#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

## FORM 6-K

Report of Foreign Private Issuer Pursuant to Rule 13a-16 or 15d-16 of the Securities Exchange Act of 1934

Date of Report: February 6, 2017 Commission File Number: 001-36891

# **Cellectis S.A.**

(Exact Name of registrant as specified in its charter)

8, rue de la Croix Jarry 75013 Paris, France +33 1 81 69 16 00 (Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F: Form 20-F 🗹 Form 40-F 🗌

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

## EXHIBIT INDEX

#### Exhibit <u>Title</u>

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99.1 Press release, dated February 6, 2017.

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

## CELLECTIS S.A.

(Registrant)

By: /s/ André Choulika

André Choulika Chief Executive Officer

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February 6, 2017

### FDA Grants Cellectis IND Approval to Proceed with the Clinical Development of UCART123, the First Gene Edited Offthe-Shelf CAR T-Cell Product Candidate developed in the U.S.

## Cellectis' UCART123 Product Candidate Targets AML and BPDCN

NEW YORK--(BUSINESS WIRE)--February 6, 2017--Regulatory News:

Cellectis (Paris:ALCLS) (NASDAQ:CLLS) (Alternext: ALCLS; Nasdaq: CLLS), a biopharmaceutical company focused on developing immunotherapies based on gene edited CAR T-cells (UCART), has received an Investigational New Drug (IND) approval from the U.S. Food and Drug Administration (FDA) to conduct Phase 1 clinical trials with UCART123, the Company's most advanced, wholly owned TALEN® gene-edited product candidate, in patients with acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN). This marks the first allogeneic, "off-the-shelf" gene-edited CAR T-cell product candidate that the FDA has approved for clinical trials. Cellectis intends to initiate Phase 1 trials in the first half of 2017.

UCART123 is a gene-edited T-cell investigational drug that targets CD123, an antigen expressed at the surface of leukemic cells in AML, tumoral cells in BPDCN. The clinical research for AML will be led, at Weill Cornell, by principal investigator Dr. Gail J. Roboz, Director of the Clinical and Translational Leukemia Programs and Professor of Medicine. The UCART123 clinical program for BPDCN will be led, at the MD Anderson Cancer Center, by Dr. Naveen Pemmaraju, MD, Assistant Professor, and Professor Hagop Kantarjian, MD, Department Chair, Department of Leukemia, Division of Cancer Medicine.

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.

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

"The FDA's approval of Cellectis' UCART123 – the first "off-the-shelf" CAR T-cell product candidate to enter clinical trials in the U.S. – is a major milestone not only for the Company but also for the medical community, global biotech and pharmaceutical industries at large," said Dr. Loan Hoang-Sayag, Cellectis Chief Medical Officer. "Cellectis' allogeneic UCART products have the potential to create an important shift with regard to availability, and cost-effectiveness, to make these therapies widely accessible to patient population across the world."

"After the National Institutes of Health's Recombinant DNA Advisory Committee (RAC)'s unanimous approval of two Phase 1 study protocols for Cellectis' UCART123 in December 2016, the FDA's approval of Cellectis' IND is a new major regulatory milestone achieved, for having UCART123 proceed into clinical development and reaching cancer patients in need," added Stephan Reynier, Chief Regulatory and Compliance Officer, Cellectis.

Information about ongoing clinical trials are publically available on dedicated websites such as: <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a> in the U.S. <a href="https://www.clinicaltrialsregister.eu">www.clinicaltrials.gov</a> in the U.S.

## **About Cellectis**

Cellectis 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. Cellectis capitalizes on its 17 years of expertise in genome engineering - based on its flagship TALEN® products and meganucleases as well as its 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, 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 the NYSE Alternext market (ticker: ALCLS). To find out more about us, visit our website: <u>www.cellectis.com</u>

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

## 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 Cellectis 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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