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ASIA EDITION

Innovent doses first patient in Phase III tri-specific antibody trial

June 25, 2026 | News

The TriadicMM-1 study is evaluating IBI3003 against investigatorâ??s choice therapy in relapsed or refractory multiple myeloma.

Innovent Biologics has dosed the first patient in the Chinese pivotal Phase III TriadicMM-1 trial of IBI3003 for relapsed or refractory multiple myeloma.

IBI3003 is Innovent's self-developed anti-GPRC5D, BCMA and CD3 tri-specific antibody. The company said it is China's first self-developed GPRC5D/BCMA/CD3 tri-specific antibody to enter a pivotal registrational Phase III trial.

This is relevant because multiple myeloma remains largely incurable despite major advances in proteasome inhibitors, immunomodulatory drugs, monoclonal antibodies and cellular therapies. Most patients eventually relapse, and treatment effectiveness typically declines with each subsequent line of therapy.

TriadicMM-1 is a multicentre, randomised, controlled, open-label Phase III study. It is evaluating IBI3003 against investigator's choice of regimen: pomalidomide, bortezomib and dexamethasone, or daratumumab, pomalidomide and dexamethasone. The primary endpoint is progression-free survival assessed by an Independent Review Committee.

The study targets patients receiving second- to fifth-line treatment for relapsed or refractory multiple myeloma. This is an important setting because patients may still be fit enough for active treatment, but often face increasing resistance and shorter remissions.

IBI3003 is built on Innovent's proprietary Sanbody platform. Its design targets GPRC5D and BCMA on myeloma cells while engaging CD3 on T cells. The dual tumour-antigen targeting strategy is intended to reduce the risk of antigen escape, a known challenge in single-target approaches.

Earlier clinical data presented at the American Society of Hematology Annual Meeting in December 2025 showed promising activity. Among 24 patients treated at doses of at least 120 ?g/kg, the overall response rate was 83.3 per cent. The response rate was 80 per cent among patients with extramedullary disease and 77.8 per cent among patients previously treated with BCMA- or GPRC5D-directed therapies.

Among patients who achieved complete response or better, the minimal residual disease negativity rate was 100 per cent, assessed by next-generation sequencing at a threshold of 10^-5. Safety data showed all cytokine release syndrome cases were Grade 1 or 2, with two Grade 1 or 2 immune effector cell-associated neurotoxicity syndrome cases reported.

IBI3003 has also received U.S. FDA Fast Track Designation for relapsed or refractory multiple myeloma in patients who have received four or more prior lines of therapy, including at least a proteasome inhibitor, an immunomodulatory drug and an anti-CD38 monoclonal antibody. A Phase I/II trial is ongoing in the United States.

The Phase III start is commercially and scientifically important because tri-specific antibodies are emerging as a next-generation immunotherapy format in haematologic malignancies. If successful, IBI3003 could strengthen Innovent’s position in multiple myeloma and support wider global development of China-originated biologics.

Adoption will depend on Phase III efficacy, durability of response, safety management, dosing convenience, manufacturing scalability and positioning against existing bispecific antibodies, CAR-T therapies and standard combination regimens. For clinicians, the key question will be whether tri-specific targeting can produce deeper and longer responses without adding unacceptable toxicity.

The development reflects the increasing sophistication of China’s biologics pipeline. As more domestic companies move from early innovation into registrational trials, China-originated immunotherapies may become more competitive in global oncology development.