Twist Bioscience Announces Clinical Progression of Pure Biologics' Antibody Candidate Discovered Using Twist's Antibody Libraries

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Pure Biologics' exploratory Phase 0 study to evaluate pharmacodynamic activity of PBA-0405 in solid tumors

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 18, 2024-- Twist Bioscience Corporation (NASDAQ: TWST), a company enabling customers to succeed through its offering of high-quality synthetic DNA using its silicon platform, today announced that the first patient has been dosed in Pure Biologics' exploratory Phase 0 clinical study of PBA-0405. PBA-0405 is a fully human IgG1 antibody that was discovered using Twist Biopharma Solutions' synthetic antibody phage display libraries. Twist Biopharma Solutions, a division of Twist Bioscience, provides an integrated offering of in vitro, in vivo, and in silico tools for antibody discovery research. This exploratory study is designed to provide early insights into the biological effects of PBA-0405 within the tumor environment.

"Solid tumors are historically difficult for drug developers to target and treat. This is the first antibody identified using our Twist Biopharma Solutions Library of Libraries to be tested in patients and it validates the potential of our synthetic antibody libraries to be used to discover novel drug candidates for hard-to-treat cancer indications," said Emily M. Leproust, Ph.D., CEO and co-founder of Twist Bioscience. "This is one of two of Pure's candidates discovered using our synthetic antibody libraries and we look forward to seeing their progression."

PBA-0405 targets ROR1, a tumor-associated antigen expressed on many solid tumors and B cell malignancies. PBA-0405 is designed to make tumors visible to the immune system, and to induce an immune response by recruiting and activating tumor-killing cytotoxic immune cells.

Pure Biologics' multi-center, single arm, open-label pharmacodynamic biomarker Phase 0 trial is designed to study the biological effects within the tumor microenvironment of PBA-0405 when administered intratumorally in microdose quantities via the CIVO device. The study will evaluate the pharmacodynamic activity of PBA-0405 in solid tumors including head and neck squamous cell carcinoma, certain subtypes of soft-tissue sarcomas and triple-negative breast cancer. Pure Biologics is conducting the clinical study and holds full responsibility for the development and potential regulatory submission of PBA-0405. ClinicalTrials.gov ID NCT06273852

"With the dosing of the first patient in our exploratory Phase 0 study, PBA-0405 is the first ROR1-targeting compound of its mode of action to enter into studies in patients. We're encouraged by the preclinical data we've seen so far and are eager to evaluate its pharmacodynamic activity in human studies," said Pieter Spee, PhD, Chief Scientific Officer at Pure Biologics. "By working with Twist Bioscience to leverage their synthetic antibody libraries for early-stage discovery, we were able to move quickly to the development stage. We look forward to continuing to advance our pipeline of immuno-oncology antibody candidates and drive toward our goal of delivering first-in-class therapies to patients."

About the Collaboration

PBA-0405 was discovered as part of an ongoing collaboration between Twist Bioscience and Pure Biologics. Under the terms of the agreement announced in 2021, Twist Biopharma Solutions, a division of Twist Bioscience, grants Pure Biologics access to select synthetic antibody phage display libraries derived only from sequences that exist in the human body and further optimized by leveraging state-of-the-art approaches, including artificial intelligence and big data analytics. Certain libraries among the portfolio are deliberately tailored to match chosen classes of biological targets as well as to enhance bispecific antibody forming capabilities. Together, the companies work to discover, validate and optimize new antibody candidates against targets useful for immuno-oncology applications. Pure Biologics will pay Twist annual maintenance fees in addition to future payments for clinical and commercial achievement for any antibodies resulting from the collaboration. The Phase 0 study does not trigger a milestone payment for Twist.

About Twist Biopharma Solutions (The Biologics Discovery and Optimization Division of Twist Bioscience)

Twist Biopharma Solutions combines high-throughput DNA synthesis technology, deep expertise in antibody engineering and in vivo, in vitro and in silico discovery methods to provide end-to-end antibody discovery solutions across the preclinical continuum and tailored to our partners' specific needs. By leveraging our unique ability to manufacture DNA at scale, we can construct proprietary antibody libraries with discovery beginning with either in vivo or in vitro diversity. Our Library of Libraries gives our partners an integral and unbiased resource for antibody therapeutic discovery and optimization. This precise and rational approach to library fabrication combined with sophisticated bioinformatics and software expertise expedites antibody discovery by decreasing risk, increasing speed, and lowering the failure rate for antibody therapeutic development. Additionally, in vivo discovery approaches including single B cell screening and hybridoma discovery enable parallel paths where multiple technology methods can be leveraged to create a panel of highly diverse antibody leads. Our automated screening and panning processes enable us to identify high affinity leads that our partners can move forward into the clinic. We also offer supporting development capabilities, including IgG conversion, expression, purification, biophysical characterization, and functional characterization.

For more information visit: https://www.twistbioscience.com/twist-biopharma-solutions

About Twist Bioscience Corporation

Twist Bioscience is a leading and rapidly growing synthetic biology and genomics company that has developed a disruptive DNA synthesis platform to industrialize the engineering of biology. The core of the platform is a proprietary technology that pioneers a new method of manufacturing synthetic

DNA by “writing” DNA on a silicon chip. Twist is leveraging its unique technology to manufacture a broad range of synthetic DNA-based products, including synthetic genes, tools for next-generation sequencing (NGS) preparation, and antibody libraries for drug discovery and development. Twist is also pursuing longer-term opportunities in digital data storage in DNA and biologics drug discovery. Twist makes products for use across many industries including healthcare, industrial chemicals, agriculture and academic research.

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Twist Bioscience Legal Notice Regarding Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts contained herein are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 including but not limited to, statements regarding the potential of Twist Bioscience’s synthetic antibody libraries to be used to discover candidates for hard-to-treat cancer indications; the potential benefits of any of Pure Biologics’ current or future product candidates in treating patients, including the potential of PBA-0405 to make tumors visible to the immune system and to induce an immune response by recruiting and activating tumor-killing cytotoxic immune cells; and the potential achievement of any clinical and commercial milestones resulting from the collaboration between Twist Bioscience and Pure Biologics. Forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause Twist Bioscience’s actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the ability to achieve the expected benefits of Twist Bioscience’s restructuring activities and reduced investments in DNA data storage; the ability to attract new customers and retain and grow sales from existing customers; the ability of Twist Bioscience to achieve sufficient revenue to achieve or maintain positive cash flow from operations or profitability in any given period; risks and uncertainties of rapidly changing technologies and extensive competition in synthetic biology that could make the products Twist Bioscience is developing obsolete or non-competitive; uncertainties of the retention of significant customers; the ability of Twist Bioscience to successfully integrate acquired companies and to achieve expected benefits from acquisitions; supply chain and other disruptions; risks of third party claims alleging infringement of patents and proprietary rights or seeking to invalidate Twist Bioscience’s patents or proprietary rights; and the risk that Twist Bioscience’s proprietary rights may be insufficient to protect its technologies. For a description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Twist Bioscience’s business in general, see Twist Bioscience’s risk factors set forth in Twist Bioscience’s Annual Report on Form 10-K filed with the SEC on November 21, 2023 and subsequent filings with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and Twist Bioscience specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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