## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **SCHEDULE 14A**

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant

Filed by a Party other than the Registrant  $\Box$ 

Check the appropriate box:

- □ Preliminary Proxy Statement
- □ Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
- □ Definitive Proxy Statement
- Definitive Additional Materials
- Soliciting Material Pursuant to §240.14a-12

## **Orchard Therapeutics plc**

(Name of Registrant as Specified In Its Charter)

#### (Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

- ⊠ No fee required.
- □ Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.
- □ Fee paid previously with preliminary materials.

#### **Explanatory** Note

This Schedule 14A filed on form DEFA14A (the "Amended Filing") is being filed to amend the definitive additional materials filed on form DEFA14C with the Securities and Exchange Commission ("SEC") on October 5, 2023 (the "Original Filings"). The Original Filings inadvertently were filed as the incorrect submission type, DEFA14C. This Amended Filing correctly files the Original Filings on form DEFA14A.

Please refer to this Amended Filing instead of the Original Filings. Except for the amendment described above, this Amended Filing contains the same information and materials as the Original Filings.

# Srchard therapeutics

### 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<sup>®</sup> (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 <sup>®</sup> (atidarsagene autotemcel), also known as OTL-200, intended for eligible patients with earlyonset 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<sup>®</sup> 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 F	loor London W6 8PW United Kingdom
(3)	Job title and name of representative	Chief Executive Officer Bobby	y Gaspar
(4)	Description of business	Development and commerciali	zation of hematopoietic stem cell gene therapy
(5)	Share capital	\$29,456 thousand (as of June 3	0, 2023)
(6)	Date of establishment	2015	
(7)	Major shareholders and ownership ratios	RA Capital Management, LP ( Zentree Investment Manageme (as of June 30, 2023)	25.7%) Deep Track Capital LP (9.0%) nt Pte Ltd (8.3%)
(8)	Relationship between Kyowa Kirin and Orchard	Capital relationship Personnel relationship Business relationship Related Party Status	None None None 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: <a href="https://www.kyowakirin.com">https://www.kyowakirin.com</a>.

#### **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 <u>www.orchard-tx.com</u>, and follow us on <u>X (Twitter)</u> and <u>LinkedIn</u>.

#### About Libmeldy / OTL-200

Libmeldy<sup>®</sup> (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 <u>Summary of Product Characteristics (SmPC)</u> 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.

#### Internal Q&A: Orchard Therapeutics & Kyowa Kirin Acquisition Agreement Last updated: October 5, 2023

This document is intended to provide answers to anticipated questions the Orchard Therapeutics team may have about the planned acquisition of Orchard by Kyowa Kirin.

#### Announcement / Rationale

#### 1. What was announced?

Orchard announced it has signed an agreement to be acquired by Kyowa Kirin Co., Ltd., a global specialty pharmaceutical company based in Tokyo, Japan.

Under the terms of the proposed acquisition, Kyowa Kirin will make an upfront cash payment of \$16.00 per Orchard American Depositary Share (ADS), or an aggregated value of \$387.4 million at closing.

In addition, Orchard shareholders will receive a contingent value right (CVR) entitling holders to an additional cash payment of \$1.00 per ADS related to the approval of OTL-200 in the U.S. as defined in the CVR agreement.

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 a favourable vote by Orchard shareholders, receipt of applicable regulatory approvals and other customary closing conditions.

#### Who is Kyowa Kirin? 2.

For more than 70 years, Kyowa Kirin has contributed to human health and well-being worldwide through the discovery and commercialisation of innovative biopharmaceuticals, driven by state- of-the-art antibody technologies, in its core therapeutic areas of nephrology, oncology, immunology and neurology.

With more than \$3 billion in annual revenue and nearly 6,000 employees worldwide. Kyowa Kirin is one of the top 500 companies traded on the Tokyo Stock Exchange (TSE).

The company maintains a global presence across four regions—Japan, Asia Pacific, North America and EMEA/International—and is united by its values of commitment to life, teamwork/Wa, innovation, and integrity. Kyowa Kirin is known for its expansive portfolio of commercial therapies in various regions and countries, including Crysvita® and POTELIGEO® (mogamulizumab-kpkc). They also have a robust pipeline of investigational therapies in development.

