

PureTech Founded Entity Karuna Therapeutics to be Acquired by Bristol Myers Squibb for \$14 Billion

December 22, 2023

RNS Number : 8322X
PureTech Health PLC
22 December 2023

22 December 2023

PureTech Founded Entity Karuna Therapeutics to be Acquired by Bristol Myers Squibb for \$14 Billion

Transaction Delivers KarXT, a First-in-Class M1 / M4 Muscarinic Receptor Agonist, with Differentiated Efficacy and Safety

KarXT Is a Potential First-in-Class Treatment for Schizophrenia and as an Adjunctive Therapy, and First-in-Disease Treatment for Alzheimer's Disease Psychosis, with Promise in Additional Neuropsychiatric and Neurodegenerative Indications

KarXT Is Expected to Launch in the U.S. for the Treatment of Schizophrenia in Adults with a Prescription Drug User Fee Act Date of September 26, 2024

Bristol Myers Squibb to Host a Conference Call Today at 8:00 a.m. ET

[PureTech Health plc](#) (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company, noted today that its Founded Entity, Karuna Therapeutics, Inc., and (Nasdaq: KRTX) Bristol Myers Squibb (NYSE: BMY) announced that they have entered into a definitive merger agreement under which Bristol Myers Squibb has agreed to acquire Karuna for \$330.00 per share in cash, for a total equity value of \$14.0 billion, or \$12.7 billion net of estimated cash acquired. The transaction was unanimously approved by both the Bristol Myers Squibb and Karuna Boards of Directors.

Karuna is a biopharmaceutical company driven to discover, develop and deliver transformative medicines for people living with psychiatric and neurological conditions. Karuna's lead asset, KarXT (xanomeline-trospium), is an antipsychotic with a novel mechanism of action and differentiated efficacy and safety. Karuna's New Drug Application for KarXT for the treatment of schizophrenia in adults was accepted for review by the U.S. Food and Drug Administration, with a Prescription Drug User Fee Act date of September 26, 2024. KarXT is also in registrational trials both for adjunctive therapy to existing standard of care agents in schizophrenia and for the treatment of psychosis in patients with Alzheimer's disease. Bristol Myers Squibb believes KarXT represents a significant revenue contribution opportunity. Bristol Myers Squibb also sees potential from Karuna's early-stage and pre-clinical pipeline.

PureTech is a founder of Karuna and co-inventor of the KarXT program. If approved, KarXT will be the third therapeutic candidate to be taken from inception at PureTech to FDA regulatory approval.

The full text of the joint announcement from Karuna and Bristol Myers Squibb is as follows:

Bristol Myers Squibb Strengthens Neuroscience Portfolio with Acquisition of Karuna Therapeutics

Transaction Delivers KarXT, a First-in-Class M1 / M4 Muscarinic Receptor Agonist, with Differentiated Efficacy and Safety

KarXT Is a Potential First-in-Class Treatment for Schizophrenia and as an Adjunctive Therapy, and First-in-Disease Treatment for Alzheimer's Disease Psychosis, with Promise in Additional Neuropsychiatric and Neurodegenerative Indications

KarXT Is Expected to Launch in the U.S. for the Treatment of Schizophrenia in Adults with a Prescription Drug User Fee Act Date of September 26, 2024

Bristol Myers Squibb to Host a Conference Call Today at 8:00 a.m. ET

PRINCETON, N.J. & BOSTON -- Bristol Myers Squibb (NYSE: BMY) and Karuna Therapeutics, Inc. (NASDAQ: KRTX) ("Karuna") today announced that they have entered into a definitive merger agreement under which Bristol Myers Squibb has agreed to acquire Karuna for \$330.00 per share in cash, for a total equity value of \$14.0 billion, or \$12.7 billion net of estimated cash acquired. The transaction was unanimously approved by both the Bristol Myers Squibb and Karuna Boards of Directors.

