

Brenus Pharma announces FDA acceptance of IND application for STC-1010 (BreAK-CRC001) in MSS metastatic Colorectal Cancer (mCRC)

- STC-1010 is a first-in-class allogeneic in vivo immunotherapy for which the FDA has authorized clinical evaluation in the U.S. under the [BreAK-CRC 001](#) study.
- This strategic milestone enables the company to execute a global clinical strategy following European regulatory approvals ([ANSM](#), [AFMPS](#)), first patients dosed with preliminary results and good tolerability observed in early Phase Ia.
- First data are expected to be presented during [ESMO annual congress 2026](#).

Lyon, 27th May – Brenus Pharma, a clinical stage biotechnology company developing novel in vivo immunotherapies for solid tumors, announced that the U.S. [Food and Drug Administration \(FDA\)](#) has accepted the company's Investigational New Drug (IND) application for its first drug candidate, STC-1010, in microsatellite stable (MSS) metastatic colorectal cancer (mCRC).

STC-1010 is designed to address a critical unmet need worldwide. Approximately 95% of mCRC patients have MSS tumors, which demonstrate minimal response to standard immunotherapies. The FDA validated Brenus Pharma's advanced regulatory and manufacturing capabilities. This operational readiness will accelerate patient access and data generation across both European and US sites for a Phase II program planned for 2027.

"FDA's acceptance of our IND represents a major validation of our program and enables the full execution of our clinical strategy across Europe and the United States. Achieving regulatory alignment across multiple jurisdictions reflects our team's deep expertise and our commitment to bringing STC-1010 to patients who need it." said [Paul BRAVETTI, CEO](#).

"This is an impressive accomplishment for Brenus, opening the door to planned clinical program expansion in the U.S. By generating de novo, multi-specific lymphocyte responses in immunologically 'cold' tumors, the therapy promises to address one of oncology's biggest challenges. I am very excited to contribute to the company's strategic growth." said [Dr. Diala EZZEDDINE](#) (PhD), US-based Independent Board Director at Brenus Pharma.

About Brenus Pharma

Brenus Pharma develops an off-the-shelf platform advancing novel modalities in immuno-oncology. This cutting-edge precision technology mimics tumor protein expression and makes it visible to the immune system, enabling a multi-specific in vivo immune response adapting to tumor evolution in hard-to-treat solid tumors, where current therapies fall short. Combining a data-driven approach with scalable GMP manufacturing, the company brings precision medicine at scale.

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