



Kyowa Kirin to Acquire Orchard Therapeutics

October 5, 2023

*-Orchard Therapeutics is a global gene therapy leader with experience successfully developing and commercializing medicines for rare diseases-
-Acquisition enriches Kyowa Kirin's portfolio, enables the development of numerous promising candidates with a clinically differentiated platform, and helps resource the ongoing and future launches of Libmeldy® (atidarsagene autotemcel)-
-Acquisition price of \$16.00 per ADS in cash plus an additional contingent value right of \$1.00 per ADS, representing a total maximum equity value of approximately \$477.6 million-
-Kyowa Kirin to host investor conference call on Oct 5 at 18:30 p.m. JST-*

TOKYO and LONDON and BOSTON, Oct. 05, 2023 (GLOBE NEWSWIRE) -- Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE: 4151), a Japan-based global specialty pharmaceutical company (J-GSP) creating innovative medical solutions utilizing the latest biotechnology, and Orchard Therapeutics plc (Orchard Therapeutics, Nasdaq: ORTX), a global gene therapy leader, today announced the companies have entered into a definitive agreement under which Kyowa Kirin will acquire Orchard Therapeutics for \$16.00 per American Depositary Share (ADS) in cash (approximately \$387.4 million, or ¥57.3 billion), under which Orchard shareholders will hold an additional contingent value right (CVR) of \$1.00 per ADS. An additional \$1.00 CVR will be paid for a total of \$17.00 per ADS, or approximately \$477.6 million (¥70.7 billion) if the conditions are met.

Kyowa Kirin has established a 2030 Vision to consistently create and deliver medicines with life-changing value that ultimately makes people smile, as a J-GSP. At the core of this strategy is a commitment to life, and a desire to match transformative science to areas of great unmet need. Kyowa Kirin believes the potential of cell and gene therapies to help patients aligns well with its Vision, patient commitment, and emerging expertise in commercializing rare disease medicines worldwide.

The gene therapy approach pioneered by Orchard Therapeutics harnesses the unique power of a patient's own genetically modified hematopoietic stem cells (HSCs) to potentially correct the underlying cause of a genetic disease using a single administration. Upon closing, the acquisition would provide Kyowa Kirin with a global leadership position in the burgeoning field of genetic medicine, including a portfolio spanning commercial, clinical, and pre-clinical HSC gene therapies designed to address serious diseases where the burden is immense for patients, families and society and current treatment options are limited or do not exist.

Orchard Therapeutics' portfolio comprises Libmeldy® (atidarsagene autotemcel), also known as OTL-200, intended for eligible patients with early-onset metachromatic leukodystrophy (MLD), a rare and life-threatening inherited disease of the body's metabolic system. In the most severe form of MLD, babies develop normally but in late infancy start to rapidly lose the ability to walk, talk and interact with the world around them. Libmeldy is approved by the European Commission (EC) and UK Medicines and Healthcare products Regulatory Agency (MHRA) for the treatment of "late infantile" and "early juvenile" MLD patients. It is currently an investigational drug under Priority Review by the Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) goal date of March 18, 2024.

Using the same HSC gene therapy technology platform, Orchard Therapeutics is progressing two clinical-stage programs known as OTL-203 and OTL-201 for the treatment of another group of severe pediatric neurometabolic disorders, mucopolysaccharidosis type I Hurler's syndrome (MPS-IH) and mucopolysaccharidosis type IIIA (MPS-IIIA), also known as Sanfilippo syndrome, respectively.

This acquisition will allow Kyowa Kirin to maximize the value of Libmeldy® and efficiently accelerate the development of Orchard Therapeutics' next-in-line MPS programs, as well as its other early research programs, including a severe, genetic form of Crohn's disease and frontotemporal dementia (FTD). Furthermore, the combination of Orchard Therapeutics' innovative HSC gene therapy platform technology and Kyowa Kirin's capabilities, resources and infrastructure will enable the continued development of numerous promising biopharmaceutical candidates with the potential to deliver life-changing value in medical care, including in therapeutic areas and indications where Kyowa Kirin has deep experience, such as oncology and autoimmune diseases.

"We are excited to announce that we have signed the Transaction Agreement to acquire Orchard Therapeutics, one of the leading providers of HSC gene therapy," said Takeyoshi Yamashita, Ph.D., Director of the Board, chief medical officer, senior managing executive officer of Kyowa Kirin. "With this transaction, we anticipate being able to use a new modality that can have a profound impact on patients' lives. Orchard Therapeutics is a company with a steady track record in this field and has already launched its HSC gene therapy in Europe and filed for review in the U.S. Our hope is to combine the strengths of Kyowa Kirin and Orchard Therapeutics with mutual respect to realize the successful creation and delivery of life-changing value for patients living with rare and life-threatening inherited diseases."