Karuna is a biopharmaceutical company driven to discover, develop and deliver transformative medicines for people living with psychiatric and neurological conditions. Karuna's lead asset, KarXT (xanomeline-trospium), is an antipsychotic with a novel mechanism of action (MoA) and differentiated efficacy and safety. Karuna's New Drug Application (NDA) for KarXT for the treatment of schizophrenia in adults was accepted for review by the U.S. Food and Drug Administration (FDA), with a Prescription Drug User Fee Act (PDUFA) date of September 26, 2024. KarXT is also in registrational trials both for adjunctive therapy to existing standard of care agents in schizophrenia and for the treatment of psychosis in patients with Alzheimer's disease. Bristol Myers Squibb believes KarXT represents a significant revenue contribution opportunity. Bristol Myers Squibb also sees potential from Karuna's early-stage and pre-clinical pipeline.

"There are tremendous opportunities in neuroscience, and Karuna strengthens our position and accelerates the expansion and diversification of our portfolio in the space. We expect KarXT to enhance our growth through the late 2020s and into the next decade," said Christopher Boerner, Ph.D., Chief Executive Officer of Bristol Myers Squibb. "This transaction fits squarely within our business development priorities of pursuing assets that are strategically aligned, scientifically sound, financially attractive, and have the potential to address areas of significant unmet medical need. We look forward to welcoming the talented Karuna team to Bristol Myers Squibb."

"Schizophrenia and Alzheimer's disease psychosis affect millions of people worldwide, with limited to no treatment options. KarXT's novel mechanism has resulted in a transformational profile in schizophrenia, with compelling efficacy and a differentiated safety profile," said Samit Hirawat, M.D., Executive Vice President, Chief Medical Officer, Drug Development of Bristol Myers Squibb. "KarXT also has the potential to deliver meaningful benefits to patients as an adjunctive treatment for patients with schizophrenia and as a first treatment for Alzheimer's disease psychosis."

Bill Meury, President and Chief Executive Officer of Karuna Therapeutics, said, "Karuna's portfolio offers advancements in treatment not seen in many years. With Bristol Myers Squibb's long-standing expertise in developing and commercializing medicines on a global scale and legacy in neuroscience, KarXT and the other assets in our pipeline will be well-positioned to reach those living with schizophrenia and Alzheimer's disease psychosis. This announcement is a testament to the Karuna team's talent, hard work, and innovation."

Delivering Meaningful Benefits to Patients with KarXT

KarXT targets both the M1 and M4 muscarinic receptors, resulting in a differentiated safety and efficacy profile. KarXT has demonstrated improvements in cognition and is not associated with common side effects of currently approved treatments, including no meaningful weight gain, extrapyramidal symptoms, increased prolactin levels, akathisia and/or sedation.

Given this differentiated profile, KarXT has meaningful and expanding revenue potential in schizophrenia and with upside in additional indications and geographies:

- **Schizophrenia:** KarXT is expected to launch in late 2024 in the U.S. as a treatment for schizophrenia in adults. There are approximately 1.6 million¹ people treated for schizophrenia in the U.S., a significant portion of whom do not respond to currently available therapies and experience unacceptable side effects.
- **Adjunctive schizophrenia:** A registrational clinical trial is currently underway evaluating KarXT as adjunctive treatment with current standard of care agents for the treatment of schizophrenia, with data expected in 2025.
- **Alzheimer's disease psychosis:** Registrational clinical trials are currently underway evaluating KarXT for the treatment of Alzheimer's disease psychosis, with data expected in 2026. There are more than 6 million² people living with Alzheimer's disease in the U.S. There are currently no approved treatments for Alzheimer's disease psychosis.
- **Additional indications:** Bristol Myers Squibb believes KarXT also has potential in additional indications, including Bipolar I disorder, which impacts approximately 1.4 million¹ people in the U.S., and Alzheimer's disease agitation.

The transaction is expected to be dilutive to Bristol Myers Squibb's non-GAAP diluted earnings per share by approximately \$0.30 in 2024 from the financing cost of the transaction, as Bristol Myers Squibb expects to offset the operational expenses of the transaction through continued resource allocation, cost efficiencies and portfolio prioritization. The accounting treatment as a business combination or asset acquisition will be determined upon the expected close of the transaction. Bristol Myers Squibb expects to finance the acquisition with primarily new debt issuance. Bristol Myers Squibb's cash flows and strong financial profile enable continued commitment to strong investment-grade credit ratings and investment for growth through business development opportunities and distributions to shareholders through ongoing dividends and share repurchases.

