# 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

For the month of December 2019

Commission File Number: 001-38722

## **ORCHARD THERAPEUTICS PLC**

(Translation of registrant's name into English)

108 Cannon Street
London EC4N 6EU
United Kingdom
(Address of principal executive offices)

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): $\Box$	
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): □	

On December 2, 2019, Orchard Therapeutics plc issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Exhibit 99.1 to this Report on Form 6-K (the "Report") shall be deemed to be incorporated by reference into the registration statements on Form F-3 (File No. 333-234439) and Form S-8 (File No. 333-230432) of Orchard Therapeutics plc and to be a part thereof from the date on which this Report is filed, to the extent not superseded by documents or reports subsequently furnished.

### **EXHIBITS**

Exhibit	Description	
99.1	Press Release dated December 2, 2019	

#### **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.

#### ORCHARD THERAPEUTICS PLC

Date: December 2, 2019 By: /s/ Frank E. Thomas

Frank E. Thomas Chief Financial Officer





# Orchard Therapeutics Announces the Filing and Validation of Marketing Authorization Application by European Medicines Agency for OTL-200 for the Treatment of Metachromatic Leukodystrophy

#### **Application Being Evaluated Under Accelerated Assessment**

BOSTON and LONDON, Dec. 02, 2019 -- Orchard Therapeutics (Nasdaq: ORTX), a leading commercial-stage biopharmaceutical company dedicated to transforming the lives of patients with serious and life-threatening rare diseases through innovative gene therapies, today announced that the European Medicines Agency (EMA) has validated the company's Marketing Authorization Application (MAA) for OTL-200, an ex vivo, autologous, hematopoietic stem cell-based gene therapy that has been developed in partnership with the San Raffaele-Telethon Institute for Gene Therapy (SR-Tiget) in Milan, Italy, for the treatment of metachromatic leukodystrophy (MLD). Validation of the MAA confirms that the submission is sufficiently complete to begin the formal review process.

"We are pleased that OTL-200 for the treatment of MLD is now under review with the EMA, bringing us another step closer to potentially making an approved gene therapy treatment a reality for children and families affected by this devastating and rapidly progressing disease," said Mark Rothera, president and chief executive officer of Orchard Therapeutics. "We are committed to working with the EMA as they evaluate our application. Due to the nature of the disease and the urgency to treat those affected by MLD, we have also been working diligently in parallel to make OTL-200, if approved, available to patients in the EU as quickly as possible, while continuing our efforts to expand patient access outside the EU."

Orchard previously announced in November 2019 that the EMA had granted accelerated assessment for OTL-200. Accelerated assessment potentially provides a reduced review timeline from 210 to 150 days once the MAA is filed and validated, not counting clock stops when applicants are requested to provide additional information.

#### **About MLD and OTL-200**

Metachromatic leukodystrophy (MLD) is a rare and life-threatening inherited disease of the body's metabolic system occurring in approximately one in every 100,000 live births. MLD is caused by a mutation in the arylsulfatase-A (ARSA) gene that results in the accumulation of sulfatides in the brain and other areas of the body, including the liver, the gallbladder, kidneys, and/or spleen. Over time, the nervous system is damaged and patients with MLD will experience neurological problems such as motor, behavioral and cognitive regression, severe spasticity and seizures, finding it more and more difficult to move, talk, swallow, eat and see. Currently, there are no effective treatments for MLD. In its late infantile form, mortality at 5 years from onset is estimated at 50% and 44% at 10 years for juvenile patients.1 OTL-200 is an ex vivo, autologous, hematopoietic stem cell-based gene therapy being studied for the treatment of MLD. OTL-200 was acquired from GSK in April 2018 and originated from a pioneering collaboration between GSK and the Hospital San Raffaele and Fondazione Telethon, acting through their joint San Raffaele-Telethon Institute for Gene Therapy in Milan, initiated in 2010.

#### **About Orchard**

Orchard Therapeutics is a fully integrated commercial-stage biopharmaceutical company dedicated to transforming the lives of patients with serious and life-threatening rare diseases through innovative gene therapies.

Orchard's portfolio of ex vivo, autologous, hematopoietic stem cell (HSC) based gene therapies includes Strimvelis®, a gammaretroviral vector-based gene therapy and the first such treatment approved by the European Medicines Agency for severe combined immune deficiency due to adenosine deaminase deficiency (ADA-SCID). Additional programs for neurometabolic disorders, primary immune deficiencies and hemoglobinopathies are all based on lentiviral vector-based gene modification of autologous HSCs and include three advanced registrational studies for metachromatic leukodystrophy (MLD), ADA-SCID and Wiskott-Aldrich syndrome (WAS), clinical programs for X-linked chronic granulomatous disease (X-CGD), transfusion-dependent beta-thalassemia (TDT) and

mucopolysaccharidosis type I (MPS-I), as well as an extensive preclinical pipeline. Strimvelis, as well as the programs in MLD, WAS and TDT were acquired by Orchard from GSK in April 2018 and originated from a pioneering collaboration between GSK and the San Raffaele Telethon Institute for Gene Therapy in Milan, Italy initiated in 2010.

Orchard currently has offices in the U.K. and the U.S., including London, San Francisco and Boston.

#### Forward-Looking Statements

This press release contains certain forward-looking statements about Orchard's strategy, future plans and prospects, which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may be identified by words such as "anticipates," "believes," "expects," "intends," "projects," and "future" or similar expressions that are intended to identify forwardlooking statements. Forward-looking statements include express or implied statements relating to, among other things, Orchard's expectations regarding the timing of regulatory submissions for approval of its product candidates, including the product candidate or candidates referred to in this release, the timing of interactions with regulators and regulatory submissions related to ongoing and new clinical trials for its product candidates, including the product candidate or candidates referred to in this release, the timing of announcement of clinical data for its product candidates, including the product candidate or candidates referred to in this release, and the likelihood that such data will be positive and support further clinical development and regulatory approval of its product candidates, and the likelihood of approval of such product candidates by the applicable regulatory authorities. These statements are neither promises nor guarantees and are subject to a variety of risks and uncertainties, many of which are beyond Orchard's control, which could cause actual results to differ materially from those contemplated in these forward-looking statements. In particular, the risks and uncertainties include, without limitation; delay of any of Orchard's regulatory submissions, the failure to obtain marketing approval from the applicable regulatory authorities for any of Orchard's product candidates, including the product candidate or candidates referred to in this release, the receipt of restricted marketing approvals, or delays in Orchard's ability to commercialize its product candidates, if approved. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements.

Other risks and uncertainties faced by Orchard include those identified under the heading "Risk Factors" in Orchard's annual report on Form 20-F for the year ended December 31, 2018 as filed with the U.S. Securities and Exchange Commission (SEC) on March 22, 2019, as well as subsequent filings and reports filed with the SEC. The forward-looking statements contained in this press release reflect Orchard's views as of the date hereof, and Orchard does not assume and specifically disclaims any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

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1 Mahmood et al. Metachromatic Leukodystrophy: A Case of Triplets with the Late Infantile Variant and a Systematic Review of the Literature. Journal of Child Neurology 2010, DOI: http://doi.org/10.1177/0883073809341669