Burning Rock's Liquid Biopsy Assay Achieved Strong Performance in the FDA-led SEQC2 Study, with Results Published on Nature Biotechnology

April 13, 2021

GUANGZHOU, China, April 13, 2021 (GLOBE NEWSWIRE) -- Burning Rock Biotech Limited (NASDAQ: BNR, the "Company" or "Burning Rock") today announced that its liquid biopsy assay has achieved strong performance in the FDA-led Sequencing Quality Control Phase 2 (SEQC2) study, the results of which have been published on Nature Biotechnology.

The ability to diagnose and monitor cancer through circulating-tumor DNA (ctDNA) sequencing promises to revolutionize clinical oncology. Accordingly, there is considerable interest and investment in the ongoing development of NGS-based ctDNA assays. Yet the reliable detection of trace amounts of fragmented ctDNA from a routine blood-draw remains a major technical challenge.

The sequencing quality control (SEQC) series of projects is an FDA-led community wide consortium effort to address issues relating to the application of constantly evolving high-throughput genomics technologies. As part of the SEQC2 study, a multi-site, cross-platform evaluation of the analytical performance of five industry-leading circulating-tumor DNA (ctDNA) assays was performed. The study provides the first large-scale assessment of analytical performance among industry-leading ctDNA assays.

Burning Rock's liquid biopsy assay achieved strong performance in this study. For samples at 25ng input, Burning Rock's assay (BRP) was the most accurate assay, with roughly equivalent sensitivity but superior precision compared to other assays. This is shown in the precision-recall curves below which rank known variants and false-positives according to the observed variant allele frequencies (VAF).

Fig 1. Precision recall curves compare diagnostic performance of participating ctDNA assays for Lbx-low (25 ng input; VAF range, 2.5–0.1%): https://www.globenewswire.com/NewsRoom/AttachmentNg/e6441fea-62f3-4b91-b162-a733a8fe7c5b

Burning Rock's panel (BRP) is one of the most sensitive NGS-based liquid biopsy panels in this study. When the VAF is as low as 0.3-0.5%, the panel's sensitivity is still higher than 90%.

Fig 2. (upper), Ordered heat maps show the detection of known variants (rows) in ctDNA assay replicates (columns). All on-target variants for a given assay are shown. Variants are sorted by expected VAF in descending order, and replicates are arranged hierarchically by assay type, test lab and replicate number. Heat maps show results for Lbx-low at 25 ng input.

(lower), Aligned below each heat map column, bar charts indicate the sensitivity of variant detection in each replicate. Sensitivity is reported separately for known variants in the following VAF ranges: 2.5–0.5%, 0.5–0.3%, 0.3–0.2% and 0.2–0.1%, with measurements taken from both Lbx-high (high and mid VAF) and Lbx-low (low VAF).

https://www.globenewswire.com/NewsRoom/AttachmentNg/11172384-dc2d-405b-a879-16b4134df536

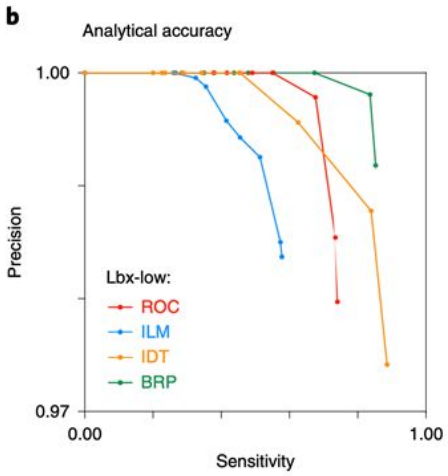
After accounting for panel sizes, Burning Rock's panel (BRP) exhibited the lowest false-positive rate (0.03 FP/kb).

Table 1. The false-positive rates of different panels at the DNA input of 25 ng: https://www.globenewswire.com/NewsRoom/AttachmentNg/59522686-fe01-45d5-bc12-bd1f334dd89e

Overall, the greater fragment depth achieved by an assay at a given input level, the more robust that assay was to variation in input quantity, with Burning Rock's assay being the most stable.

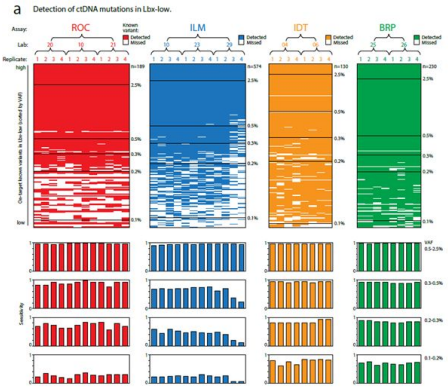
Liquid biopsy is increasingly being used by clinicians due to its clear, complementary advantages over tissue (accounting for 44% of Burning Rock's central lab testing volume in 2020, with the rest being tissue-based testing). The collection of ctDNA is fast, cheap and minimally invasive and can be performed serially to monitor tumor evolution or response to therapy. CtDNA can also provide a representative cross-section of heterogeneous tumors and multi-focal disease. Burning Rock will continue its efforts of advancing existing and new ctDNA-based testing products, so

Analytical Accuracy



Precision recall curves compare diagnostic performance of participating ctDNA assays for Lbx-low (25 ng input; VAF range, 2.5–0.1%).

Detection of ctDNA mutations in Lbx-low



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that more cancer patients may benefit from the latest developments in precision oncology technology.

The publication, titled “Evaluating the analytical validity of circulating tumor DNA sequencing assays for precision oncology”, can be found here.

About Burning Rock

Burning Rock Biotech Limited (NASDAQ: BNR), whose mission is to guard life via science, focuses on the application of next generation sequencing (NGS) technology in the field of precision oncology. Its business consists of i) NGS-based therapy selection testing for late-stage cancer patients, with the leading market share in China and over 273,000 tissue and liquid-based tests completed cumulatively, and ii) cancer early detection, which has moved beyond proof-of-concept R&D into the clinical validation stage.

For more information about Burning Rock, please visit: ir.brbiotech.com.

Table

Assay	Known negatives (kb)	FPs per replicate (mean [range])	FP-rate (FP / kb) at specified VAF threshold		
			> 0%	> 0.1%	> 0.5%
ROC	47.1	2.91 [1-6]	0.061	0.044	0.000
ILM	133	5.25 [2-10]	0.039	0.039	0.008
IDT	39.3	2.75 [0-6]	0.070	0.057	0.000
BRP	53.4	1.65 [0-5]	0.030	0.007	0.000

The false-positive rates of different panels at the DNA input of 25 ng

Safe Harbor Statement

This press release contains forward-looking statements. These statements constitute “forward-looking” statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and as defined in the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by terminology such as “will,” “expects,” “anticipates,” “future,” “intends,” “plans,” “believes,” “estimates,” “target,” “confident” and similar statements. Burning Rock may also make written or oral forward-looking statements in its periodic reports to the SEC, in its annual report to shareholders, in press releases and other written materials and in oral statements made by its officers, directors or employees to third parties. Statements that are not historical facts, including statements about Burning Rock’s beliefs and expectations, are forward-looking statements. Such statements are based upon management’s current expectations and current market and operating conditions, and relate to events that involve known or unknown risks, uncertainties and other factors, all of which are difficult to predict and many of which are beyond Burning Rock’s control. Forward-looking statements involve risks, uncertainties and other factors that could cause actual results to differ materially from those contained in any such statements. All information provided in this press release is as of the date of this press release, and Burning Rock does not undertake any obligation to update any forward-looking statement as a result of new information, future events or otherwise, except as required under applicable law.

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