Ichnos Glenmark Innovation (IGI) Receives U.S. FDA Fast Track Designation for ISB 2001 for Relapsed/Refractory Multiple Myeloma

Results from the dose-escalation portion of the Phase 1 clinical study of ISB 2001 in patients with heavily pretreated multiple myeloma to be presented at the 2025 ASCO Annual Meeting

New York, NY, May 5, 2025 – IGI, a global, fully integrated clinical-stage biotechnology company focused on developing multispecifics™ in oncology, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for ISB 2001. This important designation was granted for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least three prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. ISB 2001 is an investigational trispecific antibody therapeutic that targets BCMA and CD38 on myeloma cells and CD3 on T cells. ISB 2001 is currently being evaluated in a Phase 1 dose-expansion study.

"A growing number of patients with multiple myeloma have been heavily pretreated, have exhausted currently approved therapies, and continue to face disease progression," said Cyril Konto, M.D., President and CEO of IGI. "At IGI, we have long recognized the urgent need for novel treatment options – particularly for patients who have already received first-generation bispecifics or CAR T-cell therapies. Our trispecific candidate is designed to enhance tumor targeting while reducing on-target, off-tumor toxicity. We are honored to receive this Fast Track designation and look forward to working closely with the FDA to advance our Multispecific™ T-cell engager, with the goal of delivering a first-in-class therapy for patients with relapsed or refractory multiple myeloma."

IGI recently completed the dose-escalation portion of its Phase 1 clinical study in patients with heavily pretreated multiple myeloma. Initial study results, presented in an oral session at the American Society of Hematology (ASH) Annual Meeting in December 2024, demonstrated a high overall response rate (ORR) with durable responses and a favorable safety profile. Complete results from the dose-escalation portion will be presented in a rapid oral session at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting on Monday, June 2, 2025.

The FDA's Fast Track designation is designed to enable the development and expedite the review of drugs that treat serious conditions and address unmet medical needs, with the

ultimate goal of getting important new drugs to patients earlier. A drug that receives Fast Track designation may be eligible for more frequent meetings and communications with the FDA and rolling review of any application for marketing approval. A drug receiving Fast Track designation also may be eligible for Priority Review if relevant criteria are met. ISB 2001 was previously granted Orphan Drug Designation by the FDA in July 2023.

ASCO Rapid Oral Presentation

Details:
Session title: *Phase 1, first-in-human study of ISB 2001: A BCMAxCD38xCD3-targeting trispecific antibody for patients with relapsed/refractory multiple myeloma (RRMM)—Dose escalation results.* (Abstract # 7514)

Session Name: *Hematologic Malignancies—Plasma Cell Dyscrasia*

Date & Time: June 2, 2025, 8 AM – 9:30 AM CDT

About ISB 2001 and Relapsed/Refractory Multiple Myeloma

ISB 2001 is a first-in-class trispecific T-cell engager that targets BCMA and CD38 on myeloma cells and CD3 on T cells. Developed using IGI's proprietary BEAT® protein platform, ISB 2001 was engineered with two distinct binders against myeloma-associated antigens to enhance avidity, even at low target expression levels, while aiming to improve safety over first-generation bispecific antibodies. The dose-expansion portion of the ongoing Phase 1 trial in patients with RRMM (NCT05862012) is currently enrolling patients across 9 sites in the United States and Australia.

Nearly all patients with relapsed or refractory multiple myeloma (RRMM) ultimately experience disease progression. With no cure currently available and limited treatment options once approved therapies are exhausted, there remains a significant unmet need. IGI is developing ISB 2001 to address this gap, specifically for patients who have previously received T-cell–directed therapies, including CAR T-cell treatments and bispecific antibodies.

About IGI

IGI is a global, fully integrated clinical-stage biotechnology company focused on developing innovative biologics in oncology. Headquartered in New York, NY, IGI is advancing a robust pipeline of novel, first-in-class multispecifics™ aimed at addressing complex diseases and treating patients holistically. Powered by its proprietary BEAT technology platform, IGI is committed to delivering breakthrough, curative therapies to improve and extend the lives of patients battling hematological malignancies and solid tumors. For more information, visit www.IGInnovate.com.

For more information, please contact:
IGI Corporate Communications Team
Corporate.communications@iginnovate.com