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# Biocartis Receives FDA Approval for the Idylla™ CDx MSI Test

*First-ever fully automated, sample-to-result, cartridge-based companion diagnostic test approved in the US for colorectal cancer patients*

**Itasca (IL), United States, 15 September 2025** – Biocartis Group of Companies ("Biocartis"), an innovative molecular diagnostics company, is pleased to announce that its Idylla™ CDx MSI Test developed in partnership with Bristol Myers Squibb, has received the first-ever Premarket Approval (PMA) from the FDA for a cartridge-based, fully automated, "sample-to-result" companion diagnostic test.

The Idylla™ CDx MSI Test aids in identifying eligible microsatellite instability-high (MSI-H) colorectal cancer (CRC) patients, who may benefit from treatment with OPDIVO® (nivolumab) alone, or in combination with YERVOY® (ipilimumab), as established in the CheckMate-8HW trial (Bristol Myers Squibb Company) (André et al., 2024[1]; André et al., 2025[2])[3].

*"The approval of this new MSI companion diagnostic for patients with colorectal cancer is a meaningful achievement from our collaboration with Biocartis and a strong reflection of our Precision Medicine strategy at Bristol Myers Squibb," said* ***Sarah Hersey, Vice President, Precision Medicine, Bioanalytical and Translational Sciences, Bristol Myers Squibb****. "Rapid and accurate diagnosis is crucial to enabling access to appropriate therapeutic approaches, and this latest advancement exemplifies our commitment to delivering innovative, targeted solutions that have the potential to improve outcomes for patients."*

Designed for use on the Idylla™ Platform, the Idylla™ CDx MSI Test qualitatively detects a panel of seven monomorphic biomarkers (ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2) for detection of MSI in CRC tissue samples. The Test runs in a single-use cartridge, requiring less than **three minutes** of hands-on-time and delivering straightforward results in under **three hours**.

*"Achieving FDA approval for our Idylla™ CDx MSI Test represents a key milestone for Biocartis," said* ***Michael Korn, M.D., Chief Medical and Scientific Officer at Biocartis****. "It underscores our commitment to helping oncology patients receive the right therapy without delay and the recent CheckMate-8HW data reinforce the critical importance of accurate MSI-H/dMMR testing in colorectal cancer. With its speed, accuracy, and automation, the Idylla™ CDx MSI Test offers a powerful solution that enables clinicians to make timely, confident and data-driven treatment decisions when every moment counts."*

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[1] Andre, T. et al. (2024). Nivolumab plus Ipilimumab in Microsatellite-Instability-High Metastatic Colorectal Cancer. *The New England journal of medicine*, *391*(21), 2014–2026. https://doi.org/10.1056/NEJMoa2402141

[2] Andre, T. et al. (2025). Nivolumab plus ipilimumab versus nivolumab in microsatellite instability-high metastatic colorectal cancer (CheckMate 8HW): a randomised, open-label, phase 3 trial. *The Lancet, 405*(10476), 383–395. https://doi.org/10.1016/S0140-6736(24)02848-4

[3] Please see U.S. Full Prescribing Information for OPDIVO and YERVOY.

The Idylla™ CDx MSI Test will be made available across the US soon, with availability in other non-US markets expected to follow. For more information about the Test, please visit the Biocartis website or contact the Biocartis team.

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**About Biocartis**

Biocartis is committed to helping cancer patients worldwide access the right treatment faster. With our proprietary Idylla™ Platform, we deliver in-house molecular biomarker results in only 3 hours, enabling healthcare professionals to make timely, informed decisions that guide personalized therapy. Our expanding portfolio of diagnostic tests and research assays addresses key unmet clinical needs across multiple cancers, including lung, skin, thyroid, colorectal, endometrial, blood, brain, and breast cancer.

Learn more at www.biocartis.com and follow us on LinkedIn, Facebook and X (Twitter).

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