



PRESS RELEASE

## **Collectis Announces Recombinant DNA Advisory Committee's (RAC) Unanimous Approval of UCART123 Phase 1 Study Protocols in AML and BPDCN**

**December 15, 2016** – New York (N.Y.) – Collectis (Alternext: ALCLS; Nasdaq: CLLS), a biopharmaceutical company focused on developing immunotherapies based on gene edited CAR T-cells (UCART), today announced the National Institute of Health's Recombinant DNA Advisory Committee (RAC)'s unanimous approval of two Phase 1 study protocols for Collectis' UCART123, the Company's most advanced, wholly owned TALEN<sup>®</sup> gene edited product candidate in patients with acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN).

Collectis will host a conference call in the next coming days. The details will be communicated shortly.

The RAC hearing was held on December 14, 2016 during a session dedicated to UCART projects and TALEN<sup>®</sup> based gene editing. This was the first time that allogeneic CAR T-cell programs gene edited with TALEN<sup>®</sup> technology were presented during a RAC hearing.

Collectis expects to file an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) by the end of 2016 and, pending FDA clearance, plans to initiate Phase 1 clinical trials in the first half of 2017. These programs will be the first therapeutic applications of a gene edited allogeneic "off-the-shelf" product candidate in the U.S.

UCART123 is a gene edited T-cell product candidate that targets CD123, an antigen that is located on CD123-expressing leukemic cells in AML, as well as in leukemic and other tumoral cells in BPDCN.

AML is a devastating clonal hematopoietic stem cell neoplasm that is characterized by uncontrolled proliferation and accumulation of leukemic blasts in bone marrow, peripheral blood and, occasionally, in other tissues. These cells disrupt normal hematopoiesis and rapidly cause bone marrow failure and death. In the U.S. alone, there are an estimated 19,950 new AML cases per year, with 10,430 estimated deaths per year.

The clinical research at Weill Cornell will be led by principal investigator Dr. Gail J. Roboz, Director of the Clinical and Translational Leukemia Programs and Professor of Medicine.

BPDCN is a very rare and aggressive hematological malignancy that is derived from plasmacytoid dendritic cell precursors. BPDCN is primarily a disease of bone marrow and blood cells but also often affects skin and lymph nodes.

The UCART123 clinical program at MD Anderson will be led by Professor Hagop Kantarjian, MD, Department Chair, Department of Leukemia, Division of Cancer Medicine and Professor Naveen Pemmaraju, MD, Assistant Professor.

Collectis' allogeneic CAR T-cell product line, Universal CARTs or UCARTs, yields frozen, off-the-shelf, engineered CAR T-cells. UCARTs are meant to be readily available CAR T-cells for a large patient population. Their production can be industrialized and standardized with defined pharmaceutical release criteria.

### **About RAC**

The Recombinant DNA Advisory Committee (RAC) is a federal advisory committee that provides recommendations to the NIH Director related to basic and clinical research involving recombinant or synthetic nucleic acid molecules. The NIH, through the RAC, reviews the most innovative clinical study protocols involving a gene therapy product.

### **About Collectis**

Collectis is a biopharmaceutical company focused on developing immunotherapies based on gene edited CAR T-cells (UCART). The company's mission is to develop a new generation of cancer therapies based on engineered T-cells. Collectis capitalizes on its 16 years of expertise in genome engineering - based on its flagship TALEN<sup>®</sup> products and meganucleases and pioneering electroporation PulseAgile technology - to create a new generation of immunotherapies. CAR technologies are designed to target surface antigens expressed on cells. Using its life-science-focused, pioneering genome-engineering technologies, Collectis' goal is to create innovative products in multiple fields and with various target markets. Collectis is listed on the Nasdaq market (ticker: CLLS) and on the NYSE Alternext market (ticker: ALCLS). To find out more about us, visit our website: [www.collectis.com](http://www.collectis.com)

Talking about gene editing? We do it. TALEN<sup>®</sup> is a registered trademark owned by the Collectis Group.

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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. The risks and uncertainties include, but are not limited to, the risk that the preliminary results from our product candidates will not continue or be repeated, the risk of not obtaining regulatory approval to commence clinical trials on the UCART product candidates, the risk that any one or more of our product candidates will not be successfully developed and commercialized. Further information on the risks factors that may affect company business and financial performance, is included in filings Collectis makes with the Security Exchange Commission from time to time and its financial reports. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons 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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