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Brown University Health and Arcamyra to launch Phase I trial of ACM-CpG in peritoneal carcinomatosis

August 20, 2026 | News

FDA clearance of Arcamyraâ??s IND enables the investigator-initiated BrUOG 452 study of a polymersome-encapsulated TLR9 agonist in patients with peritoneal carcinomatosis.

Brown University Health and Arcamyra Therapeutics are preparing to launch a Phase I clinical trial of ACM-CpG in patients with peritoneal carcinomatosis following US Food and Drug Administration clearance of Investigational New Drug application 180703.

The investigator-initiated BrUOG 452 study will be coordinated by the Brown University Oncology Research Group and led by Dr Khaldoun Almhanna at Brown University Health and The Warren Alpert Medical School of Brown University.

The trial, listed on ClinicalTrials.gov as NCT07658196, represents the first clinical evaluation of ACM-CpG in peritoneal carcinomatosis.

Peritoneal carcinomatosis occurs when cancer spreads to the peritoneum, the membrane lining the abdominal cavity. It is commonly associated with advanced gastrointestinal or gynaecological cancers and can be difficult to treat because medicines may not reach the disease site effectively.

ACM-CpG is a polymersome-encapsulated TLR9 agonist developed using Arcamyra’s proprietary block-copolymer nanoparticle platform.

In the BrUOG 452 study, the therapy will be administered intraperitoneally to deliver innate immune activation directly within the peritoneal cavity.

The approach is designed to address drug-delivery barriers in this disease setting while evaluating the safety, tolerability and early biological activity of the investigational therapy.

Potentially eligible patients will have documented peritoneal carcinomatosis arising from colorectal or appendiceal cancer. Patients may have an intact primary tumour, while limited liver or lung disease is permitted.

The trial builds on earlier clinical evaluation of ACM-CpG in other indications, where the therapy has been reported to be well tolerated and to show evidence of innate immune activation.

“This FDA clearance marks an important step for Arcamyra and for patients with peritoneal carcinomatosis, a disease with few effective treatment options,” said Madhavan Nallani, Chief Executive Officer and Co-founder of Arcamyra Therapeutics.

“We are pleased to advance ACM-CpG into this Phase 1 trial with Dr. Almhanna and the teams at Brown University Health and The Warren Alpert Medical School of Brown University, whose experience in gastrointestinal oncology and peritoneal disease will be essential to this work.”

Dr Khaldoun Almhanna said the trial will explore whether the therapy’s regional immunotherapy approach can offer a new option for patients with peritoneal disease.

“Peritoneal carcinomatosis remains one of the most challenging disease settings we treat, and patients need new options,” he said.

“ACM-CpG’s early tolerability and immune-activation profile provide a strong rationale for studying this regional immunotherapy approach in patients with peritoneal disease.”

The Phase I study is expected to generate data on safety, tolerability and early biological activity to support future development of ACM-CpG across additional tumour settings and administration routes.