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Promega to develop microsatellite instability companion diagnostic IVD kit in collaboration with GSK

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To identify patients with the MSI biomarker who may be eligible for potential treatment with Jemperli



US-headquartered Promega Corporation has announced plans to develop and commercialise a microsatellite instability (MSI) companion diagnostic (CDx) in vitro diagnostic (IVD) kit with UK-based pharmaceutical company GlaxoSmithKline (GSK) to identify adult cancer patients with MSI-H solid tumorus who may be eligible for potential treatment with GSK's Jemperli (dostarlimab-gxly).

The collaboration agreement leverages the companies' complementary strengths to expand personalised healthcare options to more patients using high quality diagnostic tools and treatments.

The future CDx indication under development will utilise 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 tumours, 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 tumours.

Promega's OncoMate™ MSI Dx Analysis System has been cleared by the US FDA as an IVD medical device to determine MSI status in colorectal cancer tumours.