It is owned by the Kirin Holdings Company, a diversified multinational company known for such brands as Kirin Lager, one of Japan's oldest beers that has been brewed commercially since the 1880s.

#### Why is this good for Orchard and the patient communities we serve? 3.

This transaction creates significant immediate value and long-term benefits for all our key stakeholders, including our people, investors, and the patient communities we serve.

We believe this is the best path forward to maximise the potential impact of Orchard's HSC gene therapy platform. It delivers substantial and immediate cash value to our shareholders and ensures we are well-resourced to accelerate the achievement of our near- and longer-term goals for our portfolio. It means we are less reliant on capital markets as a primary source of funding, which as you know has been a difficult financing environment of late.

As a combined entity, we look forward to working with our new colleagues at Kyowa Kirin to unlock the full potential of our approach for the benefit of patients, families and society.

#### 4. Why is Orchard being acquired now?

This transaction was the culmination of extensive discussions between the companies. It started as an exploratory early research collaboration to utilise Orchard's hematopoietic stem cell (HSC) gene therapy platform to produce investigational medicines based on Kyowa Kirin proprietary antibody sequences and technologies in certain indications and therapeutic targets.

As engagement around this potential collaboration progressed, Kyowa Kirin recognised the broad applicability and differentiated profile of our technology and approached us about a more extensive partnership which over time evolved to an offer to acquire Orchard. They came to understand the unique capabilities and expertise within Orchard, the quality of our people, and our leadership position in HSC gene therapy.

Throughout the subsequent negotiations and due diligence process, it became apparent that Orchard and Kyowa Kirin shared a common vision with many overlapping core values, and that the business combination would be mutually beneficial.

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 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.

For Orchard, we believe the planned acquisition will allow us to achieve our vision of ending the devastation caused by severe genetic diseases through the curative potential of HSC gene therapy faster than if we remained an independent company reliant on capital markets as a primary source of funding. It allows us to continue our programmes and potentially do more than if we were to remain independent.

This transaction is the outcome of thorough review process overseen by Orchard's Board of Directors. Additional details will be provided in our proxy statement, which will be filed with the SEC in due course.

#### 5. What is Kyowa Kirin's vision for Orchard?

The planned acquisition of Orchard Therapeutics is aligned with Kyowa Kirin's vision of delivering life-changing medicines that have the potential to make a profound impact on patients' lives.

With the planned acquisition of Orchard, Kyowa Kirin is making its foray into the burgeoning field of gene therapy as it strives to enhance its research base and solidify itself as a science- driven organisation. Throughout the discussions and negotiations around the planned acquisition, Kyowa Kirin has made clear that Orchard's business, portfolio—and particularly our people—will be a central component of their corporate growth strategy in the gene therapy field.

As a combined entity, we look forward to working with our new colleagues at Kyowa Kirin to unlock the full potential of our approach for the benefit of patients, families and society.

### 6. What are the next steps in the process?

We expect the transaction to close in the first quarter of 2024 subject to Orchard Therapeutics' shareholder approval, receipt of applicable regulatory approvals and other customary closing conditions.

As we move ahead, we will assemble a cross-functional team with appointed representatives from both Orchard and Kyowa Kirin to help plan and execute the path forward and work toward closing the transaction. We will provide ongoing relevant updates between now and closing, as appropriate.

#### 7. What does this mean for my daily responsibilities?

There will be no changes in your daily responsibilities as a result of this announcement unless otherwise communicated by your manager or functional team lead.

We are counting on everyone to remain focused on your day-to-day work to ensure our collective success and the achievement of our near- and longerterm corporate objectives. After all, the success of this acquisition for Kyowa Kirin and for Orchard is directly related to our ability to continue executing on our major programme priorities.

#### 8. What is a CVR? What does the CVR component of the purchase price mean for me? When will I receive the CVR payments?

A Contingent Value Right, or CVR, allows holders to receive additional payment if a certain event occurs in the future, especially when a company being acquired has a near-term value inflection point. As a shareholder in Orchard, the CVR will allow you to participate in the opportunity for additional cash upside. In this case, the CVR is aligned to the approval of OTL- 200 in the U.S., subject to the terms and conditions contained in the CVR agreement.