Transaction Terms and Financing

Under the terms of the merger agreement, Bristol Myers Squibb will acquire all outstanding shares of Karuna common stock for \$330.00 per share in cash representing an approximately 53.4% premium to Karuna Therapeutic's closing stock price on December 21, 2023, for a total equity value of approximately \$14.0 billion, or \$12.7 billion net of estimated cash acquired.

The transaction is expected to close in the first half of 2024, subject to customary closing conditions, including approval of Karuna stockholders and receipt of required regulatory approvals.

Conference Call Information

Bristol Myers Squibb will host a conference call today, Friday, December 22, 2023, at 8:00 a.m. ET during which company executives will review discuss the transaction and address inquiries from investors and analysts. Investors and the general public are invited to listen to a live webcast of the call at <http://investor.bms.com>.

Investors and the public can register for the live conference call [here](#). Those unable to register can access the live conference call by dialing in the U.S. toll-free 1-866-777-2509 or international +1 412-317-5413. Materials related to the call will be available at <http://investor.bms.com> prior to the start of the conference call.

A replay of the webcast will be available at <http://investor.bms.com> approximately three hours after the conference call concludes. A replay of the conference call will be available beginning at 11:30 a.m. ET on December 22, 2023, through 11:30 a.m. ET on January 4, 2024, by dialing in the U.S. toll free 1-877-344-7529 or international +1 412-317-0088, confirmation code: 3194180.

Advisors

Gordon Dyal & Co. and Citi are serving as financial advisors to Bristol Myers Squibb, and Covington & Burling LLP is serving as legal counsel. Goldman Sachs & Co. LLC is serving as exclusive financial advisor to Karuna, and Simpson Thacher & Bartlett LLP is serving as legal counsel.

About Bristol Myers Squibb

Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol Myers Squibb, visit us at [BMS.com](https://www.bms.com) or follow us on [LinkedIn](#), [Twitter](#), [YouTube](#), [Facebook](#), and [Instagram](#).

About Karuna Therapeutics

Karuna Therapeutics is a biopharmaceutical company driven to discover, develop, and deliver transformative medicines for people living with psychiatric and neurological conditions. At Karuna, we understand there is a need for differentiated and more effective treatments that can help patients navigate the challenges presented by serious mental illness. Utilizing our extensive knowledge of neuroscience, we are harnessing the untapped potential of the brain in pursuit of novel pathways to develop medicines that make meaningful differences in peoples' lives. For more information, please visit www.karunatx.com.

Additional Information and Where to Find It

In connection with the proposed acquisition of Karuna Therapeutics by Bristol Myers Squibb, Karuna Therapeutics intends to file a preliminary and definitive proxy statement. The definitive proxy statement and proxy card will be delivered to the stockholders of Karuna Therapeutics in advance of the special meeting relating to the proposed acquisition. This press release is not a substitute for the proxy statement or any other document that may be filed by Karuna Therapeutics with the SEC. KARUNA THERAPEUTICS' STOCKHOLDERS AND INVESTORS ARE URGED TO READ THE DEFINITIVE PROXY STATEMENT IN ITS ENTIRETY WHEN IT BECOMES AVAILABLE AND ANY OTHER DOCUMENTS FILED BY EACH OF BRISTOL MYERS SQUIBB AND KARUNA THERAPEUTICS WITH THE SEC IN CONNECTION WITH THE PROPOSED ACQUISITION OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED ACQUISITION AND THE PARTIES TO THE PROPOSED ACQUISITION. Investors and security holders will be able to obtain a free copy of the proxy statement and such other documents containing

important information about Bristol Myers Squibb and Karuna Therapeutics, once such documents are filed with the SEC, through the website maintained by the SEC at www.sec.gov. Bristol Myers Squibb and Karuna Therapeutics make available free of charge at Bristol Myers Squibb's website at www.bms.com/investors and Karuna Therapeutics' website at <https://karunatx.com/>, respectively, copies of materials they file with, or furnish to, the SEC.

