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Biocartis, BMS partner for MSI test for cancer detection

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Biocartis Announces New Immuno-Oncology Project with Bristol-Myers Squibb Aimed at Registration of Idylla MSI test in China



Biocartis, an innovative molecular diagnostics company has announced a new project under its existing collaborationwith Bristol-Myers Squibb Company (BMS), a global biopharmaceutical company.

The existing collaboration aims at the potential registration and use as a companion diagnostic (CDx) of the Idylla MSI test in connection with immuno-oncology therapies of Bristol-Myers Squibb.

The initial focus under the collaboration is to achieve registration in the United States of the Idylla MSI test as a CDx test in metastatic colorectal cancer (mCRC). Bristol-Myers Squibb and Biocartis have now agreed to add a new project under their collaboration which pursues the registration of the Idylla MSI test as a CDx test in mCRC in the People's Republic of China.

MSI ('Microsatellite Instability') is the result of inactivation of the body's so-called DNA mismatch repair (MMR) system. Consequently, errors that spontaneously occur during the normal process of DNA replication are no longer corrected, contributing to tumor growth and evolution. Approximately 15% of colorectal (CRC) patients and 4-5% of mCRC patients have MSI-High or mismatch repair deficient (dMMR) biomarkers. In addition to prognostic applications for CRC, MSI is believed to be an independent factor that may predict a patient's response to certain immunotherapies. The fully automated and CE-marked IVD Idylla MSI Test provides information on the MSI status of CRC tumors within approximately 150 minutes from just one slice of FFPE tumor tissue, without the need of a reference sample.

Bristol-Myers Squibb's *Opdivo* (nivolumab) plus low-dose *Yervoy* (ipilimumab) is the first immuno-oncology combination treatment approved by the US FDA for MSI-High or mismatch repair deficient (dMMR) mCRC that has progressed following treatment with certain chemotherapies.

Biocartis' joint venture Wondfo-Cartis will commercialize the Idylla MSI test in the People's Republic of China upon obtaining regulatory approval.

Herman Verrelst, CEO of Biocartis, **commented**: “We are pleased to announce this new immuno-oncology project in our ongoing collaboration with Bristol-Myers Squibb. Over the last years we actively expanded our commercial footprint to offer global collaboration opportunities to our pharma partners. Today’s announcement shows the potential of that approach and marks a major milestone for our Chinese joint venture as this is its first companion diagnostics partnership. Especially in the Chinese market, many patients may benefit from the advantages of our Idylla™ MSI test as it has the potential to make MSI testing available to a broader population.”