#### 9. Is the acquisition price fair market value?

This transaction is the outcome of a thorough process overseen by the Orchard Board of Directors. We believe the financial terms deliver great value and the combination of our businesses has the potential to make a transformative impact on patients and society globally.

The Orchard Board of Directors unanimously approved the transaction and recommends that Orchard shareholders vote in favour of the acquisition.

#### **Business / Portfolio**

#### 10. Do we anticipate this transaction will have any impact on the BLA review for OTL-200?

No. The review, evaluation and potential approval of OTL-200 will solely be based on the merits of our Biologics License Application file, and this transaction should have no bearing on the outcome.

#### 11. Will the registrational trial for OTL-203 in MPS-IH move forward as planned?

Yes. We plan to move forward and remain on track to initiate the global registrational trial for OTL-203 in MPS-IH by year end. It is very important that we continue to execute against our corporate goals during this transition and after completion.

# 12. Will Kyowa Kirin continue to support our earlier-stage programmes in MPS-IIIA, HAE, larger indications and HSC-Treg and vectorised mAb technologies?

Yes. The proposed acquisition price recognises the tremendous value of our HSC gene therapy platform and portfolio. Throughout the due diligence process, Kyowa Kirin has indicated an interest in advancing a broad portfolio of programmes in our pipeline.

#### 13. Does this transaction allow us to reinvest in previously discontinued programmes in primary immune deficiencies?

No. The decision to discontinue investment in and seek alternatives for our legacy programmes in primary immune deficiencies (PIDs) was incredibly difficult for Orchard, but necessary to ensure the long-term sustainability of our company at the time. We do not expect the transaction to alter our current development plans or strategy for where we plan to apply our HSC gene therapy approach.

# 14. Given its focus in immunology, did Orchard approach Kyowa Kirin as a potential partner for our legacy programmes in primary immune deficiencies?

Due to the confidential nature of these discussions, we are unable to provide specifics; however, we explored potential partnerships with an exhaustive list of commercial partners for our legacy PID programmes prior to returning them to our clinical and academic collaborators.

#### Communications

#### 15. What should I say to external vendors, consultants, business partners, etc.?

We issued a press release announcing this transaction publicly and are in the process of communicating with our external partners.

Should you receive inquiries from external partners, please emphasise that it will remain business as usual. Please do not speculate or, under any circumstances, disclose non-public information concerning the transaction.

If you have any questions or are unsure what you can say, please reach out to your respective ELT member or functional team lead.

#### 16. What if I am approached by investors or media?

Please direct any investor or media inquiries to Corporate Communications should you receive them.

#### 17. Can I post about this on social media?

Social media postings are permissible in accordance with applicable company policies. Please reach out to Corporate Communications if you have any questions.

Please also remember your confidentiality obligations to Orchard remain in place and apply to information concerning the transaction.

#### 18. Can I interact with employees of Kyowa Kirin?

Prior to closing, Kyowa Kirin and Orchard will continue to operate independently of each other. As we move ahead, we will assemble a cross-functional team with appointed representatives from both companies to help plan and execute the path forward.

We will look for opportunities for the Orchard team to get to know our new colleagues at Kyowa Kirin in the coming months and we encourage discussions on a social basis. Any formal business discussions should be referred to the applicable ELT member or to the joint business combination team that will be formed between signing and closing.

#### 19. What can I share with my family and friends?

Only publicly available information can be shared with family and friends outside the organisation. As always, information that has not been made public needs to remain confidential within Orchard. The public announcement is available on Orchard's website.

#### 20. What resources and communications are available to me from now until the transaction closes?

We are committed to being as transparent and timely as possible in our communications throughout this process, keeping in mind that there are some limitations and restrictions inherent to these types of business combinations. However, we will continue to provide ongoing relevant updates between now and closing, as appropriate.

#### 21. Who can I ask for additional questions?

Please contact your respective ELT member or functional team lead if you have further questions. We are committed to keeping you informed as we have updates to share.

