

## Riken Genesis Receives Regulatory Approval in Japan for Burning Rock's OncoGuide™ OncoScreen™ Plus CDx System to Guide Capivasertib Companion with Indications for *PIK3CA*, *AKT1*, or *PTEN* Alterations in Breast Cancer

**Tokyo and Guangzhou — September 24, 2025**

Riken Genesis Co., Ltd. (Riken Genesis) and Burning Rock Biotech Limited (NASDAQ: BNR, “Burning Rock”) today announced that the OncoGuide™ OncoScreen™ Plus CDx System based on OncoScreen™ Plus to be used as a companion diagnostic for AstraZeneca’s capivasertib has received Manufacturing and Marketing Approval from Japan’s Ministry of Health, Labour and Welfare (MHLW).



The CDx System is a combination medical device consisting of the OncoGuide™ OncoScreen™ Plus CDx Kit and the OncoGuide™ OncoScreen™ Plus CDx Analysis Program, designed to be used with a next-generation sequencer. It enables the detection of *PIK3CA*, *AKT1*, and *PTEN* alterations in a single test. This diagnostic tool is intended to guide treatment decisions for adult patients with unresectable or recurrent hormone-receptor (HR)-positive, HER2-negative breast cancer who have progressed following endocrine therapy and whose tumors carry one or more *PIK3CA*, *AKT1*, or *PTEN* gene alterations.

The approval of this CDx system supports the use for patient selection for capivasertib in combination with fulvestrant.

With the introduction of this CDx System into clinical practice, access to precision

diagnostics for breast cancer patients in Japan is expected to improve, ultimately expanding therapeutic opportunities. Riken Genesis will begin preparations for insurance coverage, aiming to ensure timely and equitable access for all eligible patients.

Yusheng Han, Founder and CEO of Burning Rock, commented:

"We are delighted to collaborate with Riken Genesis to achieve the approval of the CDx System in Japan. This is a significant milestone in Burning Rock's global strategy. Research shows that this CDx System can assist in guiding clinical treatment for breast cancer, optimizing treatment plans, and enhancing patient outcomes. We are concurrently advancing the product's registration application in China, hoping that its approval there will benefit more breast cancer patients."

Yuko Oi, President and CEO of Riken Genesis, commented:

"We are honored to receive our first approval for a combination medical device product in partnership with Burning Rock. This achievement represents a promising step toward expanding treatment options for breast cancer patients in Japan. We are committed to delivering this innovative diagnostic tool to patients as quickly as possible."

## **Notes**

### **1 Combination Medical Device:**

A combination of two or more types of items (pharmaceuticals, medical devices or regenerative medicines) constituting a medical device to be manufactured and marketed.

### **2 Companion diagnostics:**

Clinical testing performed to predict the efficacy and side effects of drugs before using them for treatment, particularly testing that is performed at the same time as pharmaceutical development.

### About OncoGuide™ OncoScreen™ Plus CDx System

(1) Product name	OncoGuide™ OncoScreen™ Plus CDx System		
(2) Approval No.	30700BZX00235000		
(3) Components	a combination medical device OncoGuide™ OncoScreen™ Plus CDx Kit OncoGuide™ OncoScreen™ Plus CDx Analysis Program		
(4) Testing method	Next-Generation Sequencing (NGS)		
(5) Specimen	DNA extracted from FFPE tumor tissue		
(6) Purpose of use	This CDx System is intended to detect relevant genetic alterations to assist in determining the indications for the pharmaceutical products listed below.		
	Gene	Indication	Drug Trade Name (Generic)
	AKT1	Breast Cancer	Truqap® (Capivasertib)
	PIK3CA		
	PTEN		
(7) Marketing Authorization Holder	Riken Genesis Co., Ltd.		
(8) Manufacturer	Guangzhou Burning Rock Dx Co., Ltd.*		

\* Guangzhou Burning Rock Dx Co., Ltd is a variable interest entity's subsidiary of Burning Rock.

### About Riken Genesis Co., Ltd.

RIKEN GENESIS, founded in October 2007, provides lab-assay services as well as products for genetic testing based on cutting-edge gene analysis technologies and bioinformatics, and has experience in the field of personalized medicine. The company provides highly reliable tests based on international quality standards, as demonstrated by its CLIA certification, being the first organization in Japan to meet this U.S. quality control standard for clinical laboratories.

For more information, please visit: <https://www.rikengenesis.jp>

### **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 1) NGS-based therapy selection testing for late-stage cancer patients, 2) Global pharmaceutical services on biomarker detection and companion diagnostics development, and 3) Early cancer detection which has moved beyond proof-of-concept R&D into the clinical validation stage. Burning Rock provides dedicated services to pharmaceutical partners, encompassing genomic data solutions, clinical trial solutions, precision patient recruitment, and companion diagnostics development and commercialization. Burning Rock has achieved two NMPA-approved IVD kits, four assays with CE marking, and a breakthrough device designation (BDD) received from both US FDA and China NMPA for multi-cancer detection blood test.

For more information about Burning Rock, please visit:  
<https://www.brbiotech.com>

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