"This is an exciting opportunity designed to accelerate the realization of our shared vision of ending the devastation caused by severe genetic diseases and deliver life-changing value in medical care," said Bobby Gaspar, co-founder and chief executive officer of Orchard Therapeutics. "We remain as true to our mission as ever, and joining Kyowa Kirin's global network ensures we are well-resourced to progress anticipated commercialization of OTL-200 in the U.S., if approved, continue investing in initiatives aimed at accelerating Libmeldy growth in Europe, capitalize on opportunities for global expansion, as well as advance our next-in-line neurometabolic programs in MPS disorders and earlier-stage research programs. We look forward to collaborating with our new colleagues at Kyowa Kirin to fully unlock the curative potential of HSC gene therapy for the benefit of patients and society."

Kyowa Kirin will hold a conference for investors on October 5 at 18:30 p.m. JST.

Outline of the transaction

Under the terms of the agreement, Kyowa Kirin will initiate a scheme of arrangement to acquire all Orchard Therapeutics' ADSs at a price of \$16.00

per ADS in cash (or aggregated value of approximately \$387.4 million, or approximately ¥57.3 billion) at closing, which represents a premium of 144% to Orchard Therapeutics' volume-weighted average price per ADS over the previous 30 days ended October 4.

In connection with the transaction, a non-transferable CVR will be distributed to Orchard Therapeutics shareholders. Holders of the CVR will be entitled to receive a cash payment of \$1.00 per ADS related to the approval of OTL-200 for the treatment of MLD in the U.S. as defined in the CVR Agreement.

Warrants outstanding as of the date of the Transaction Agreement will continue to be satisfied in accordance with their terms.

The transaction has been unanimously approved by both company's Board of Directors and is expected to close in the first quarter of 2024 subject to Orchard Therapeutics' shareholder approval, receipt of applicable regulatory approvals and other customary closing conditions.

Following the completion of the acquisition, Orchard Therapeutics will become a wholly-owned subsidiary of Kyowa Kirin.

Kyowa Kirin is represented by Goldman Sachs Japan Co., Ltd. as financial advisor and Morrison & Foerster LLP. as legal advisor. Orchard Therapeutics is represented by Guggenheim Securities, LLC as financial advisor, Goodwin Procter LLP as U.S. legal advisor, and Slaughter & May Ltd. as UK legal advisor.

Overview of Orchard Therapeutics

(1) Name	Orchard Therapeutics plc	
(2) Location	245 Hammersmith Road, 3rd Floor London W6 8PW United Kingdom	
(3) Job title and name of representative	Chief Executive Officer Bobby Gaspar	
(4) Description of business	Development and commercialization of hematopoietic stem cell gene therapy	
(5) Share capital	\$29,456 thousand (as of June 30, 2023)	
(6) Date of establishment	2015	
(7) Major shareholders and ownership ratios	RA Capital Management, LP (25.7%) Deep Track Capital LP (9.0%) Zentree Investment Management Pte Ltd (8.3%) (as of June 30, 2023)	
(8) Relationship between Kyowa Kirin and Orchard	Capital relationship	None
	Personnel relationship	None
	Business relationship	None
	Related Party Status	None

About Kyowa Kirin

Kyowa Kirin strives to create and deliver novel medicines with life-changing value. As a Japan-based Global Specialty Pharmaceutical Company with a heritage of 70+ years, we apply cutting-edge science including an expertise in antibody research and engineering, to address the needs of patients and society across multiple therapeutic areas including Nephrology, Oncology, Immunology/Allergy and Neurology. Across our four regions – Japan, Asia Pacific, North America and EMEA/International – we focus on our purpose, to make people smile, and are united by our shared values of commitment to life, teamwork/Wa, innovation, and integrity. You can learn more about the business of Kyowa Kirin at: <https://www.kyowakirin.com>.

About Orchard Therapeutics

At Orchard Therapeutics, our vision is to end the devastation caused by genetic and other severe diseases. We aim to do this by discovering, developing and commercializing new treatments that tap into the curative potential of hematopoietic stem cell (HSC) gene therapy. In this approach, a patient's own blood stem cells are genetically modified outside of the body and then reinserted, with the goal of correcting the underlying cause of disease in a single treatment.