#### Closing / Business Combination

#### 22. Is shareholder approval required for this transaction to be completed?

The transaction is subject to approval by Orchard's shareholders, as well as applicable regulatory approvals and other customary closing conditions.

#### 23. How will Orchard be managed/operated/led post-closing?

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

Our understanding is that Orchard will be run as a business unit within Kyowa Kirin's global network. As such, Orchard's organisational structure is expected to remain the same with the leadership continuing to report to Bobby Gaspar, M.D., Ph.D., who is expected to report to Kyowa Kirin's Chief Executive Officer Masashi Miyamoto. We view this as a strong signal of the important role Orchard will play within Kyowa Kirin.

#### 24. Who will lead the business combination process and how will it be managed?

Please keep in mind that we are early in the process and there are still many decisions to be made. As we move ahead, we will assemble a crossfunctional team with appointed representatives from both companies to help plan and execute the path forward. We will communicate more information about the process in due course.

#### 25. Do we anticipate there being any redundancies or restructuring?

Kyowa Kirin has made it clear they value the way Orchard operates and has not indicated any intention to restructure our organisation. In fact, throughout the discussions and negotiations around the planned acquisition, Kyowa Kirin has communicated Orchard's people will be a central component of their gene therapy growth strategy. Consequently, retention of our talent throughout the business combination and beyond is a top priority of Kyowa Kirin to ensure the realisation of our shared vision.

#### 26. Will Orchard be renamed or rebranded?

We anticipate Orchard Therapeutics will maintain its current name given its recognition among the patient and physician communities we serve with the potential for some adjustments to our corporate brand identity and positioning post-closing to more closely align with Kyowa Kirin.

#### 27. Who will my new employer be?

You will continue to be employed by the same legal entity that you are today, and the entity will become wholly owned by Kyowa Kirin on the completion date of the acquisition.

#### 28. Will I need to sign a new contract/employment agreement?

No. After closing, you will be employed under the same legal entity as you are today. This may change in the future as we rationalise the proper legal entity structure for the combined organisation.

#### 29. Are there opportunities to leverage resources and expertise in Kyowa Kirin and how will this work?

We expect that as part of the business combination some of Kyowa Kirin's employees will be embedded in our research labs in London, and possibly other functional groups, to learn and identify opportunities for cross-pollination.

The Orchard team will likely have similar reciprocal opportunities within Kyowa Kirin's global network over time. In addition to its global headquarters and laboratories in Tokyo, Kyowa Kirin currently has significant operations in Marlow (UK), New Jersey (U.S.), and La Jolla (U.S.).

#### 30. Will we continue to employ a flexible/hybrid work model under Kyowa Kirin?

We will continue to employ Orchard's Hybrid Working Policy and do not expect any near-term changes as part of the business combination.

### 31. What will happen to our London and Boston offices? Will office-based employees need to relocate to Kyowa Kirin's offices?

We do not anticipate any impact on our London or Boston offices or changes to our work locations. Office-based employees will continue to work from these locations under Orchard's Hybrid Working Policy.

#### 32. How should I handle previously scheduled travel, conferences, or business meetings?

You should continue to perform your job as you normally would, which includes keeping meetings and traveling as scheduled, unless you are instructed to do otherwise by your manager or functional team lead.

#### 33. I have an open or budgeted position this year, can I still hire the position?

We will continue to fill roles critical to our business objectives, but will be evaluating the need for current open positions in the context of the combined business entity.

If you currently have an open position but are unsure how to proceed, please consult your ELT member and HR business partner.

#### 34. If someone leaves Orchard, will we be able to backfill their position?

Yes, subject to the normal approval of your ELT member and HR.

#### 35. How will this impact budgeting/corporate goals for next year?

We are continuing our annual operating plan, budgeting, and corporate/department/individual goal-setting processes as part of the normal course of business. Additional details will be shared by the finance department, as well as your functional team lead and manager in due course.

#### 36. Are there plans to merge Information Systems & Platforms (Business / Finance / HR / QA, etc.)?

This announcement is just the first step in the process, so, while we don't have all the answers, we are committed to keeping everyone updated as we work on closing the transaction. Kyowa Kirin shares our goal of making this as seamless a process as possible.

