



BillionToOne's Tissue-Free Northstar Response® Demonstrates On-Par to Superior Cancer Treatment Monitoring vs. Tumor-Informed Assay, New Peer-Reviewed Study Finds

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Head-to-head comparison shows 94% concordance with tumor-informed ctDNA testing, with the clinical ground-truth in all discordant cases supporting Northstar Response

MENLO PARK, Calif., Oct. 07, 2026 (GLOBE NEWSWIRE) -- BillionToOne, Inc. (Nasdaq: BLLN), a next-generation molecular diagnostics company with a mission to create powerful and accurate tests that are accessible to all, announced the publication of the first peer-reviewed head-to-head [study](#) comparing Northstar Response®, a tissue-free, methylation-based liquid biopsy assay utilizing patented single-molecule counting technology to measure the absolute number of circulating tumor DNA (ctDNA) molecules, with a commercially available tumor-informed ctDNA assay for advanced cancer patients undergoing treatment. The study found that Northstar Response tracked disease dynamics on par with or better than the tumor-informed comparator, without requiring tissue sequencing.

The retrospective real-world study, published in *The Journal of Liquid Biopsy*, evaluated 169 paired samples from 61 patients, with 71 samples from 36 patients that had sequential concurrent draws for the two assays collected within seven days of each other. Quantitative results, after patient-specific baseline normalization, across repeated measurements were shown to be closely aligned (conditional $R^2 = 0.97$). Across evaluable sequential pairs, the two approaches reached the same conclusion of the change in tumor burden direction in 94% of cases (67 of 71).

Importantly, in all of the divergent cases, Northstar Response results were concordant with the ground truth substantiated by imaging and/or biopsy, indicating that the tumor-informed results were either false-positives or false-negatives. For instance, Northstar Response detected progression in cases where the tumor had evolved since the original biopsy, including a case of hormone receptor conversion in advanced breast cancer. Together, the cases illustrate the particular value of tumor-agnostic monitoring to track tumor burden and evolution.

"The ability to combine cancer-associated methylation with single-molecule precision to track changing tumor signal directly from blood is game-changing, as so many patients in the clinic will benefit," said Vaia Florou, MD, MS, Associate Professor Division of Oncology at the Huntsman Cancer Institute at the University of Utah. "These results showing that a standardized assay can deliver precise longitudinal monitoring without tissue dependency are incredibly relevant for those of us practicing on the frontlines of cancer care."

Since Northstar Response is not limited to alterations selected from an earlier tissue sample at a fixed point in time, it can capture clinically meaningful changes in disease biology that emerge under treatment pressure. Northstar Response's simplified workflow can also significantly accelerate the start of molecular monitoring of treatment, potentially by weeks, and enable testing when tissue is unavailable, inadequate, or difficult to biopsy.

"Not only does Northstar Response deliver highly accurate insight into how disease is evolving during treatment, but it also has the added advantage of a streamlined and efficient workflow that can bring molecular testing to more patients," said Allen Chen, MD, Vice President of Oncology Clinical Development and Medical Affairs at BillionToOne. "Treatment monitoring must be both reliable and practical for it to be effective in routine oncology care. These results show that clinicians do not need to compromise one for the other."

About Northstar Response

Northstar Response is BillionToOne's tissue-free, methylation-based ctDNA assay purpose-built for treatment response monitoring in patients with cancer. Powered by the company's patented QCT™ molecular counting platform -- the only multiplex technology capable of counting DNA molecules at the single-molecule level -- Northstar Response quantifies tumor burden through serial blood draws with no dependence on tumor tissue at any stage of the patient journey.

About BillionToOne

Headquartered in Menlo Park, California, BillionToOne is a next-generation molecular diagnostics company with a mission to create powerful and accurate tests that are accessible to all. The company's proprietary single-molecule next-generation sequencing (smNGS) platform is the only multiplex technology that can detect and precisely quantify genetic targets at the physical limit of detection, down to the single DNA molecule. Enabled by Quantitative Counting Templates™ (QCTs™), the platform quantifies disease-related DNA fragments with single base-pair resolution, providing absolute quantification. For more information, visit www.billiontoone.com.

Disclaimer

Northstar Response may produce false-positive or false-negative results. Test results are not a guarantee of the presence or absence of disease or treatment response and should not be used as the sole basis for medical decision-making. Results should be interpreted in conjunction with the patient's clinical presentation, radiographic findings, and other diagnostic information. Northstar Response is intended to complement, not replace, standard clinical and radiographic assessment of disease status. Northstar Response is a laboratory-developed test (LDT) performed in a CLIA-certified and CAP-accredited laboratory. The test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). Test performance may vary based on factors including cancer type, disease burden, treatment, and specimen characteristics.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of federal securities laws. These forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will," "would," "will be," "will continue," "will likely result," and similar expressions. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Forward-looking statements in this press release include, but are not limited to, statements regarding the clinical performance of Northstar Response. These statements are based on management's current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, some of which are beyond BillionToOne's control. These and additional risks and uncertainties could affect BillionToOne's financial and operating results and cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. These risks and uncertainties include, but are not limited to, those discussed

under the captions “Risk Factors” and “Management's Discussion and Analysis of Financial Condition and Results of Operation” and elsewhere in BillionToOne's Annual Report on Form 10K, most recently filed Quarterly Report on Form 10-Q, and other filings we make with the Securities and Exchange Commission from time to time. The forward-looking statements in this press release are based on information available to BillionToOne as of the date hereof, and BillionToOne disclaims any obligation to update any forward-looking statements provided to reflect any change in its expectations or any change in events, conditions, or circumstances on which any such statement is based, except as required by law. These forward-looking statements should not be relied upon as representing BillionToOne's views as of any date subsequent to the date of this press release.

Reference

Choksi A, Varga MG, Farmer T, et al. Concordance of tumor-informed and tumor-agnostic ctDNA assays for treatment response monitoring in advanced solid tumors. The Journal of Liquid Biopsy. Volume 14, 2026, 100669.

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