Participants in the Solicitation

This press release does not constitute a solicitation of a proxy, an offer to purchase or a solicitation of an offer to sell any securities. Bristol Myers Squibb, Karuna Therapeutics and their respective directors, executive officers and certain employees may be deemed to be participants in the solicitation of proxies from the stockholders of Karuna Therapeutics in connection with the proposed acquisition. Information regarding Bristol Myers Squibb's directors and executive officers is contained in Bristol Myers Squibb's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, which was filed with the SEC on February 14, 2023, and its definitive proxy statement for the 2023 annual meeting of stockholders, which was filed with the SEC on March 23, 2023. Information regarding Karuna Therapeutics' directors and executive officers is contained in Karuna Therapeutics' definitive proxy statement for the 2023 annual meeting of stockholders, which was filed with the SEC on April 27, 2023. To the extent holdings of Bristol Myers Squibb's or Karuna Therapeutics' securities by their respective directors or executive officers have changed since the amounts set forth in such 2023 proxy statements, such changes have been or will be reflected on Initial Statements of Beneficial Ownership on Form 3 or Statements of Beneficial Ownership on Form 4 filed with the SEC. Additional information regarding the identity of potential participants, and their direct or indirect interests, by security holdings or otherwise, will be included in the definitive proxy statement relating to the proposed acquisition when it is filed with the SEC. These documents (when available) may be obtained free of charge from the SEC's website at www.sec.gov, Bristol Myers Squibb's website at www.bms.com and Karuna Therapeutics' website at <https://karunatx.com/>.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, regarding, among other things, the proposed acquisition of Karuna Therapeutics by Bristol Myers Squibb, the expected timetable for completing the transaction, future opportunities for the combined businesses, the expected benefits of Bristol Myers Squibb's acquisition of Karuna Therapeutics and the development and commercialization of Karuna Therapeutics' product candidates, including the therapeutic and commercial potential of KarXT and Karuna Therapeutics' other technologies and products in development. These statements may be identified by the fact they use words such as "should," "could," "expect," "anticipate," "estimate," "target," "may," "project," "guidance," "intend," "plan," "believe," "will" and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance, although not all forward-looking statements contain such terms. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. These statements are only predictions, and such forward-looking statements are based on current expectations and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them, that are difficult to predict, may be beyond our control and could cause actual outcomes and results to differ materially from those expressed in, or implied by, the forward-looking statements. Actual results may differ materially because of numerous risks and uncertainties including with respect to (i) the approval of Karuna Therapeutics' stockholders of the proposed acquisition, which may be delayed or may not be obtained, (ii) the risk that the expected benefits or synergies of the acquisition will not be realized, (iii) the risk that legal proceedings may be instituted related to the merger agreement, (iv) any competing offers or acquisition proposals for Karuna Therapeutics, (v) the possibility that various conditions to the consummation of the acquisition may not be satisfied or

waived, including that a governmental entity may prohibit, delay or refuse to grant approval for the acquisition and (vii) unanticipated difficulties or expenditures relating to the proposed acquisition, including the response of business partners and competitors to the announcement of the proposed acquisition or difficulties in employee retention as a result of the announcement and pendency of the proposed acquisition. The actual financial impact of this transaction may differ from the expected financial impact described in this press release. In addition, the compounds described in this press release are subject to all the risks inherent in the drug development process, and there can be no assurance that the development of these compounds will be commercially successful. No forward-looking statement can be guaranteed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect Bristol Myers Squibb's business and market, particularly those identified in the cautionary statement and risk factors discussion in Bristol Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2022, and Karuna Therapeutics' business, particularly those identified in the risk factors discussion in Karuna Therapeutics' Annual Report on Form 10-K for the year ended December 31, 2022, as well as other documents that may be filed by Bristol Myers Squibb or Karuna Therapeutics from time to time with the SEC. Neither Bristol Myers Squibb nor Karuna Therapeutics undertakes any obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. The forward-looking statements made in this press release relate only to events as of the date on which the statements are made and readers are cautioned not to place undue reliance on such statements.

