# 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: January 10, 2022

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): □ This report on Form 6-K (excluding Exhibit 99.1) shall be deemed to be incorporated by reference in the registration statements of Cellectis S.A. on Form F-3 (No. 333-238881) and Form S-8 (Nos. 333-204205, 333-214884, 333-222482 and 333-227717), to the extent not superseded by documents or reports subsequently filed.

#### Cellectis' Licensed Partner, Allogene Therapeutics, Announces Removal of FDA Clinical Hold on their Clinical Trials

On January 10, 2022 Cellectis S.A. ("Cellectis") reported that the U.S. Food and Drug Administration (FDA) has lifted the hold on the clinical trials of Cellectis' licensed partner Allogene Therapeutics, Inc. ("Allogene").

The FDA had placed a clinical hold on all five of Allogene's clinical trials on October 7, 2021 following a report of a chromosomal abnormality detected in ALLO-501A CAR+ T-cells from a single patient enrolled in Allogene's ALPHA2 study. Allogene reported today that the investigations concluded that the chromosomal abnormality was unrelated to TALEN® gene editing or Allogene's manufacturing process and had no clinical significance. The abnormality was not detected in any manufactured AlloCAR T<sup>™</sup> product or in any other patient treated with the same ALLO-501A lot. The abnormality occurred in the patient after the cell product was administered. It involved regions of the T cell receptor and immunoglobulin genes known to undergo rearrangement as part of the natural T cell or B cell maturation process.

A copy of the press release issued by Cellectis in connection with the above matters is filed herewith as Exhibit 99.1.

#### Forward-looking Statements

This report 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 "anticipate," "believe," "intend", "expect," "plan," "scheduled," "could" and "will," or the negative of these and similar expressions. These forward-looking statements, which are based on our management's current expectations and assumptions and on information currently available to management, including information provided by our licensed partner Allogene, include statements about Allogene's reinitiation of its clinical trials and its advancement to the Phase 2 portion of its ALPHA2 trial of ALLO-501A; the final results of the investigation relating to the FDA's clinical hold on Allogene's clinical trials, including the clinical significance of the chromosomal abnormality and any relationship to gene editing technology or manufacturing; as well as our research and development projects and priorities, our pre-clinical project development efforts and the timing of our presentation of data. 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 as well as the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to the evolving situation. With respect to our cash runway, our operating plans, including product development plans, may change as a result of various factors, including factors currently unknown to us. 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, 2020 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.

### EXHIBIT INDEX

Exhibit <u>Title</u>

99.1 <u>Press Release dated January 10, 2022</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.

CELLECTIS S.A.

(Registrant)

January 10, 2022 By: /s/ André Choulika

André Choulika Chief Executive Officer



#### PRESS RELEASE

#### Cellectis' Licensed Partner, Allogene Therapeutics, Announces Removal of FDA Clinical Hold on their Clinical Trials

- o Allogene reported that Chromosomal Abnormality Was Not the Result of TALEN® Gene Editing or Allogene's Manufacturing Process
- o Allogene to Initiate a Phase 2 Pivotal Clinical Trial of ALLO-501A in Relapsed/Refractory Large B-cell Lymphoma Mid-year 2022 Pending FDA Discussion

**January 10, 2022 – New York (N.Y.)** – <u>Cellectis</u> (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 stated that its licensed partner, Allogene Therapeutics, Inc. (Nasdad: ALLO) announced that the U.S. Food and Drug Administration (FDA) has lifted the hold on its clinical trials.

The FDA had placed a clinical hold on all five of Allogene's clinical trials on October 7, 2021 following a report of a chromosomal abnormality detected in ALLO-501A CAR+ T-cells from a single patient enrolled in Allogene's ALPHA2 study. Allogene reported today that the investigations concluded that the chromosomal abnormality was unrelated to TALEN® gene editing or Allogene's manufacturing process and had no clinical significance. The abnormality was not detected in any manufactured AlloCAR T™ product or in any other patient treated with the same ALLO-501A lot. The abnormality occurred in the patient after the cell product was administered. It involved regions of the T cell receptor and immunoglobulin genes known to undergo rearrangement as part of the natural T cell or B cell maturation process.

"We are very pleased that our licensed partner Allogene is now able to resume its clinical trials, bringing us one step closer to delivering these innovative therapies to patients with unmet medical needs", said Dr. André Choulika, CEO of Cellectis. "TALEN® gene editing technologies were not involved in the findings leading to the clinical hold. More than 170 patients with relapsed or refractory malignancies have been administered TALEN®-edited allogeneic CAR-T cell product candidates with a favorable safety profile, making it the largest and most robust disclosed clinical dataset of any gene editing technology in the world."

Allogene also announced that following the lift of the clinical holds and pending final discussions with the FDA, Allogene intends to initiate a Phase 2 pivotal trial of ALLO-501A in relapsed/refractory large B-cell lymphoma mid-year 2022.



Allogene's allogeneic CAR-T programs utilize Cellectis' technologies. ALLO-501 and ALLO-501A are anti-CD19 products being jointly developed under a collaboration agreement between Servier and Allogene based on an exclusive license granted by Cellectis to Servier. Servier grants to Allogene exclusive rights to ALLO-501 and ALLO-501A in the U.S. while Servier retains exclusive rights for all other countries.

Allogene has an exclusive license to Cellectis' technologies for ALLO-715, ALLO-605 (both directed at BCMA) and ALLO-316 (directed at CD70) and holds development and commercial rights for these investigational product candidates.

#### **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 22 years of 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.

As part of its commitment to a cure, Cellectis remains dedicated to its goal of providing lifesaving UCART product candidates for multiple cancers including acute myeloid leukemia (AML), B-cell acute lymphoblastic leukemia (B-ALL) and multiple myeloma (MM). .HEAL is a new platform focusing on hemopoietic stem cells to treat blood disorders, immunodeficiencies and lysosomal storage diseases.

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).

AlloCAR T<sup>™</sup> is a trademark of Allogene Therapeutics, Inc.

For more information, visit <u>www.cellectis.com</u> Follow Cellectis on social media: @cellectis, LinkedIn and YouTube.

#### For further information, please contact:

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#### 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 "anticipate," "believe," "intend", "expect," "plan," "scheduled," "could" and "will," or the negative of these and similar expressions. These forward-looking statements, which are based on our management's current expectations and assumptions and on information currently available to management, including information provided by our licensed partner Allogene, include statements about Allogene's reinitiation of its clinical trials and its advancement to the Phase 2 portion of its ALPHA2 trial of ALLO-501A; the final results of the investigation relating to the FDA's clinical hold on Allogene's clinical trials, including the clinical significance of the chromosomal abnormality and any relationship to gene editing technology or manufacturing; as well as our research and development projects and priorities, our pre-clinical project development efforts and the timing of our presentation of data. 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 as well as the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to the evolving situation. With respect to our cash runway, our operating plans, including product development plans, may change as a result of various factors, including factors currently unknown to us. 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, 2020 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.