#### Compensation / Benefits / Equity

#### 37. Will my compensation and/or benefits change?

Except for the impact to the equity plans (stock options, RSUs and ESPP) that the acquisition will have (outlined in question 45 and 50), all other elements of your compensation and benefits are expected to remain substantially the same.

#### 38. Does my annual bonus target remain the same?

Yes. Your annual bonus target will remain the same.

#### 39. Will my title remain the same?

Yes. Your employment title will remain the same.

#### 40. What does this mean as it pertains to funding the 2023 bonus pool?

The 2023 annual bonus will be funded as part of the normal course of business and payment will be subject to the achievement of both our corporate and your individual goals as usual.

#### 41. Will Orchard provide promotions and salary increases for 2023?

Yes. We will continue to operate our annual performance review and talent planning processes. Year-end assessments and evaluations will be conducted per the usual timeframe, during which managers will recommend promotions and salary increases subject to approval by the ELT, and certain conditions outlined in the transaction agreement.

#### 42. Will Orchard employees be eligible for Kyowa Kirin's employee services and benefits?

Orchard employees will remain eligible for Orchard services and benefits. Accessing Kyowa Kirin's services and benefits is something that will be discussed as part of the business combination process.

#### 43. What happens to any Orchard shares I hold?

For employees who hold American Depositary Shares (ADS) of Orchard—either through previously exercised options, the Employee Stock Purchase Plan (ESPP) or previous open market purchases, upon closing of the transaction following all required steps and approvals, you will receive \$16.00 per ADS in cash for each ADS held.

In addition, you will receive a non-transferable contingent value right (CVR) which entitles shareholders to receive \$1.00 per ADS in cash payable upon the approval of OTL-200 in the U.S., subject to the terms and conditions contained in the CVR agreement.

#### 44. Are we still in a blackout? Can I sell my shares that I hold prior to the transaction closing, or can I exercise and sell my vested options?

As a reminder, the trading window under Orchard's insider trading policy is currently closed, and transactions in Orchard securities are not permitted. In order to facilitate a seamless completion of the transaction and given the material nature of this transaction, we expect all Orchard employees will remain subject to a trading blackout through the closing. If you have any questions about trading, please contact the Legal department.

#### 45. What will happen to my stock options and RSUs?

- Stock options:
  - Each *vested* in-the-money Orchard stock option will be automatically converted into the right to receive:
    - (i) an amount in cash *paid at closing* equal to \$16.00 per ADS less the strike price of such option, and
    - (ii) one CVR for \$1.00 per ADS *to be paid contingent upon approval of OTL-200*, without interest and less applicable tax withholdings
  - Each *unvested* in-the-money Orchard stock option will be cancelled at closing.

However, Kyowa Kirin will implement a new transitional cash plan (the "Transitional Cash Plan") and grant cash awards ("Transition Awards") under such plan to holders of unvested in-the-money Orchard stock option. The Transition Awards will be equal to the aggregate value of:

- An amount in cash equal to \$16.00 per ADS less the strike price of such option, and
- (ii) one CVR for \$1.00 per ADS *to be paid contingent upon approval of OTL-200 in 2024*, without interest and less applicable tax withholdings
- The Transition Award will vest and be paid at the same time as the unvested Orchard stock option would have vested pursuant to its original terms, subject to the holder's continued service with Kyowa Kirin or its subsidiaries (including Orchard) through each vesting date. At the end of 2024, a lump-sum cash payment will be made for the value of all remaining unvested Transition Awards.
- Any Orchard stock options (whether vested or unvested) with an exercise price per ADS that is greater than \$16 will be cancelled for no consideration.
- RSUs:
  - Each vested but unsettled restricted stock units (RSU) will be automatically converted into the right to receive:
    - (i) an amount in cash equal to \$16.00 per ADS and
    - (ii) one CVR for \$1.00 per ADS without interest and less applicable tax withholdings
  - Each unvested RSU will be cancelled at closing. However, under the Transitional Cash Plan (as described above under the "Stock Options" treatment), Kyowa Kirin will grant Transition Awards under such plan to holders

of unvested RSUs. The Transition Awards will be equal to the aggregate value of:

