Hummingbird Bioscience Announces Positive Phase I Clinical Data for HMBD-001 Monotherapy Trial at the European Society for Medical Oncology Congress 2023

23 October 2023

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HMBD-001 is Hummingbird Bioscience's proprietary anti-HER3 antibody in Phase I/IIa trials in the UK and Phase Ib trials in Australia, targeting multiple solid tumors.
The clinical data shows that HMBD-001 is safe and well-tolerated with no dose-limiting toxicities and no severe treatment-related adverse events.
Disease control rate (DCR) was 43% (9/21), with one patient achieving a partial response after two cycles of HMBD-001 monotherapy and a best overall response of 51% tumor shrinkage.

United Kingdom & Singapore, October 23, 2023– Hummingbird Bioscience, a data-driven precision biotherapeutics company discovering and developing transformative biologic medicines for hard-to-treat diseases, today announced presentation of positive clinical data for the dose escalation part of the HMBD-001 Phase I/IIa trial (NCT05057013) at the European Society for Medical Oncology Congress 2023 (ESMO 2023). The trial is evaluating HMBD-001 as a monotherapy across various tumor types in the UK.

As of the data cut-off on 8 September 2023, the trial had enrolled 23 heavily pre-treated patients across various tumor types where HER3 may play an important role. The dose escalation trial cleared six monotherapy cohorts with no dose-limiting toxicities (DLTs) and there were no treatment discontinuations due to related adverse events. Of the enrolled patients, 21 were evaluable for efficacy. Disease control rate (DCR) was 43% (9/21), with one patient achieving partial response with a 51% tumor shrinkage after four cycles of HMBD-001 treatment. HMBD-001 as monotherapy had a maximal half-life of 12 days in this trial.

"The favorable safety and tolerability profile of HMBD-001 and its monotherapy activity in biomarker-unselected cohorts are very encouraging and shows that HMBD-001 is an active antibody that effectively inhibits HER3 signaling, which has been shown to be important for cancer growth and survival. HMBD-001 is designed to be a best-in-class HER3 antibody with a differentiated mechanism of action, leveraging knowledge around HER3 biology built up by Hummingbird Bio over the years. To optimize clinical development, we are executing a phased strategy to demonstrate benefit in patients with gene signatures most likely to benefit from HMBD-001. We look forward to evaluating HMBD-001 in patients with squamous non-small cell lung cancer (sqNSCLC) and patients with HER3 aberrations, including NRG1 fusions, in the precision Phase Ib clinical trials recently initiated in Australia," said Jerome Boyd-Kirkup, Ph.D., Chief Scientific Officer, Hummingbird Bioscience.

"I am convinced that HER3 remains an important target for treating many cancers including prostate cancer, where it is implicated in treatment resistance through an interaction between tumor cell HER3

and hijacked white blood cells generating the protein activating it called NRG1. This clinical trial of a novel antibody targeting HER3 has demonstrated good tolerability and early evidence of anti-tumor activity, with an impressive and ongoing response in a patient with advanced pancreatic cancer who has clearly had clinical benefit. We envision that biology-based trials targeting HER3 deserve to be prioritized to continue this important effort," said Johann De Bono, Chief Investigator of the trial, Professor in Experimental Cancer Medicine at The Institute of Cancer Research, and Consultant Medical Oncologist at The Royal Marsden NHS Foundation Trust.

Stephen Nabarro, Ph.D., Interim Director of Cancer Research UK's Centre for Drug Development said: "We are proud to have played an integral part in the significant progress that HMBD-001 has made in the clinic since we presented at ESMO 2022. A year on, and following successful completion of the dose escalation phase, we are seeing promising results emerging from the trial. Having observed anti-tumor activity in one patient already, we are excited about the opening of the metastatic castration-resistant prostate cancer (mCRPC) expansion arm and hope to continue on this path to bring HMBD-001 to patients with HER3-driven cancers." The Phase I/IIa clinical trial in the UK is sponsored and managed by Cancer Research UK's Centre for Drug Development. This trial began enrolling in October 2021 and is ongoing in the UK.

Based on the encouraging clinical data from the Phase I clinical trial in the UK, Hummingbird Bioscience has initiated two Phase Ib trials studying HMBD-001 in combination with various agents, in patients with sqNSCLC (NCT05910827) and in patients with NRG1 fusions and HER3 mutations (NCT05919537), in Australia in Q3 2023.

Session Details

Date and time: 23rd October 2023, Monday, October 23, 2023, 12:00 – 13:00 CEST

Location: Hall 8

HMBD-001 Clinical Data Poster Details

Poster Title: A CRUK phase I/IIA, first in human dose-escalation and expansion trial of HMBD-001 (an anti-HER3 antibody) in patients with advanced HER3 positive solid tumours

Number: 687P
Presenter: Johann de Bono, Professor in Experimental Cancer Medicine at The Institute of Cancer Research, and Consultant Medical Oncologist at The Royal Marsden NHS Foundation Trust

HMBD-001 Pharmacokinetic Data Poster Details

Poster Title: Pharmacokinetics of HMBD-001, a human monoclonal antibody targeting HER3, a CRUK first-in-human phase I trial in patients with advanced solid tumours

Number: 688P
Presenter: Oladipo Idowu, Ph.D., Biomarker Research Associate, Cancer Pharmacology, Newcastle University Centre for Cancer

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About HMBD-001

HMBD-001 is a clinical-stage IgG1 antibody designed to target HER3, discovered using Hummingbird Bioscience's proprietary Rational Antibody Discovery (RAD) platform. We believe HMBD-001 is the only anti-HER3 antibody in development that has the potential to fully block both ligand-dependent and -independent HER3 activation and oncogenic signaling, by targeting a key epitope located at the interface where HER3 forms heterodimers with HER2 or EGFR. In preclinical models evaluating HMBD-001, superior affinity and more potent tumor growth inhibition compared to existing anti-HER3 antibodies were observed. HMBD-001 is currently in Phase Ib clinical trials for biomarker-selected indications with a strong scientific rationale, which includes squamous non-small cell lung cancer, NRG1 fusions, and HER3 mutations.

About Hummingbird Bioscience

Hummingbird Bioscience is a data-driven precision biotherapeutics company discovering and developing transformative biologic medicines for hard-to-treat diseases. The Hummingbird Bioscience model combines computational and systems biology with wet lab drug discovery in a multi-disciplinary, collaborative environment spanning initial discovery through clinical development. The company harnesses this integrated approach across target identification and patient selection, enabling the team to increase the efficiency of translating novel scientific insights while reducing the inherent risk in drug discovery and development. The company is currently developing two clinical-stage assets: HMBD-001, a humanized anti-HER3 monoclonal antibody targeting a novel epitope on HER3, and HMBD-002, a humanized anti-VISTA IgG4 monoclonal antibody. Both programs are currently in Phase I studies. At Hummingbird Bioscience, the commitment to rigorous science, teamwork, and intellectual integrity underpins our passion to accelerate the journey of new drugs from concept to clinic.

For more information, please visit www.hummingbirdbioscience.com, and follow Hummingbird Bioscience on LinkedIn, X (formerly Twitter), and YouTube.

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