



## PRESS RELEASE

### **FDA Grants Collectis IND Approval for UCART22 in B-ALL**

#### *Collectis' 3<sup>rd</sup> TALEN®-based Gene-Edited Allogeneic CAR T-Cell Product Candidate Entering Clinical Development*

**June 4, 2018 – 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 today that the U.S. Food and Drug Administration (FDA) has approved the Company's Investigational New Drug (IND) application to initiate a Phase 1 clinical trial for UCART22, Collectis' second wholly controlled TALEN® gene-edited product candidate, for the treatment of B-cell acute lymphoblastic leukemia (B-ALL) in adult patients.

UCART22 is the 3<sup>rd</sup> allogeneic, off-the-shelf, gene-edited CAR T-cell product candidate approved by the FDA for clinical trials in the U.S., following UCART19 (exclusively licensed to Servier and under joint development agreement between Servier and Allogene), and Collectis' UCART123. Collectis intends to begin the UCART22 Phase 1 study in the second half of 2018. The research for UCART22 will be led by Dr. Nitin Jain, Assistant Professor, and Prof. Hagop Kantarjian, Chairman in the Department of Leukemia and University Chair in Cancer Medicine, at The University of Texas MD Anderson Cancer Center in Houston.

"The FDA's approval of Collectis' UCART22 IND application for the treatment of B-ALL puts us one step closer to providing patients in need with a better access to an effective drug candidate for such a rare, devastating disease," said Prof. Stéphane Depil, Senior Vice President, Research & Development, and Chief Medical Officer, Collectis. "With this opportunity, Collectis is well-positioned to further its work in the off-the-shelf gene-editing space, in the hope of helping patients to beat B-ALL in the near future."

"Given that Collectis is leading the allogeneic CAR-T approach across today's medical landscape – first, with the FDA's IND approval for UCART123 last year and now, with approval of UCART22 IND – we are eager to bring an innovative therapy to the market for patients who are suffering from B-ALL everywhere," added Stephan Reynier, Chief Regulatory and Compliance Officer, Collectis. "The bottom line is that patients are in dire need of effective, affordable and easily accessible treatments across the board, and our off-the-shelf product candidates aim to do just that."

#### **About UCART22**

UCART22 is an allogeneic, off-the-shelf gene-edited T-cell product candidate designed for the treatment of 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.<sup>1</sup>

UCART22 clinical trial is a Phase 1, open label dose-escalation and dose-expansion study to evaluate the safety, expansion, persistence and clinical activity of UCART22 (allogeneic engineered T-cells expressing anti-CD22 chimeric antigen receptor) in patients with relapsed or refractory CD22+ B-cell acute lymphoblastic leukemia (B-ALL). Dose level 1 to be administered is  $1 \times 10^5$  UCART22 cells per kilogram. Dose levels 2 and 3 are respectively at  $1 \times 10^6$  and  $5 \times 10^6$ .

ALL is a heterogeneous hematologic disease characterized by the proliferation of immature lymphoid cells in the bone marrow, peripheral blood, and other organs. It can start either with early B-cells or T-cells at different stages of maturity. The American Cancer Society's estimates for acute lymphocytic leukemia (ALL) in the United States for 2018 (including both children and adults) are about 5,960 new cases of ALL and about 1,470 deaths from ALL. Approximately 85% of ALL cases involve precursor B-cells (B-ALL).

The manufacturing process of Cellectis' allogeneic CAR T-cell product line, Universal CARTs or UCARTs, yields frozen, off-the-shelf, non-alloreactive engineered CAR T-cells. UCARTs are meant to be readily available CAR T-cells for a large patient population. Their production is industrialized with defined pharmaceutical release criteria.

Information about ongoing clinical trials is publicly available on dedicated websites, such as:

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) in the U.S.

[www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu) in Europe

### **About Cellectis**

Cellectis is a clinical-stage biopharmaceutical company focused on developing a new generation of cancer immunotherapies based on gene-edited T-cells (UCART). By capitalizing on its 18 years of expertise in gene editing – built on its flagship TALEN® technology and pioneering electroporation system PulseAgile – Cellectis uses the power of the immune system to target and eradicate cancer cells.

Using its life-science-focused, pioneering genome engineering technologies, Cellectis' goal is to create innovative products in multiple fields and with various target markets.

Cellectis is listed on the Nasdaq market (ticker: CLLS) and on Euronext Growth (ticker: ALCLS). To find out more about us, visit our website: [www.cellectis.com](http://www.cellectis.com)

Talking about gene editing? We do it. TALEN® is a registered trademark owned by Cellectis.

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<sup>1</sup> Shah et al., 2015

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**Disclaimer**

This press release contains “forward-looking” statements that are based on our management’s current expectations and assumptions and on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Further information on the risk factors that may affect company business and financial performance is included in Collectis’ Annual Report on Form 20-F and the financial report (including the management report) for the year ended December 31, 2017 and subsequent filings Collectis makes with the Securities Exchange Commission from time to time. 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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