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Promega brings MSI companion diagnostic IVD kit for cancer patients in China

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Shanghai Promega Biological Products and Shanghai Henlius Biotech, Inc. will develop and commercialize a microsatellite instability (MSI) companion diagnostic IVD kit to identify cancer patients likely to benefit from serplulimab, a novel anti-PD-1 monoclonal antibody (mAb) developed by Henlius for the potential treatment of microsatellite instability-high (MSI-H) solid tumors.

The kit will be available to doctors in the Chinese Mainland to screen for MSI and inform immunotherapy options.

The collaboration agreement allows the companies to leverage complementary strengths. The New Drug Application (NDA) of serplulimab was recently granted priority review by the National Medical Products Administration (NMPA) in China.

Promega has more than 15 years of experience in MSI research, and its MSI assay has been applied to several clinical studies around the world.

The companion diagnostic method being co-developed is multiplex polymerase chain reaction (PCR) by capillary electrophoresis, which is regarded as the “gold standard” of MSI testing in the industry with high accuracy and specificity.

MSI is a form of genomic instability caused by the insertion or deletion of repeating bases called microsatellites during DNA replication and the failure of the mismatch repair (MMR) system to correct these errors. MSI status is a measure of MMR deficiency commonly found in solid tumors.