Twist Bioscience Launches Circulating Tumor DNA Reference Controls for Development of Liquid Biopsy Assays

December 7, 2021

– Represents First Industry Standard Control for Cancer Testing –

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Dec. 7, 2021-- Twist Bioscience Corporation (NASDAQ: TWST), a company enabling customers to succeed through its offering of synthetic DNA using its silicon platform, today announced the launch of the Twist cfDNA Pan-cancer Reference Standards, a high-quality standardized control for use in the development and continuous monitoring of liquid biopsy tests to detect cancer from blood samples.

Liquid biopsy tests, which rely on NGS-based circulating tumor DNA (ctDNA) analysis, are a promising and growing area in clinical oncology. Liquid biopsy assays can accurately identify a single tumor variant in the presence of thousands of healthy cells. The most sought-after applications in the ctDNA field include early detection of disease, personalization of therapy, monitoring response to therapy, and monitoring for relapse of disease. Developing and standardizing these ultra-sensitive yet accurate ctDNA-based assays is paramount to ensure the resulting analysis from the test informs clinical decisions reliably.

“As the number of clinical validations of liquid biopsies increase, a true ctDNA pan-cancer reference standard, beyond the few variants that are widely available today, will increase liquid biopsies’ accuracy in detecting specific oncogenes and variants,” said Florian Battke, director of development at CeGaT GmbH. “There is an obvious benefit of using a synthetic approach like the Twist ctDNA standards, as they are very high quality and closely mimic the properties of real samples without the instability.”

The Twist cfDNA Pan-cancer Reference Standards material consists of synthetically designed variant sequences that mimic ctDNA combined with background DNA that is derived from, and closely mimics, human-derived cell-free DNA (cfDNA).

This reference standard can be used by researchers to assist in the development of liquid biopsy assays to establish the analytical limit of detection (LoD) for specific cancer variants and as a control to track the quality of an NGS assay workflow to ensure the fidelity of the assay process.

The Twist cfDNA Pan-cancer Reference Standards can be used within the liquid biopsy workflow, which includes Twist Library Preparation Kit and the Twist Mechanical Fragmentation Kit, for maximum efficacy and provides a large and diverse number of clinically relevant variants, combining best in class methods for variant synthesis with unrivaled control over the specific target allele frequencies in a format which closely mimics the size distribution and fragmentation profile of cfDNA. In contrast, traditional reference standards are limited in the number and variation of variants and typically use cell line-derived DNA which can carry unwanted sequence variations and variable fragment length.

Emily Leproust, CEO and co-founder of Twist Bioscience said, “Building on the success of our SARS-CoV-2 positive controls that are now used in COVID-19 tests worldwide, we believe having precise standard cancer reference controls that can be used in a validated workflow will be a gamechanger to confirm clinical insights from genetic information. While it is possible to create cell-based controls specific to each test, using a robust, precise control set that detects variation in test assays will be pivotal in both development and ongoing monitoring of a wide variety of liquid biopsy assays.”

Applying the right reference materials is essential to benchmark the complexity and biological content of DNA found in liquid biopsy samples for assay development and validation. The Twist ctDNA reference material contains over 400 variants, including SNVs, indels, fusions and structural variants, as well as more than 140 clinically relevant variants. All variants are offered with a unique tiling design, which accurately mimics the pattern of naturally derived ctDNAs. All of these features make the Twist ctDNA reference a high-quality standard for the ctDNA variants that cancer liquid biopsy assays are designed to detect.

To demonstrate the limit of detection (LoD) of an ultra sensitive NGS-based liquid biopsy assay, using an accurately quantified ctDNA control is key. Twist’s silicon platform provides an advantage by specifically writing individual variants of interests, thus preventing any interference caused by contaminants derived from cell culture-based methods. Twist’s ctDNA reference material is also well-characterized and quantified, using industry-standard and proprietary methods (NGS, ddPCR, and fluorescence-based quantification).

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.

Legal Notice Regarding Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts contained herein, including without

limitation the expected impact of the Twist ctDNA reference standards, 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. Such 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 risks and uncertainties of the ability to attract new customers and retain and grow sales from existing customers; risks and uncertainties of rapidly changing technologies and extensive competition in synthetic biology could make the products Twist Bioscience is developing obsolete or non-competitive; the retention of employees of acquired companies and the ability of Twist Bioscience to successfully integrate acquired companies and to achieve expected benefits, 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 further 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 Form 10-K filed with the Securities and Exchange Commission on November 23, 2021, 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 because of new information, future events or otherwise.

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Source: Twist Bioscience Corporation