- An amount in cash equal to \$16.00 per ADS, and
- (ii) one CVR for \$1.00 per ADS *to be paid contingent upon approval of OTL-200*, without interest and less applicable tax withholdings
- The Transition Award will vest and be paid at the same time as the unvested Orchard RSUs would have vested pursuant to their original terms, subject to the holder's continued service with Kyowa Kirin and its subsidiaries (including Orchard) through each vesting date. At the end of 2024, a lump-sum cash payment will be made for the value of all remaining unvested Transition Awards.
- HR and Finance will be scheduling informational sessions in the coming weeks to provide additional information and answer any questions you may have.

#### 46. What happens to my unvested options if I resign?

Employees voluntarily transitioning from Orchard will forfeit any future potential payouts of unvested options and RSUs.

#### 47. Will Orchard continue to grant equity awards in 2023?

It is not anticipated that Orchard will grant any new equity awards between now and the transaction closing. Vested options and RSUs will be automatically converted and paid out as described in question 45.

#### 48. What about equity grants for new hires?

For new hires, we are exploring cash-based alternatives to our existing equity plan.

#### 49. I am participating in the ESPP plan right now, what will happen to this purchase period?

In order to facilitate a seamless completion of the transaction, all Orchard employees will remain subject to a trading blackout through the closing, including via the ESPP, which is being suspended after completion of the current offering.

Following closing, Orchard's ESPP will be discontinued since there will no longer be tradable Orchard securities applicable for such a plan.

#### 50. Is there going to be a supplemental retention or bonus plan to replace our equity- based compensation?

We are evaluating long-term cash-based incentives as an alternative to our current equity incentive plan and will share additional details in due course.

#### 51. Who should I contact with my stock-related questions?

Please reach out to Legal with any stock-related questions.

###

#### PRIVILEGED AND CONFIDENTIAL

Dear all,

I am excited and delighted to announce the next chapter in Orchard Therapeutics' evolution. In the early hours this morning, we signed an agreement to be acquired by Kyowa Kirin Co., Ltd., a global specialty pharmaceutical company based in Tokyo, Japan for up to \$17.00 per American Depositary Share (ADS) in a transaction valued at up to \$477.6 million.

This is an incredibly important moment for us, our stakeholders, and the patients we serve. The decision was the outcome of a deliberative and thorough process, and the opportunity was thoughtfully assessed by the ELT with support from our Board of Directors who unanimously approved the transaction.

Ultimately, we made this decision because we believe that it will be the best path forward to maximise the potential impact of our HSC gene therapy platform. The acquisition creates significant immediate value and will also provide long-term benefits for all our key stakeholders.

I am confident the combination of our businesses will be mutually beneficial. For Orchard, we believe the acquisition will allow us to achieve our vision by ensuring a reliable source of funding. This potentially allows us to advance our portfolio faster and to do more. Orchard will be a major strategic acquisition for Kyowa Kirin and together we will continue building a global leadership position in gene therapy.

Throughout the discussions and negotiations around the acquisition, Kyowa Kirin has made clear that Orchard's business, portfolio—and particularly our people—will be a central component of its corporate growth strategy. Getting to know more about Kyowa Kirin and spending extensive time with their team, it became clear our organizations are already very aligned in terms of our philosophy, core values and long-term vision. We look forward to working with our new colleagues at Kyowa Kirin to unlock the full potential of our approach for the benefit of patients, families and society.

# Additional details can be found in the below press release which will be issued at 8:35 a.m. BST / 3:35 a.m. EDT. **As this is highly confidential material non-public information, we ask you keep this information internal to Orchard until then.**

We will discuss this informally at the UK Breakfast meeting this morning and are scheduling an AHC later today to walk through the merits of the acquisition and outline the path ahead.

In the meantime, I will emphasise that this acquisition came about because of our hard work and execution on our major priorities. This has been central to our success. It is very important that we continue to execute against our corporate goals during this process and after closing which is expected to occur in the first quarter of 2024 subject to a favourable vote by Orchard shareholders and other customary closing conditions.

