



PureTech Health and Royalty Pharma Enter into KarXT Royalty Agreement for up to \$500 Million

March 23, 2023

23 March 2023

PureTech Health plc

PureTech Health and Royalty Pharma Enter into KarXT Royalty Agreement for up to \$500 Million

Royalty Pharma has acquired an interest in PureTech's royalty in Karuna Therapeutics' KarXT; Royalty Pharma and PureTech will share in royalties above certain annual sales thresholds.

PureTech retains its current equity stake in Karuna in addition to milestone payments and 20% of sublicense revenues due to PureTech.

Transaction provides further non-dilutive capital for PureTech's growing and rapidly advancing Wholly Owned Pipeline, with five clinical-stage candidates expected by the end of 2023.

[PureTech Health plc](#) (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company dedicated to changing the treatment paradigm for devastating diseases, and Royalty Pharma (Nasdaq: RPRX), the largest buyer of biopharmaceutical royalties and a leading funder of innovation across the life sciences industry, today announced that Royalty Pharma has acquired an interest in PureTech's royalty in Karuna Therapeutics' KarXT for up to \$500 million, with \$100 million in cash up front and up to \$400 million in additional payments contingent on the achievement of certain regulatory and commercial milestones.

"We are delighted to partner with PureTech, which began a remarkable innovation story with KarXT that has demonstrated an impressive clinical profile in Phase 3," said Pablo Legorreta, Royalty Pharma's Founder and Chief Executive Officer. "We believe this important therapy will have a significant impact on patients with schizophrenia if approved by the FDA. This medicine is a notable addition to our royalty portfolio and is well aligned with our strategy of investing in breakthrough therapies that address areas of high unmet medical need."

"We've seen extraordinary clinical success demonstrated by KarXT, which, if approved, will be the first new mechanism for treating schizophrenia in more than fifty years. KarXT has now demonstrated efficacy in registration enabling studies and is heralded as a potential treatment paradigm shift that could impact millions of patients," said Daphne Zohar, Founder and Chief Executive Officer of PureTech. "This agreement will provide PureTech with additional non-dilutive capital to advance our Wholly Owned Pipeline, including our rapidly maturing clinical programs, towards potential commercialization. Such non-dilutive sources of capital have allowed us to fund our pipeline and operations without having to raise capital from the public markets in over five years, and we are pleased to be able to benefit from the success of our invented programs."

As part of this transaction, PureTech has sold its right to receive a 3% royalty from Karuna to Royalty Pharma on sales up to \$2 billion annually, after which threshold Royalty Pharma will receive 33% and PureTech will retain 67% of the royalty payments. PureTech retains its 3.1% equity ownership in Karuna.^[1] Additionally, under its license agreement with Karuna, PureTech retains the right to receive milestone payments upon the achievement of certain regulatory approvals and 20% of sublicense income.

KarXT was invented by a team at PureTech, including its Chief Innovation Officer, Eric Elenko, Ph.D., who served as the founding CEO of Karuna Therapeutics. KarXT is an oral, investigational M1/M4-preferring muscarinic agonist in development for the treatment of psychiatric and neurological conditions, including schizophrenia as a monotherapy and adjunctive therapy and psychosis in Alzheimer's disease. Karuna has announced that it plans to submit a New Drug Application for KarXT in schizophrenia to the U.S. Food and Drug Administration (FDA) in mid-2023.

Sills Cummis & Gross P.C., acted as legal advisors to PureTech and Gibson, Dunn & Crutcher, LLP, Jones Day and Maiwald GmbH acted as legal advisors to Royalty Pharma.

About PureTech's Wholly Owned Pipeline

In addition to the excellent progress across its Founded Entities, PureTech's Wholly Owned Pipeline is rapidly advancing, and the Company's operational runway, including its \$341.4 million Cash and Cash Equivalents as of June 30, 2022, not including this transaction, is expected to support this growth into the first quarter of 2026. PureTech's pipeline is comprised of six therapeutic candidates, four of which are currently clinical stage, including one partnered program. These candidates are centered on a strategy of leveraging validated biology to rapidly advance therapeutics with proven efficacy. Several upcoming milestones are anticipated for these candidates, including the following:

- LYT-100 (deupirfenidone) is in development for the potential treatment of conditions involving inflammation and fibrosis, including idiopathic fibrosis (IPF), for which current standards of care are associated with significant tolerability issues, resulting in approximately three out of four patients in the U.S. foregoing treatment with these otherwise efficacious

medicines.^[2] LYT-100 is a deuterated form of one of the two standard of care treatments, pirfenidone, which has proven efficacy and has been shown to improve survival in these patients by approximately three years, but its side effects cause patients to discontinue or dose reduce, thereby limiting its effectiveness.^[3] LYT-100 has shown a 50% reduction in gastrointestinal tolerability issues in a head-to-head study versus pirfenidone, and it can be dosed at a higher exposure level, but with a lower C_{max}, than the FDA-approved dosage of pirfenidone, potentially enabling improved efficacy.