Use of Non-GAAP Financial Information and Financial Guidance

In discussing financial guidance, Bristol Myers Squibb refers to financial measures that are not in accordance with U.S. Generally Accepted Accounting Principles (GAAP). The non-GAAP financial measures are provided as supplemental information to the financial measures presented in this communication that are calculated and presented in accordance with GAAP and are presented because management has evaluated the company's financial results both including and excluding the adjusted items or the effects of foreign currency translation, as applicable, and believes that the non-GAAP financial measures presented portray the results of the company's baseline performance, supplement or enhance management, analysts and investors overall understanding of the company's underlying financial performance and trends and facilitate comparisons among current, past and future periods.

Non-GAAP earnings and related EPS information are adjusted to exclude certain costs, expenses, gains and losses and other specified items that are evaluated on an individual basis after considering their quantitative and qualitative aspects and typically have one or more of the following characteristics, such as being highly variable, difficult to project, unusual in nature, significant to the results of a particular period or not indicative of past or future operating results. These items are excluded from non-GAAP earnings and related EPS information because Bristol Myers Squibb believes they neither relate to the ordinary course of Bristol Myers Squibb's business nor reflect Bristol Myers Squibb's underlying business performance. Similar charges or gains were recognized in prior periods and will likely reoccur in future periods.

Because the non-GAAP financial measures are not calculated in accordance with GAAP, they should not be considered superior to or as a substitute for the related financial measures that are prepared in accordance with GAAP and are not intended to be considered in isolation and may not be the same as or comparable to similarly titled measures presented by other companies due to possible differences in method and in the items being adjusted. We encourage investors to review our financial statements and publicly-filed reports in their entirety and not to rely on any single financial measure.

A reconciliation of the forward-looking non-GAAP measures presented in this communication is not provided due to the inherent difficulty in forecasting and quantifying items that are necessary for such reconciliation. Namely, we are

not able to reliably predict the impact of specified items such as unwind of inventory purchase price adjustments, accelerated depreciation and impairment of property, plant and equipment and intangible assets and stock compensation resulting from acquisition-related equity awards, or currency exchange rates beyond the next twelve months. As a result, the reconciliation of these non-GAAP measures to the most directly comparable GAAP measures is not available without unreasonable effort. In addition, Bristol Myers Squibb believes such a reconciliation would imply a degree of precision and certainty that could be confusing to investors. The variability of the specified items may have a significant and unpredictable impact on our future GAAP results. In addition, the non-GAAP financial guidance in this communication excludes the impact of any potential additional future strategic acquisitions and divestitures and any specified items that have not yet been identified and quantified. The financial guidance is subject to risks and uncertainties applicable to all forward-looking statements as described elsewhere in this communication.

About PureTech Health

PureTech is a clinical-stage biotherapeutics company dedicated to giving life to new classes of medicine to change the lives of patients with devastating diseases. The Company has created a broad and deep pipeline through its experienced research and development team and its extensive network of scientists, clinicians and industry leaders that is being advanced both internally and through its Founded Entities. PureTech's R&D engine has resulted in the development of 28 therapeutics and therapeutic candidates, including two (Plenity[®] and EndeavorRx[®]) that have received both US FDA clearance and European marketing authorization and a third (KarXT) that has been filed for FDA approval. A number of these programs are being advanced by PureTech or its Founded Entities in various indications and stages of clinical development, including registration enabling studies. 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.

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

Cautionary Note Regarding Forward-Looking Statements

This press release contains statements that are or may be 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 related to the definitive merger agreement under which Bristol Myers Squibb has agreed to acquire Karuna, the acceptance of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for KarXT (xanomeline-trospium) for the treatment of schizophrenia and Karuna's and PureTech's 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, 2022 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.

¹ Source: DRG - Clarivate, as of July 2023.

² Source: "Alzheimer's Disease Association Facts and Figures," 2023.

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

This information is provided by Reach, the non-regulatory press release distribution service of RNS, part of the London Stock Exchange. 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

NRAFZMZZFZGGFZM