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Mestastop takes CDSCO-approved anti-metastasis candidate to US FDA, launching Phase 2 IND application

31 October 2026 | News

Bengaluru biotech has formally opened the US regulatory pathway for its repurposed MSAP031 candidate



Mestastop Solutions, the Bengaluru-based biotechnology startup dedicated to stopping cancer metastasis, has formally initiated the process of approaching the US Food and Drug Administration (FDA) for an Investigational New Drug (IND) application to conduct a Phase 2 clinical study of its lead clinical candidate, MSAP031, repurposed to delay metastasis.

The candidate has already received approval from India's Central Drugs Standard Control Organisation (CDSCO) for a Phase II clinical trial in post-surgical colorectal cancer patients.

Mestastop has executed a Master Services Agreement and Work Order with Aleon Pharma International, Inc., a regulatory affairs consulting firm headquartered in Parsippany, New Jersey.

Under the Work Order, Aleon is responsible for three workstreams: a High-Level Gap Assessment of Mestastop's nonclinical, clinical and CMC data for MSAP031, MSAP030 and their combination; a Type B pre-IND meeting with the FDA; and the preparation, eCTD publishing and submission of the amlodipine IND in line with 21 CFR Part 312 and FDA/ICH guidance. Aleon also acts as Mestastop's U.S. Regulatory Agent and manages direct communication with the FDA.

Metastasis is responsible for approximately 90% of cancer deaths, yet current therapies are built mainly to shrink the primary tumour. Mestastop identified its candidate through its MetGuard® repurposing platform, which tests approved drugs across the proprietary METAssay® and METVivo® panels and then evaluates them against real-world patient outcomes using METSCAN®. In retrospective analyses, cancer patients who used Mestastop's lead repurposed drug showed statistically significant improvements in survival and delayed metastasis.