PureTech is currently evaluating two doses of LYT-100, one with comparable exposure to the approved dose of pirfenidone and one with a higher level of exposure, in a global, randomized double blind, placebo-controlled trial in patients with IPF, which is expected to serve as the first of two registration enabling trials. As previously noted, the Company has taken measures to accelerate enrollment. Topline results are now expected in 2024.

- LYT-300 (oral allopregnanolone) is in development for the potential treatment of anxiety disorders and postpartum depression (PPD) where there is a need for more effective treatments that work quickly, have more favorable tolerability and can be administered orally. A placebo-controlled, Phase 2a, proof-of-concept trial using a validated clinical model of anxiety in healthy volunteers is expected to begin in the first half of 2023, with topline results anticipated by the end of 2023. An open-label, Phase 2a, proof-of-concept clinical trial in women with PPD is expected to initiate in the second half of 2023.
- LYT-200 (anti-galectin-9 mAb) is in development for the potential treatment of metastatic solid tumors that have poor survival rates as well as hematological malignancies, such as acute myeloid leukemia (AML), where more than 50% of patients either don't respond to initial treatment or experience relapse after responding to initial treatment.^[4] PureTech recently initiated a Phase 1b trial in acute myeloid leukemia, and initial results are expected by the end of 2023. PureTech also recently initiated a Phase 1b trial of LYT-200 in combination with an anti PD-1 antibody, tislelizumab, in patients with urothelial or head and neck cancer. Topline results are expected in 2024.
- LYT-310 (oral cannabidiol [CBD]) is in development to expand the therapeutic application of CBD across a range of epilepsies and neurological disorders. LYT-310 is designed to enable oral administration of CBD in a capsule; expand the use of CBD into a broad range of therapeutic areas and patient populations (such as adolescents and adults) where higher doses are required to achieve a therapeutic effect; potentially improve safety and reduce gastrointestinal (GI) tract side effects that are associated with the currently approved CBD-based treatment by reducing GI and liver exposure; and allow for a readily scalable, consistent product in a cost-effective manner. LYT-310 is expected to enter the clinic in the fourth quarter of 2023.

About PureTech

PureTech is a biotherapeutics company dedicated to changing the treatment paradigm for devastating diseases. The Company has created a broad and deep pipeline through the expertise of its experienced research and development team and its extensive network of scientists, clinicians and industry leaders. This pipeline, which is being advanced both internally and through PureTech's Founded Entities, is comprised of 26 therapeutics and therapeutic candidates, including two (Plenity® and EndeavorRx®) that have received both U.S. FDA clearance and European marketing authorization and a third (KarXT) that will soon be filed for FDA approval, as of the most recent update by the Company. All of the underlying programs and platforms that resulted in this pipeline of therapeutic candidates were initially identified or discovered and then advanced by the PureTech team through key validation points based on its unique insights and technology platforms.

For more information, visit www.puretechhealth.com or connect with us on Twitter @puretechh.

About Royalty Pharma

Founded in 1996, Royalty Pharma is the largest buyer of biopharmaceutical royalties and a leading funder of innovation across the biopharmaceutical industry, collaborating with innovators from academic institutions, research hospitals and non-profits through small and mid-cap biotechnology companies to leading global pharmaceutical companies. Royalty Pharma has assembled a portfolio of royalties which entitles it to payments based directly on the top-line sales of many of the industry's leading therapies. Royalty Pharma funds innovation in the biopharmaceutical industry both directly and indirectly - directly when it partners with companies to co-fund late-stage clinical trials and new product launches in exchange for future royalties, and indirectly when it acquires existing royalties from the original innovators. Royalty Pharma's current portfolio includes royalties on more than 35 commercial products, including Vertex's Trikafta, Kalydeco, Orkambi and Symdeko, Biogen's Tysabri, AbbVie and Johnson & Johnson's Imbruvica, Astellas and Pfizer's Xtandi, GSK's Trelegy, Novartis' Promacta, Pfizer's Nurtec ODT, Johnson & Johnson's Tremfya, Roche's Evrysdi, Gilead's Trodelvy, and 10 development-stage product candidates.

