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 UNDER THE SECURITIES EXCHANGE ACT OF 1934

Date of Report: July 25, 2024

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 [X] Form 40-F [ ]

EXHIBIT INDEX

Exhibit	Title
99.1	Press release, dated July 25, 2024

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)

Date: July 25, 2024

/s/ André Choulika
André Choulika
Chief Executive Officer

FDA Grants Orphan Drug and Rare Pediatric Disease Designation Status to Cellectis' UCART22 product candidate for Acute Lymphoblastic Leukemia (ALL) Treatment

- *ALL represents 10% of all leukemia cases in the United States, progresses rapidly, and is typically fatal within weeks or months if left untreated*[1]
- *There is an urgent need to develop new therapies for ALL for patients who are not candidates for hematopoietic stem cell transplantation (HSCT) or relapse after*
- *FDA ODD and RPDD designations for UCART22 marks an important step towards developing allogeneic CAR T products that would be readily available for all patients*

NEW YORK, July 25, 2024 (GLOBE NEWSWIRE) -- Cellectis (the "Company") (Euronext Growth: ALCLS - NASDAQ: CLLS), a clinical-stage biotechnology company using its pioneering gene-editing platform to develop life-saving cell and gene therapies, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug (ODD) and Rare Pediatric Disease Designation (RPDD) Status to UCART22 product candidate for the treatment of Acute Lymphoblastic Leukemia (ALL).

ALL represents about 10% of all leukemia cases in the United States, progresses rapidly, and is typically fatal within weeks or months if left untreated. It is estimated that 6,660 new cases of ALL and 1,560 deaths related to the disease occurred in the US in 2022[2].

Mark Frattini, M.D., Ph.D., Chief Medical Officer at Cellectis said: "We are excited that the FDA granted UCART22 both ODD and RPDD Status in the treatment of acute lymphoblastic leukemia. This decision represents additional evidence of the potential of UCART22 to bring a much-needed therapeutic option to these patients with ALL. There is an urgent need to develop new therapies for ALL for patients who are not candidates for HSCT or relapse after CD19 directed CAR T-cell therapies and/or HSCT."

UCART22 is an allogeneic CAR T-cell product candidate targeting CD22 and evaluated in BALLI-01, a Phase 1/2 open-label dose-escalation and dose-expansion study, designed to evaluate the safety, expansion, persistence and clinical activity of UCART22 in patients with relapse/refractory ALL.

The last clinical data presented by Cellectis at the American Society of Hematology in December 2023 were encouraging and suggested that UCART22-P2 (fully manufactured at Cellectis) is more potent with a preliminary response rate of 67% at Dose Level 2, compared to a 50% response rate at Dose Level 3 with UCART22-P1 (manufactured by an external CDMO). Cellectis expects to provide updates on the progress of BALLI-01 by year-end 2024.

The FDA grants ODD status to medicines intended for the treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the US, an RPDD is granted for serious or life-threatening disease in which the serious or life-threatening manifestations, such as mortality with relapsed and/or refractory disease, primarily affect individuals aged from birth to 18 years. Receiving ODD may help to expedite and reduce the cost of development, approval, and commercialization of a therapeutic agent. Receiving RPDD may lead to receiving a rare pediatric disease priority review voucher at the time of marketing approval.

About Cellectis

Cellectis is a clinical-stage biotechnology company using its pioneering gene-editing platform to develop life-saving cell and gene therapies. Cellectis utilizes an allogeneic approach for CAR-T immunotherapies in oncology, pioneering the concept of off-the-shelf and ready-to-use gene-edited CAR T-cells to treat cancer patients, and a platform to make therapeutic gene editing in hemopoietic stem cells for various diseases. As a clinical-stage biopharmaceutical company with over 24 years of experience and expertise in gene editing, Cellectis is developing life-changing product candidates utilizing TALEN®, its gene editing technology, and PulseAgile, its pioneering electroporation system to harness the power of the immune system in order to treat diseases with unmet medical needs. Cellectis' headquarters are in Paris, France, with locations in New York, New York and Raleigh, North Carolina. Cellectis is listed on the Nasdaq Global Market (ticker: CLLS) and on Euronext Growth (ticker: ALCLS).

Forward-looking Statements

This press release contains "forward-looking" statements within the meaning of applicable securities laws, including the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by words such as "potential" "expect," "would," "may," and "suggest,", or the negative of these and similar expressions. These forward-looking statements are based on our management's current expectations and assumptions and on information currently available to management. Forward-looking statements include statements about the advancement, timing and progress of clinical trials, the timing of our presentation of clinical data, and the potential of our candidate products programs, the potential of UCART22 product candidate. These forward-looking statements are made in light of information currently available to us and are subject to numerous risks and uncertainties, including with respect to the numerous risks associated with biopharmaceutical product candidate development, including the

risk of losing the orphan drug designation if it is established that the product no longer meets the orphan drug criteria before market authorization is granted (if any).The priority review voucher may also not be granted at the time of marketing authorization. Furthermore, many other important factors, including those described in our Annual Report on Form 20-F and the financial report (including the management report) for the year ended December 31, 2023 and subsequent filings Cellectis makes with the Securities Exchange Commission from time to time, as well as other known and unknown risks and uncertainties may adversely affect such forward-looking statements and cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. 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.

For further information on Cellectis, please contact:

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[1] *(Sasaki et al., 2021)*
2 *(Siegel R.L. et al., 2022)*

Attachment

- PR_ODD UCART22_FDA (https://ml.globenewswire.com/Resource/Download/b5dc4187-05b0-405a-b04f-110bd2f92e69)