In 2018, the company 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. Today, Orchard is advancing a pipeline spanning pre-clinical, clinical and commercial stage HSC gene therapies designed to address serious diseases where the burden is immense for patients, families and society 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 [X \(Twitter\)](#) and [LinkedIn](#).

About Libmeldy / OTL-200

Libmeldy® (atidarsagene autotemcel), also known as OTL-200, has been approved by the European Commission for the treatment of metachromatic leukodystrophy (MLD) in patients characterized by biallelic mutations in the ARSA gene leading to a reduction of the ARSA enzymatic activity in children with i) late infantile or early juvenile forms, without clinical manifestations of the disease, or ii) the early juvenile form, with early clinical manifestations of the disease, who still have the ability to walk independently and before the onset of cognitive decline. Libmeldy is the first therapy approved for eligible patients with early-onset MLD.

The most common adverse reaction attributed to treatment with Libmeldy was the occurrence of anti-ARSA antibodies. In addition to the risks associated with the gene therapy, treatment with Libmeldy is preceded by other medical interventions, namely bone marrow harvest or peripheral blood mobilization and apheresis, followed by myeloablative conditioning, which carry their own risks. During the clinical studies of Libmeldy, the safety profiles of these interventions were consistent with their known safety and tolerability.

For more information about Libmeldy, please see the [Summary of Product Characteristics \(SmPC\)](#) available on the EMA website.

Libmeldy is approved in the European Union, UK, Iceland, Liechtenstein and Norway. OTL-200 is an investigational therapy in the U.S.

Libmeldy was developed in partnership with the San Raffaele-Telethon Institute for Gene Therapy (SR-Tiget) in Milan, Italy.

Additional Information and Where to Find It

In connection with the proposed transaction between Kyowa Kirin Co., Ltd. ("Kyowa Kirin") and Orchard Therapeutics plc ("Orchard"), Orchard intends to file with the Securities and Exchange Commission (the "SEC") a Proxy Statement, the definitive version of which (if and when available) will be mailed to Orchard security holders. Orchard may also file other documents with the SEC regarding the proposed transaction. This document is not a substitute for the Proxy Statement or any other document which Orchard may file with the SEC. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PROXY STATEMENT (WHICH WILL INCLUDE AN EXPLANATORY STATEMENT IN RESPECT OF THE SCHEME OF ARRANGEMENT OF ORCHARD, IN ACCORDANCE WITH THE REQUIREMENTS OF THE U.K. COMPANIES ACT 2006) AND ANY OTHER RELEVANT DOCUMENTS THAT ARE FILED OR WILL BE FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY IF AND WHEN THEY BECOME AVAILABLE BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors and security holders may obtain a free copy of the Proxy Statement and other relevant documents containing important information about Kyowa Kirin, Orchard and the proposed transaction (if and when they become available) once such documents are filed with the SEC at the SEC's website at www.sec.gov. Copies of the documents filed with the SEC by Orchard will be available free of charge on Orchard's website at ir.orchard-tx.com or by contacting Orchard's Investor Relations Department at investors@orchard-tx.com.

Participants in the Solicitation

Orchard and certain of its directors and executive officers may be deemed to be participants in the solicitation of proxies in respect of the proposed transaction. Information regarding Orchard's directors and executive officers, including a description of their direct interests, by security holdings or otherwise, is contained in Orchard's proxy statement for its 2023 annual general meeting of shareholders, which was filed with the SEC on April 27, 2023, and subsequent statements of beneficial ownership on file with the SEC. Orchard shareholders may obtain additional information regarding the direct and indirect interests of the participants in the solicitation of proxies in connection with the proposed transaction, including the interests of Orchard directors and executive officers in the transaction, which may be different than those of Orchard shareholders generally, by reading the Proxy Statement if and when it is filed with the SEC and any other relevant documents that are filed or will be filed with the SEC relating to the transaction. You may obtain free copies of these documents using the sources indicated above.

