



PRESS RELEASE

Collectis Receives FDA RMAT Designation for lasme-cel, the First Allogeneic CAR-T Therapy in a Pivotal Trial for Patients with r/r B-ALL

New York, NY – June 9, 2026 - 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, today announced that the U.S. Food and Drug Administration (FDA) granted Regenerative Medicine Advanced Therapy (RMAT) designation to lasmecabtagene timgedleucel (lasme-cel), its CD22-targeting allogeneic CAR-T cell therapy product candidate, for the treatment of patients with relapsed or refractory B-cell acute lymphoblastic leukemia (r/r B-ALL).

The granting of RMAT designation reflects the FDA's recognition of the potential for lasme-cel to address the unmet medical need faced by patients with r/r B-ALL.

The RMAT designation is supported by Phase 1 BALLI-01 data demonstrating promising efficacy and a manageable safety profile. Final Phase 1 data from the BALLI-01 trial of lasme-cel will be presented in an oral session at the 2026 Congress of the European Hematology Association (EHA) this Saturday, June 13 at 5:15 – 6:30pm CET by Nitin Jain, M.D., Professor of Medicine, Department of Leukemia at MD Anderson Cancer Center in Houston (TX).

“As the company that pioneered allogeneic CAR-T, we see the RMAT designation for lasme-cel as a meaningful recognition of the need for off-the-shelf CAR-T options for patients with relapsed or refractory B-ALL, patients who cannot wait. This designation strengthens our dialogue with the FDA as we advance lasme-cel through its pivotal program” said André Choulika, Ph.D., Co-founder and Chief Executive Officer of Collectis.

The BALLI-01 trial Pivotal Phase 2 is open for enrollment. Information on participant eligibility and participating clinical centers can be found on [clinicaltrials.gov: BALLI-01 \(NCT04150497\)](https://clinicaltrials.gov/ct2/show/study/NCT04150497).

About Collectis

Collectis is a clinical-stage biotechnology company using its pioneering gene-editing platform to develop life-saving cell and gene therapies. The company 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 develop gene therapies in other therapeutic indications. With its in-house manufacturing capabilities, Collectis is one of the few end-to-end gene editing companies that controls the cell and gene therapy value chain from start to finish. Collectis' headquarters are in Paris, France, with locations in New York and Raleigh, NC. Collectis is listed on the Nasdaq Global Market (ticker: CLLS) and on Euronext Growth (ticker: ALCLS). To find out more, visit www.collectis.com and follow Collectis on [LinkedIn](#) and [X](#).

Cautionary Statement

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 “potential,” or the negative of these and/or 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 potential of the pivotal Phase 2 BALLI-01 trial to be a registrational phase, the advancement, timing and progress of clinical trials (including with respect to patient enrollment and follow-up), the timing of our presentation of data and submission of regulatory filings, the sufficiency of cash to fund operations, the potential benefit of our product candidates. These forward-looking statements are made in light of information currently available to us and are subject to significant risks and uncertainties, including with respect to the numerous risks associated with biopharmaceutical product candidate development. Among these are significant risks that the BALLI-01 Phase 1 data may not be validated by data from later stage of clinical trials and that our product candidate may not receive regulatory approval for commercialization. Particular caution should be exercised when interpreting results from Phase 1 studies and results relating to a small number of patients – such results should not be viewed as predictive of future results. In addition, there are risks of losing the RMAT designation if it is established that the product no longer meets the criteria, and that this designation will not lead to a faster development or regulatory review or approval process. Furthermore, many other important factors, including those described in our Annual Report on Form 20-F as amended and in our annual financial report (including the management report) for the year ended December 31, 2025 and subsequent filings Collectis makes with the Securities Exchange Commission from time to time, which are available on the SEC’s website at www.sec.gov, 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.

For further information on Collectis, please contact:

Media contacts:

Pascalynne Wilson, Director, Communications, + 33 (0)7 76 99 14 33, media@collectis.com

Patricia Sosa Navarro, Chief of Staff to the CEO, +33 (0)7 76 77 46 93

Investor Relations contact:

Arthur Stril, Chief Financial Officer & Chief Business Officer, investors@collectis.com