemotherapy, venetoclax, autologous CAR19, and allogeneic HSCT, achieved an MRD negative complete response with incomplete count recovery (CRi) consolidated with donor lymphocyte infusion (DLI) after Day 90 and remains in an MRD negative CRi past 7 months as of the December 31, 2022 data cutoff.
- 1 patient who failed 3 prior lines, including multiagent chemotherapy, venetoclax, autologous CAR19, and allogeneic HSCT, achieved an MRD negative MLFS up to Day 114.

Host lymphocytes remained suppressed (mean ALC <0.1 x10³ cells/mL) through Day 28 for all patients who received FCA LD. Peak ferritin levels correlated with UCART22 cell expansion and cytokine release syndrome (CRS). UCART22 continues to be safe and tolerable, with no treatment emergent serious adverse events (TEAEs) or DLTs reported. UCART22 cell expansion was detected in 9 of 13 patients in the FCA LD arm and associated with clinical activity.

Overall, these data support the preliminary safety and efficacy of UCART22 in this heavily pretreated r/r B-ALL population.

The BALLI-01 study is currently enrolling patients after FCA lymphodepletion. UCART22 is currently the most advanced allogeneic CAR T-cell product in development for r/r B-ALL. The next data set is expected to be released later this year.

About Collectis

Collectis is a clinical-stage biotechnology company using its pioneering gene-editing platform to develop life-saving cell and gene therapies. Collectis utilizes an 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, and a platform to make therapeutic gene editing in hemopoietic stem cells for various diseases. As a clinical-stage biopharmaceutical company with over 23 years of experience and expertise in gene editing, Collectis 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 treat diseases with unmet medical needs. Collectis' headquarters are in Paris, France, with 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).

Forward-looking Statements

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 “anticipate,” “believe,” “intend,” “expect,” “plan,” “scheduled,” “could” 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. Forward-looking statements include statements about the preliminary results for the BALLI-01 trial and the objectives of this trial, which remains ongoing; the ability to progress our clinical trial and to present any additional data from this trial; clinical outcomes from our trial, which may materially change as more patient data becomes available, potential benefits of our UCART product candidates, and our manufacturing capabilities. 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 numerous risks associated with biopharmaceutical product candidate development. With respect to our cash runway, our operating plans, including product development plans, may change as a result of various factors, including factors currently unknown to us. 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, 2022 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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Attachment

- EHA data PR (<https://ml.globenewswire.com/Resource/Download/3c49f687-816c-4f11-9b99-0d5a56c84bba>)