PureTech Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation those statements related to the terms of the agreement with Royalty Pharma for the Karuna royalties, KarXT, its development, clinical milestones and potential therapeutic applications, PureTech's Wholly Owned Pipeline and the development, clinical milestones and potential therapeutic applications associated with its candidates, and our future prospects, developments, and strategies. The forward-looking statements are based on current expectations and are subject to known and unknown risks, uncertainties and other important factors that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to, those risks, uncertainties and other important factors described under the caption "Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2021 filed with the SEC and in our other regulatory filings. These forward-looking statements are based on assumptions regarding the present and future business strategies of the Company and the environment in which it will operate in the future. Each forward-looking statement speaks only as at the date of this press release. Except as required by law and regulatory requirements, we disclaim any obligation to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.

The information contained within this announcement is deemed by the Company to constitute inside information as stipulated under the Market Abuse Regulations (EU) No. 596/2014 which forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018 ('MAR'). Upon the publication of this announcement via a Regulatory Information Service ('RIS'), this inside information is now considered to be in the public domain.

Royalty Pharma Forward-Looking Statements

The information set forth herein does not purport to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this document unless stated otherwise, and neither the delivery of this document at any time, nor any sale of securities, shall under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof. This document contains statements that constitute "forward-looking statements" as that term is defined in the United States Private Securities Litigation Reform Act of 1995, including statements that express the company's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results, in contrast with statements that reflect historical facts. Examples include discussion of Royalty Pharma's strategies, financing plans, growth opportunities and market growth. In some cases, you can identify such forward-looking statements by terminology such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "target," "forecast," "guidance," "goal," "predicts," "project," "potential" or "continue," the negative of these terms or similar expressions. Forward-looking statements are based on management's current beliefs and assumptions and on information currently available to the company. However, these forward-looking statements are not a guarantee of Royalty Pharma's performance, and you should not place undue reliance on such statements. Forward-looking statements are subject to many risks, uncertainties and other variable circumstances, and other factors. Such risks and uncertainties may cause the statements to be inaccurate and readers are cautioned not to place undue reliance on such statements. Many of these risks are outside of Royalty Pharma's control and could cause its actual results to differ materially from those it thought would occur. The forward-looking statements included in this document are made only as of the date hereof. Royalty Pharma does not undertake, and specifically declines, any obligation to update any such statements or to publicly announce the results of any revisions to any such statements to reflect future events or developments, except as required by law. Certain information contained in this document relates to or is based on studies, publications, surveys and other data obtained from third-party sources and Royalty Pharma's own internal estimates and research. While Royalty Pharma believes these third-party sources to be reliable as of the date of this document, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this document involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while the company believes its own internal research is reliable, such research has not been verified by any independent source. For further information, please reference Royalty Pharma's reports and documents filed with the U.S. Securities and Exchange Commission ("SEC") by visiting EDGAR on the SEC's website at www.sec.gov.

Contact:

PureTech

Public Relations

publicrelations@puretechhealth.com

Investor Relations

IR@puretechhealth.com

EU Media

Ben Atwell, Rob Winder

+44 (0) 20 3727 1000

ben.atwell@FTIconsulting.com

U.S. Media

Nichole Sarkis

+1 774 278 8273

nichole@tenbridgecommunications.com

Royalty Pharma Investor Relations and Communications

+1 (212) 883-6772

[1] As of February 23, 2023

[2] Dempsey, T. M., Payne, S., Sangaralingham, L., Yao, X., Shah, N. D., & Limper, A. H. (2021). Adoption of the Antifibrotic Medications Pirfenidone and Nintedanib for Patients with Idiopathic Pulmonary Fibrosis. *Annals of the American Thoracic Society*, 18(7), 1121-1128. <https://doi.org/10.1513/AnnalsATS.202007-901OC>

[3] Margaritopoulos, G. A., Trachalaki, A., Wells, A. U., Vasarmidi, E., Bibaki, E., Papastratigakis, G., Detorakis, S., Tzanakis, N., & Antoniou, K. M. (2018). Pirfenidone improves survival in IPF: results from a real-life study. *BMC pulmonary medicine*, 18(1), 177. <https://doi.org/10.1186/s12890-018-0736-z>

[4] Walter, R. B., Othus, M., Burnett, A. K., Löwenberg, B., Kantarjian, H. M., Ossenkoppele, G. J., Hills, R. K., Ravandi, F., Pabst, T., Evans, A., Pierce, S. R., Vekemans, M. C., Appelbaum, F. R., & Estey, E. H. (2015). Resistance prediction in AML: analysis of 4601 patients from MRC/NCRI, HOVON/SAKK, SWOG and MD Anderson Cancer Center. *Leukemia*, 29(2), 312-320. <https://doi.org/10.1038/leu.2014.242>

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lseg.com or visit www.rns.com.

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our [Privacy Policy](#).

END

AGREAFDAASADEAA