



PRESS RELEASE

Collectis Receives Orphan Drug Designation for UCART22, its Allogeneic CAR T Product for Patients with Acute Lymphoblastic Leukemia

New York, NY – June 4, 2024 – 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, announced today that the European Commission (EC) has granted an Orphan Drug Designation (ODD) to its product candidate UCART22, for the treatment of Acute Lymphoblastic Leukemia (ALL).

UCART22 is an allogeneic CAR T-cell product candidate targeting CD22 and evaluated in BALLI-01, a Phase 1/2 open-label dose-escalation and dose-expansion study, designed to evaluate the safety, expansion, persistence and clinical activity of UCART22 in patients with relapse/refractory ALL.

ALL represents 12% of all leukemia cases, progresses rapidly, and is typically fatal within weeks or months if left untreated¹. In 2024, the 10-year prevalence is estimated at 1.9 in 100,000 persons in the European Union (EU). Based on the preliminary clinical data generated with UCART22 in heavily pretreated patients who were relapsed or refractory to approved medicinal products, the European Medicines Agency (EMA) considered that the significant benefit of UCART22 has been demonstrated.

“Patients with relapsed/refractory ALL have limited, if any, treatment options, especially for those who have failed prior CD19 directed CAR T-cell therapy and allogeneic stem cell transplant” said Mark Frattini, M.D., Ph.D., Chief Medical Officer at Collectis. “The Orphan Drug Designation for UCART22 marks an important step towards developing allogeneic CAR T products that would be readily available for all patients.”

The last clinical data presented by Collectis at the American Society of Hematology in December 2023 were encouraging and suggested that UCART22-P2 (fully manufactured in-house) is more potent with a preliminary response rate of 67% at Dose Level 2, compared to a 50% response rate at Dose Level 3 with UCART22-P1 (manufactured by an external CDMO). Collectis expects to provide updates on the progress of BALLI-01 by year-end 2024.

The Orphan Drug Designation in the EU is granted by the EC based on a positive opinion issued by the EMA Committee for Orphan Medicinal Products. Medicines intended for the treatment, diagnosis or prevention of seriously debilitating or life-threatening conditions that affect fewer than five in 10,000 people in the EU are eligible for the designation. The Orphan Drug Designation allows companies certain regulatory, financial, and commercial incentives to develop medicines for rare diseases where there are no satisfactory treatment options.

¹ (Dong et al., 2020)

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 24 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 “expect,” “would,” and “suggest,” or the negative of these and similar expressions. These forward-looking statements are based on our management’s current expectations and assumptions and on information currently available to management. Forward-looking statements include statements about the advancement, timing and progress of clinical trials, the timing of our presentation of clinical data, and the potential of our candidate products programs. 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, including the risk of losing the orphan drug designation if it is established that the product no longer meets the orphan drug criteria before market authorization is granted (if any). 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, 2023 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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