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: October 8, 2021

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 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on Form F-3 (No. 333-238881) and Form S-8 (Nos. 333-204205, 333-214884, 333-222482 and 333-227717), to the extent not superseded by documents or reports subsequently filed.

Allogene clinical trial update

On October 7, 2021, Allogene Therapeutics, Inc. (“Allogene”) reported that, following a report of a chromosomal abnormality in ALLO-501A chimeric antigen receptor (“CAR”) T cells in a patient treated in its ALPHA2 study, the U.S. Food and Drug Administration (“FDA”) has placed a hold on Allogene’s clinical trials.

The clinical hold follows Allogene’s notification to the FDA of a chromosomal abnormality in an ALPHA2 study patient which was detected in a bone marrow biopsy undertaken to assess pancytopenia (low blood counts). Allogene reported that an investigation is underway to further characterize the observed abnormality, including any clinical relevance, evidence of clonal expansion or potential relationship to gene editing. Allogene reported that it expects to provide additional updates in the coming weeks following consultation with the FDA. The FDA continues to actively review the end of Phase 1 materials submitted by Allogene in anticipation for an ALLO-501A pivotal Phase 2 trial.

The single case involves a patient with Stage IV transformed follicular lymphoma and a type of genetic rearrangement, known as c-myc rearrangement, whose cancer was refractory to two prior lines of immune-chemotherapy and additional radiation therapy. The patient could not receive an autologous anti-CD19 CAR T cell therapy due to manufacturing failure associated with inadequate expansion of autologous CAR T cells.

Following infusion of ALLO-501A, the patient experienced Grade 1 cytokine release syndrome and Grade 2 immune effector cell-associated neurotoxicity syndrome, which required a course of high dose steroid therapy. The patient subsequently developed progressive pancytopenia and a bone marrow biopsy showed aplastic anemia and the presence of ALLO-501A CAR T cells with the chromosomal abnormality. Early translational data showed that the CAR T cells expanded, peaking on Day 28, and undergoing contraction thereafter. The patient had a partial response to ALLO-501A and subsequently underwent allogeneic stem cell transplantation. Prolonged cytopenia requiring rescue stem cell transplantation has been reported in autologous CAR T therapies.

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)

October 8, 2021

By: /s/ André Choulika
André Choulika
Chief Executive Officer