NEWS RELEASE

Promega to Develop Microsatellite Instability (MSI) Companion Diagnostic IVD Kit in Collaboration With GSK

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CDx IVD kit will be used to identify patients with the MSI biomarker who may be eligible for potential treatment with Jemperli (dostarlimab-gxly)

MADISON, Wis.--(BUSINESS WIRE)-- **Promega Corporation** today announced it plans to develop and commercialize a microsatellite instability (MSI) companion diagnostic (CDx) IVD kit with GSK to identify adult cancer patients with MSI-H solid tumors who may be eligible for potential treatment with GSK's Jemperli (dostarlimab-gxly). The collaboration agreement leverages the companies' complementary strengths to expand personalized healthcare options to more patients using high quality diagnostic tools and treatments.

"This collaboration underscores our commitment to enabling patient access to targeted therapies," says Alok Sharma, Global Clinical Market Director at Promega. "The results of our MSI biomarker test will be a critical step to identifying patients who may be eligible to receive this drug marketed by GSK."

The future CDx indication under development will utilize the Promega PCR-based five-marker MSI panel with Jemperli, an anti-PD-1 monoclonal antibody (mAb). Jemperli is currently approved for patients with mismatch repair deficient (dMMR) recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options. The FDA granted accelerated approval to Jemperli for this indication in August 2021. The development of this CDx IVD kit is part of GSK's post marketing commitment to the FDA to make a companion diagnostic available to support the safe and effective use of Jemperli in patients with MSI-H solid tumors.

Importance of Companion Diagnostics

CDx tests are important for providing an increased level of certainty in the use of many targeted therapeutics. Biomarkers such as MSI status can be used to select the most appropriate and effective therapies for patients, leading to more personalized and targeted medical interventions, and often enhanced treatment outcomes.

Promega continues to advance precision medicine by partnering with pharmaceutical companies and clinical research organizations (CROs) to develop novel solutions across a wide range of disease areas. The company offers global scientific expertise, regulatory capabilities and resources crucial to navigating the development path for a regulatory-approved CDx and successful market adoption. Learn more about Promega CDx services at **https://www.promega.com/applications/companion-diagnostic-cdx-services/**

Promega MSI Global Portfolio

MSI is a genetic condition characterized by the accumulation of errors or mutations in short repetitive DNA sequences known as microsatellites. Tumors with MSI-High (MSI-H) status often show higher response rates for immune checkpoint inhibitor (ICI) therapies such as anti-PD-1 mAb drugs. As a result, MSI testing has become an important tool for identifying cancer patients who may benefit from such therapies.

Promega has more than 19 years of experience in MSI research. The company's market-leading PCR method has been used extensively in clinical research around the world and is supported by **225+ independent peer-reviewed publications** across 25 different cancer types. The Promega five-marker MSI panel is widely considered the "gold standard" of MSI testing for its accuracy1,2.

The company's **OncoMate™ MSI Dx Analysis System** (OncoMate™ MSI) has been cleared by the FDA as an IVD medical device to determine MSI status in colorectal cancer tumors. OncoMate™ MSI is a CE-marked IVD medical device in the EU and United Kingdom to determine MSI status from solid tumors. Promega has received innovation status and priority review by the NMPA in China and also intends to seek regulatory clearance for a Promega MSI IVD in China.

About Promega Corporation

Promega Corporation is a leader in providing innovative solutions and technical support to the life sciences industry. The company's portfolio of over 4,000 products supports a range of life science work across areas such as cell biology; DNA, RNA and protein analysis; drug development; human identification and molecular diagnostics. These tools and technologies have grown in their application over the last 45 years and are used today by scientists and technicians in labs for academic and government research, forensics, pharmaceuticals, clinical diagnostics and

agricultural and environmental testing. Promega is headquartered in Madison, WI, USA with branches in 16 countries and over 50 global distributors. Learn more at **www.promega.com**.

1. Gilson, P., Merlin, J.-L., & Harlé, A. 2021, Cancers, 13, 1491, **https://www.ncbi.nlm.nih.gov/pubmed/33804907**
2 Wang, C., Zhang, L., Vakiani, E., & Shia, J. 2022, Modern Pathol, 14, **https://www.nature.com/articles/s41379-022-01109-4**

Penny Patterson
VP, Corporate Affairs
Promega Corporation
Phone: (608) 274-4330
E-mail: **penny.patterson@promega.com**

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