



Orchard Therapeutics and MolMed Announce Extension of Gene Therapy Manufacturing Collaboration

July 9, 2020

BOSTON and LONDON and MILAN, Italy, July 09, 2020 (GLOBE NEWSWIRE) -- Orchard Therapeutics (Nasdaq: ORTX), a global gene therapy leader, and MolMed S.p.A (MLMD.MI), one of the company's principal contract development and manufacturing partners, today announced that they have extended their collaboration – [initiated in April 2018](#) – for a period of five years through June 2025.

With the extension of the collaboration, MolMed will continue to support activities related to the development and manufacturing of vectors and drug products for several of Orchard's investigational *ex vivo* hematopoietic stem cell (HSC) gene therapies in the upcoming years, including OTL-200 for metachromatic leukodystrophy (MLD) and OTL-103 for Wiskott Aldrich syndrome (WAS), as well as for additional pipeline programs including OTL-203 for mucopolysaccharidosis type I (MPS-I). MolMed is the first company to have obtained good manufacturing practice (GMP) authorization for the gene and cell therapy markets in Europe and is the manufacturer for Strimvelis[®], Orchard's *ex vivo* HSC gene therapy for severe combined immunodeficiency due to adenosine deaminase deficiency (ADA-SCID) and the first such treatment approved by the European Medicines Agency (EMA).

"We are looking forward to continuing to build and expand upon our partnership with MolMed, who have supported the progression of many of our programs since their earliest clinical development stages," said Frank Thomas, president and chief operating officer of Orchard. "Their expertise in gene therapy manufacturing, coupled with their deep knowledge of our programs, will be invaluable as our therapies for MLD and WAS approach anticipated approval and commercialization in Europe and across the globe."

Luca Alberici, MolMed's chief business officer, added, "We are pleased to have strengthened our collaboration with Orchard to support them in their mission of bringing potentially transformative therapies to those suffering from severe rare diseases. After being Orchard's exclusive manufacturer for Strimvelis, we are looking forward to supporting their manufacturing needs for additional programs both in clinical trials and in potential commercial applications following the anticipated approval of OTL-200 for MLD in Europe later this year."

OTL-200 for MLD is currently under review by the EMA with a decision expected later this year.

About Orchard

Orchard Therapeutics is a global gene therapy leader dedicated to transforming the lives of people affected by rare diseases through the development of innovative, potentially curative gene therapies. Our *ex vivo* autologous gene therapy approach harnesses the power of genetically modified blood stem cells and seeks to correct the underlying cause of disease in a single administration. In 2018, Orchard acquired GSK's rare disease gene therapy portfolio, which originated from a pioneering collaboration between GSK and the San Raffaele Telethon Institute for Gene Therapy in Milan, Italy. Orchard now has one of the deepest and most advanced gene therapy product candidate pipelines in the industry spanning multiple therapeutic areas where the disease burden on children, families and caregivers is immense and current treatment options are limited or do not exist.

Orchard has its global headquarters in London and U.S. headquarters in Boston. For more information, please visit www.orchard-tx.com, and follow us on [Twitter](#) and [LinkedIn](#).

About MolMed

MolMed S.p.A. is a biotechnology company focused on research, development, manufacturing and clinical validation of novel cell and gene therapies. MolMed, established in 1996, has been listed since March 2008 on the Italian Stock Exchange managed by Borsa Italiana, and has its registered office in Milan, at the Biotechnology Department of Ospedale San Raffaele and an operating site at Bresso, at the OpenZone campus.

Availability of Other Information About Orchard

Investors and others should note that Orchard communicates with its investors and the public using the company website (www.orchard-tx.com), the investor relations website (ir.orchard-tx.com), and on social media ([Twitter](#) and [LinkedIn](#)), including but not limited to investor presentations and investor fact sheets, U.S. Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that Orchard posts on these channels and websites could be deemed to be material information. As a result, Orchard encourages investors, the media, and others interested in Orchard to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on Orchard's investor relations website and may include additional social media channels. The contents of Orchard's website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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. Forward-looking statements include express or implied statements relating to, among other things, Orchard's business strategy and goals, the therapeutic potential of Orchard's product candidates, including the product candidate or candidates referred to in this release, Orchard's expectations regarding the timing of regulatory submissions for or marketing approval of its product candidates, and Orchard's expectations concerning its partnership with MolMed. 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, these risks and uncertainties include, without limitation: the severity of the impact of the COVID-19 pandemic on Orchard's business, including on clinical development and commercial programs; the risk that any one or more of Orchard's product candidates, including the product candidate or candidates referred to in this release, will not be approved, successfully developed or commercialized; the risk of cessation or delay of any of Orchard's ongoing or planned clinical trials; the risk that Orchard may not successfully

recruit or enroll a sufficient number of patients for its clinical trials; the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical studies or clinical trials will not be replicated or will not continue in ongoing or future studies or trials involving Orchard's product candidates; the 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 or the receipt of restricted marketing approvals; the risk of delays in Orchard's ability to commercialize its product candidates, if approved; and the risk that Orchard may not receive the expected benefits from its collaboration with MolMed or that Orchard or MolMed will not fully perform under the terms of their collaboration agreement. 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 quarterly report on Form 10-Q for the quarter ended March 31, 2020, as filed with the U.S. Securities and Exchange Commission (SEC) on May 7, 2020, 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.

Orchard Contacts

Investors

Renee Leck
Director, Investor Relations
+1 862-242-0764
Renee.Leck@orchard-tx.com

Media

Molly Cameron
Manager, Corporate Communications
+1 978-339-3378
media@orchard-tx.com

MolMed Contacts

Investor Relations & Communications Department

MolMed S.p.A.
+39 02 21277.205
investor.relations@molmed.com

Tommasina Cazzato

Press Office
Community Group
+39 345 7357751
tommasina.cazzato@communitygroup.it



Source: Orchard Therapeutics (Europe) Limited