## 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: April 2, 2019 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 <u>(Address of principal executive office)</u>

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

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

r.

<u>99.1</u> <u>Press release, dated April 2, 2019</u>

#### 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.

April 2, 2019

CELLECTIS S.A.

(Registrant)

By: /s/ André Choulika

André Choulika Chief Executive Officer

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#### FDA Clears the IND for UCARTCS1, the First Allogeneic CAR-T to Treat Multiple Myeloma Patients

#### Successful manufacturing and release of GMP vials of UCARTCS1

#### NEW YORK--(BUSINESS WIRE)--April 2, 2019--Regulatory News:

Cellectis (Euronext Growth: ALCLS – Nasdaq: CLLS), a biopharmaceutical company focused on developing immunotherapies based on gene-edited 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 UCARTCS1, in patients with multiple myeloma (MM). The IND for UCARTCS1 was filed on December 28, 2018 and approved by the FDA within a month, on January 25, 2019. Cellectis is the sponsor of the UCARTCS1 clinical study (MUNDI-01) and successfully ensured the manufacturing and release of UCARTCS1 GMP batches, as well as an IRB approval.

UCARTCS1 is based on a tailored manufacturing process developed by Cellectis, which removes both the CS1 antigen and TCR from the T-cell surface using TALEN<sup>®</sup> gene editing technology, before adding the CS1 CAR construct. This approach has both clinical and operational benefits: the UCART is designed to have a lymphodepleting effect, and the CAR T-cell cross reaction is suppressed, allowing for successful manufacturing.

UCARTCS1 is the first allogeneic CAR-T therapy for MM to enter clinical development. This milestone reinforces Cellectis' leadership in the space, as it represents the fourth TALEN<sup>®</sup> gene-edited allogeneic CAR-T product candidate developed by Cellectis to be approved for clinical trials following UCART19<sup>1</sup> for ALL patients, UCART123 for AML patients and UCART22 for B-ALL patients. The Phase 1 of the MUNDI-01 study is designed to assess the safety and tolerability at increasing dose levels of UCARTCS1 in patients living with MM.

"The last quarters have been very productive for Cellectis' UCARTCS1 product candidate. We successfully manufactured and released GMP batches of UCARTCS1, filed an IND and secured approval from the FDA to start the MUNDI-01 Phase 1 clinical study," said Dr. André Choulika, Chairman and CEO of Cellectis. "This is the 4<sup>th</sup> time in 4 years that Cellectis demonstrates excellence with an allogeneic product candidate. It further demonstrates the strength of our innovation, our manufacturing process and our execution, as we are eager to bring the first allogeneic multiple myeloma CAR T-cell treatment to patients."

We anticipate the clinical research to be led by Dr. Krina Patel, Principal Investigator, Assistant Professor, Department of Lymphoma/Myeloma, Division of Cancer Medicine at the MD Anderson Cancer Center in Houston, Texas. We plan to have two additional sites enrolling patients for this clinical study: Weill Cornell Medicine under the leadership of Dr. Ruben Niesvizky, Director of the Multiple Myeloma Center at New York Presbyterian Hospital-Cornell Medical Center and Hackensack Meridian under the supervision of Dr. Andre Goy, Chairman and Director of John Theurer Cancer Center (JTCC) at Hackensack University Medical Center.

#### About UCARTCS1

UCARTCS1 is an allogeneic, off-the-shelf, gene-edited T-cell product candidate designed for the treatment of multiple myeloma (MM). CS1 (SLAMF7) is highly expressed on MM tumor cells and is an attractive target because there is strong evidence of tumor response to monoclonal antibody treatment targeting it. The limitation so far has been the presence of the CS1 target on the surface of T-cells, which has hindered the access to CAR-Ts and bispecific antibodies. As an example, the introduction of a CAR construct in T-cells induces cross T-cell reaction and leads to their self-destruction during manufacturing. Cellectis solved this issue by using TALEN<sup>®</sup> gene editing to knock-out the CS1 gene from T-cells before introducing the CS1 CAR construct.

The UCARTCS1 MUNDI-01 clinical trial is a Phase 1 dose-escalation and dose-expansion study to evaluate the safety, expansion, persistence and clinical activity of UCARTCS1 (allogeneic engineered T-cells) in patients with MM. Dose level 1 will be administered at  $1x10^6$  UCARTCS1 cells per kilogram, and dose levels 2 and 3 will be administered at  $3x10^6$  and  $9x10^6$ , respectively. The Dose Limiting Toxicity (DLT) period is 28 days in concordance with a 28-day staggering for the first 2 patients at each dose level.

MM is a cancer that forms in a type of white blood cell called a plasma cell, which helps the body to fight infections by making antibodies that recognize and attack germs. MM causes cancer cells to accumulate in bone marrow, where they crowd out healthy blood cells. The American Cancer Society estimates that 32,110 new cases of MM will be diagnosed and 12,960 deaths are expected to occur in the U.S. in 2019.

The manufacturing process of Cellectis' allogeneic CAR T-cell product line, Universal CARTs or UCARTs, yields frozen, off-theshelf, 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: <u>www.clinicaltrials.gov</u> (U.S.) and <u>www.clinicaltrialsregister.eu</u> (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 19 years of expertise in gene editing – built on its flagship TALEN<sup>®</sup> 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 (ticker: CLLS) and on Euronext Growth (ticker: ALCLS). To find out more about us, visit our website: <u>www.cellectis.com</u>

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

#### 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 Cellectis' Annual Report on Form 20-F and the financial report (including the management report) for the year ended December 31, 2018 and subsequent filings Cellectis 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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<sup>&</sup>lt;sup>1</sup> Developed by Cellectis, exclusively licensed to Servier and now under a joint development agreement between Servier and Allogene.