With sincere gratitude for all your hard work and dedication, Bobby

#### Kyowa Kirin to Acquire Orchard Therapeutics

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<sup>®</sup> (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, London and Boston, October 5, 2023, — 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<sup>®</sup> (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<sup>®</sup> 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 comment	rcialization of hematopoietic stem cell gene therapy
(5)	Share capital	\$29,456 thousand (as of Ju	une 30, 2023)
(6)	Date of establishment	2015	
(7)	Major shareholders and ownership ratios	RA Capital Management, Deep Track Capital LP (9. Zentree Investment Manag (as of June 30, 2023)	0%)
(8)	Relationship between Kyowa Kirin and Orchard	Capital relationship Personnel relationship Business relationship Related Party Status	None None None 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: <a href="https://www.kyowakirin.com">https://www.kyowakirin.com</a>.

#### **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 <u>www.orchard-tx.com</u>, and follow us on <u>X (Twitter)</u> and <u>LinkedIn</u>.

#### About Libmeldy / OTL-200

Libmeldy<sup>®</sup> (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.

## External partner E-mail: Orchard Therapeutics & Kyowa Kirin Acquisition Agreement

Last updated: October 5, 2023

### Suggested subject line: Orchard Therapeutics to be acquired by Kyowa Kirin

Dear XX,

I am excited to announce the next chapter in Orchard Therapeutics' evolution as we have signed an agreement to be acquired by Kyowa Kirin Co., Ltd., a global specialty pharmaceutical company based in Tokyo, Japan.

Ultimately, we believe this is the best path forward to [maximise/maximize] the potential impact of our HSC gene therapy platform for the communities we serve.

Additional details can be found in the below press release, but I wanted to reach out to schedule some time to discuss and answer any questions you may have. [Please let me know your availability for a call in the next week / alternatively sender can provide options for a time].

Importantly, Orchard's priorities and organizational structure will continue to operate as they have. XX remain(s) your primary point(s) of contact, and [I/we] look forward to our continued partnership.

With kind regards,

XX

#### Kyowa Kirin to Acquire Orchard Therapeutics

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<sup>®</sup> (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, London and Boston, October 5, 2023, — 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<sup>®</sup> (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-IIH) and mucopolysaccharidosis type IIIA (MPS-IIIA), also known as Sanfilippo syndrome, respectively.

This acquisition will allow Kyowa Kirin to maximize the value of Libmeldy<sup>®</sup> 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 H	Bobby Gaspar
(4)	Description of business	Development and comme	ercialization of hematopoietic stem cell gene therapy
(5)	Share capital	\$29,456 thousand (as of J	une 30, 2023)
(6)	Date of establishment	2015	
(7)	Major shareholders and ownership ratios	RA Capital Management, Deep Track Capital LP (9 Zentree Investment Mana (as of June 30, 2023)	9.0%)
(8)	Relationship between Kyowa Kirin and Orchard	Capital relationship Personnel relationship Business relationship Related Party Status	None None None 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: <a href="https://www.kyowakirin.com">https://www.kyowakirin.com</a>.

#### **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 <u>www.orchard-tx.com</u>, and follow us on <u>X (Twitter)</u> and <u>LinkedIn</u>.

#### About Libmeldy / OTL-200

Libmeldy<sup>®</sup> (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.



X

0

Orchard Therapeutics @orchard\_tx

We are excited to announce that Kyowa Kirin and Orchard Therapeutics announced that our companies have entered into a definitive agreement under which Kyowa Kirin will acquire Orchard Therapeutics. Read more: bit.ly/45kK1RU

...



L	i	n	k	e	d	in
	•	•••		-	~	_

Join now

Sign in

# Orchard Therapeutics' Post

Therape	39,948 follo 29m excited to a utics annou	herapeutics wers innounce that Kyowa Kirin a unced that our companies h nt under which Kyowa Kirin	nave entered into a
er en la ra	merapeur	ics. Read more: https://bit.	Ørchard
	B	REAKII NEWS	
● 37	B		

#### 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.

#### 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.