



PRESS RELEASE

## **FDA Grants Orphan Drug Designation to Collectis' CLLS52 (alemtuzumab) For ALL Treatment**

**New York, NY – August 1, 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, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to Collectis' CLLS52 (alemtuzumab), an Investigational Medicinal Product (IMP) used as part of the lymphodepletion regimen associated with UCART22, evaluated in the BALLI-01 clinical trial in relapsed/refractory B-cell acute lymphoblastic leukemia (ALL).

“We are excited that the FDA granted CLLS52 (alemtuzumab) ODD designation status. The importance of adding alemtuzumab to the lymphodepletion regimen has been demonstrated in Collectis' BALLI-01 study, where the addition of this lymphodepletion agent to the fludarabine and cyclophosphamide regimen was associated with sustained lymphodepletion and significantly higher UCART22 cell expansion allowing for greater clinical activity”, said Mark Frattini, M.D., Ph.D. Chief Medical Officer at Collectis.

Collectis is the inventor of the combination of *CD52* knockout UCART cells with a lymphodepleting regimen containing an anti-*CD52* antibody such as alemtuzumab. The *CD52* knockout aims to render the UCART product candidates resistant to alemtuzumab as part of the lymphodepleting regimen. Collectis' UCART22 product candidate has the *CD52* gene inactivated by TALEN® gene editing technology.

The FDA grants ODD status to medicines intended for the treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the US. Receiving ODD may help to expedite and reduce the cost of development, approval, and commercialization of a therapeutic agent.

### **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 25 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 “may,” “aim,” and “intent,” 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 potential of CLLS52. 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). The priority review voucher may also not be granted at the time of marketing authorization. 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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