



PRESS RELEASE

## **Collectis Announces Successful cGMP Manufacturing for Second Product Candidate: UCART123**

**November 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 that a series of production runs of UCART123, a Company's wholly-owned TALEN<sup>®</sup> gene edited product candidate, was successfully performed in large scale, according to cGMP standards, for the purpose of conducting two Phase 1 clinical trials in patients with acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN).

The cGMP manufacturing of UCART123 clinical batches has been operated with CELLforCURE, a LFB group company and the largest industrial facility for clinical and commercial production of innovative cell and gene therapies in Europe. CELLforCURE is in charge of implementing cGMP manufacturing processes that are designed and developed by Collectis.

The manufacturing process for 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.

UCART123 is an engineered T-cell product candidate that targets CD123, an antigen that is located on CD123-expressing leukemic cells in AML as well as leukemic and other tumoral cells in BPDCN. We are planning to file an Investigational New Drug application (IND) with the United States Food and Drug Administration (FDA) in order to initiate clinical studies.

AML is a devastating clonal hematopoietic stem cell neoplasm characterized by uncontrolled proliferation and accumulation of leukemic blasts in the 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.

Preclinical and translational activities on UCART123 in AML are performed in collaboration with Dr. Monica Guzman, Associate Professor of Pharmacology in Medicine at Weill Cornell Medical College. 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 the bone marrow and blood cells, but also often affects skin and lymph nodes.

Collectis collaborates with the MD Anderson Cancer Center on the preclinical development of UCART123 in BPDCN preliminary to the Phase I clinical trial in BPDCN to be activated. The UCART123 clinical program at MD Anderson will be led by Professor Hagop Kantarjian, MD, Department Chair, Department of Leukemia, Division of Cancer Medicine.

“We are proud of achieving this important milestone for UCART123, our first wholly owned product candidate. The successful translation of an R&D concept into a cGMP clinical grade industrial product is one of the key gating factors for us to move into clinical trials,” said Arjan Roozen, Vice President, GMP Solutions and Manufacturing.

“With this work and Collectis’ breakthrough TALEN<sup>®</sup>-based gene editing technology, we continue building upon the Company’s milestones as a pioneer in the field, strengthening our pipeline and bringing us closer and closer to finding efficient and cost-effective products for cancer patients across the globe,” added David J.D. Sourdive, Executive Vice President, Corporate Development, Collectis.

#### **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.

#### **For further information, please contact:**

##### **Media contacts:**

Jennifer Moore, VP of Communications, 917-580-1088, [media@collectis.com](mailto:media@collectis.com)  
Caitlin Kasunich, KCSA Strategic Communications, 212-896-1241, [ckasunich@kcsa.com](mailto:ckasunich@kcsa.com)

##### **IR contact:**

Simon Harnest, VP of Corporate Strategy and Finance, 646-385-9008, [simon.harnest@collectis.com](mailto:simon.harnest@collectis.com)

#### **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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