Cautionary Statement Regarding Forward-Looking Statements

This communication contains "forward-looking statements" within the meaning of the federal securities laws, including Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. These forward-looking statements are based on Orchard's current expectations, estimates and projections about the expected date of closing of the proposed transaction and the potential benefits thereof, its business and industry, management's beliefs and certain assumptions made by Orchard and Kyowa Kirin, all of which are subject to change. In this context, forward-looking statements often address expected future business and financial performance and financial condition, and often contain words such as "expect," "anticipate," "intend," "plan," "believe," "could," "seek," "see," "will," "may," "would," "might," "potentially," "estimate," "continue," "expect," "target," "explore," "evaluate," "predict," "project," similar expressions or the negatives of these words or other comparable terminology that convey uncertainty of future events or outcomes. All forward-looking statements by their nature address matters that involve risks and uncertainties, many of which are beyond Orchard's or Kyowa Kirin's control, and are not guarantees of future results, such as statements about the consummation of the proposed transaction and the anticipated benefits thereof. These and other forward-looking statements, are not guarantees of future results and are inherently subject to risks, uncertainties and assumptions that could cause actual results to differ materially from those expressed in any forward-looking statements. Accordingly, there are or will be important factors that could cause actual results to differ materially from those indicated in such statements and, therefore, you should not place undue reliance on any such statements and caution must be exercised in relying on forward-looking statements. Important risk factors and uncertainties that may cause such a difference include, but are not limited to, risks and uncertainties surrounding: (i) the completion of the proposed transaction on anticipated terms and timing, including in connection with obtaining shareholder and regulatory approvals, the sanction of the High Court of Justice of England and Wales, satisfaction of other closing conditions to consummate the acquisition, anticipated tax treatment, unforeseen liabilities, future capital expenditures, revenues, expenses, earnings, synergies, economic performance, indebtedness, financial condition, losses, future prospects, business and management strategies for the management, expansion and growth of Orchard's business and other conditions to the completion of the transaction; (ii) the occurrence of any event, change or other circumstance that could give rise to the termination of the definitive transaction agreement relating to the proposed transaction; (iii) Orchard's ability to implement its business model and strategic plans for its product, product candidates and pipeline, and challenges inherent in developing, commercializing, manufacturing, launching, marketing and selling existing and new products; (iv) significant transaction costs associated with the proposed transaction; (v) potential litigation relating to the proposed transaction; (vi) the risk that disruptions from the proposed transaction will harm Orchard's business, including current plans, operations and collaborations, and including as a result of diverting the attention of Orchard's and Kyowa Kirin's management from ongoing business operations; (vii) the ability of Orchard to retain and hire key personnel; (viii) potential adverse reactions or changes to business relationships resulting from the announcement or completion of the proposed transaction; (ix) legislative, regulatory and economic developments affecting Orchard's business; (x) general economic and market developments and conditions; (xi) the evolving legal, regulatory and tax regimes under which Orchard operates; (xii) potential business uncertainty, including changes to existing business relationships, during the pendency of the transaction that could affect Orchard's financial performance; (xiii) restrictions during the pendency of the proposed transaction that may impact Orchard's ability to pursue certain business opportunities or strategic transactions; (xiv) the risk that Orchard may be unable to obtain governmental and regulatory approvals required for the proposed transaction, or that required governmental and regulatory approvals may delay the consummation of the proposed transaction or result in the imposition of conditions that could reduce the anticipated benefits from the proposed transaction or cause the parties to abandon the proposed transaction; (xv) unpredictability and severity of catastrophic events, including, but not limited to, global pandemic, acts of terrorism or outbreak of war or hostilities, as well as Orchard's response to any of the aforementioned factors; (xvi) potential delays or failures related to research, clinical trials and/or development of Orchard's programs or product candidates, which are based on novel gene therapy and (xvii) the risks related to non-achievement of the CVR milestone and that holders of the CVRs will not receive payments in respect of the CVRs. Additional factors that may affect the future results of Orchard are set forth in Orchard's filings with the SEC, including Orchard's most recently filed Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the SEC, which are available on the SEC's website at www.sec.gov. See in particular Item 1A of Orchard's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023, under the headings "Risk Factors." The risks and uncertainties described above and in the SEC filings cited above are not exclusive and further information concerning Orchard and its business,

including factors that potentially could materially affect Orchard's business, financial conditions or operating results, may emerge from time to time. Moreover, other risks and uncertainties of which Orchard is not currently aware may also affect Orchard's forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. Readers are urged to consider these factors carefully in evaluating these forward-looking statements, and not to place undue reliance on any forward-looking statements, which speak only as of the date hereof and reflect the views stated therein with respect to future events as at such dates, even if they are subsequently made available by Orchard on its website or otherwise. Readers should also carefully review the risk factors described in other documents that Orchard files from time to time with the SEC. Except as required by law, Orchard assumes no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

No Offer or Solicitation

This communication is not intended to and shall not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities, or a solicitation of any vote or approval, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offer of securities shall be made in the United States absent registration under the U.S. Securities Act of 1933, as amended, or pursuant to an exemption from, or in a transaction not subject to, such registration requirements.

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