

Hummingbird Bioscience Announces First Patient Dosed in Phase II Trial of HMBD-001 and Cetuximab in Advanced Squamous Cell Cancers

- HMBD-001, a differentiated anti-HER3 monoclonal antibody discovered and developed with Hummingbird Bioscience's AI Molecular Medicine (AIMM) platform, has advanced into Phase II clinical development
- Recommended doses for expansion (RDEs) identified for HMBD-001 in combination with cetuximab, supported by safety, tolerability, and preliminary efficacy data
- Advancement of HMBD-001 in clinical development demonstrates translation of Hummingbird Bioscience's AIMM platform from drug design through clinical development and patient selection

Singapore, 30 Sep, 2026 – Hummingbird Bioscience (“Hummingbird”) a biotherapeutics company discovering and developing transformative medicines for diseases with significant unmet need, today announced that HMBD-001 has advanced into Phase II clinical development and that the first patient in the Phase II clinical study of HMBD-001-103 has been dosed.

HMBD-001 is a differentiated anti-HER3 monoclonal antibody engineered with Hummingbird Bioscience's Rational Antibody Discovery (RAD) platform, a core part of the AI Molecular Medicine (AIMM) platform. Phase II of the HMBD-001-103 clinical study is recruiting patients with advanced squamous cell cancers ([NCT05910827](#)) across multiple countries, including China, Australia, Moldova and Singapore. An Investigational New Drug (IND) application for HMBD-001 has been approved by the U.S. Food and Drug Administration (FDA).

Recommended doses for expansion (RDEs) for HMBD-001 in combination with the EGFR inhibitor cetuximab (marketed by Merck KGaA, Darmstadt, Germany as ERBITUX® globally, except for the U.S. and Canada) were identified, with advancement into Phase II supported by clinical safety, tolerability, and preliminary efficacy observed to date. Merck KGaA, Darmstadt, Germany will continue to supply cetuximab for the Hummingbird Bioscience-sponsored study under [a clinical trial collaboration and supply agreement](#), and both parties retain all commercial rights to the respective compounds.

The advancement of HMBD-001 provides important clinical-stage validation of Hummingbird Bioscience's AIMM platform, demonstrating the application of AI across the drug-development continuum: from understanding disease biology and designing differentiated therapeutics to informing clinical development strategy and identifying patients most likely to benefit.

“Advancing HMBD-001 into Phase II is an important milestone for the program and for Hummingbird’s AI-first approach to drug development,” said Piers Ingram, PhD, Chief Executive Officer of Hummingbird Bioscience. “From designing HMBD-001 to identifying the disease settings and combination strategy where its differentiated mechanism may have the greatest impact, our AIMM platform has helped shape the program at multiple stages. We look forward to further evaluating the potential of HMBD-001.”

Hummingbird Bioscience’s AIMM platform contributed to HMBD-001’s drug design and clinical development strategy. In drug design, the RAD platform identified a functionally critical epitope at the HER3 dimerization interface and engineered HMBD-001 to directly block HER3 heterodimerization with EGFR or HER2. This differentiated mechanism enables HMBD-001 to inhibit both ligand-dependent and ligand-independent HER3 activation to block oncogenic signaling. AIMM also informed the clinical development strategy for HMBD-001. Hummingbird Bioscience’s proprietary AI Reasoning Engine (AIRE) enabled rapid identification of squamous cell carcinomas as tumor types enriched for HER3 dependency, and therefore particularly vulnerable to HER3/EGFR inhibition. These findings supported prioritizing squamous cancers as an indication and informed the trial design combining HMBD-001 with cetuximab, while accounting for potential resistance mechanisms against this combination therapy.

“Genetic alterations commonly observed in squamous cell carcinomas can contribute to aberrant HER3 and EGFR signaling, which drive tumor cell proliferation and survival. Hummingbird’s AI-driven analyses identified a dependency on HER3/EGFR signaling in squamous cancers, providing a strong biological rationale for simultaneously targeting both pathways,” said Kon Yew Kwek, BM BCh, DPhil, Chief Medical Officer of Hummingbird Bioscience. “Following the encouraging clinical activity that we have seen, we will continue using our AIMM platform to help enrich our patient population, so that we can optimally deliver a chemo-free treatment to patients suffering from advanced squamous cancers and who will most likely benefit from HMBD-001 plus cetuximab.”

The advancement of HMBD-001 in clinical development reflects Hummingbird Bioscience’s AI-first approach to drug discovery and development, which has recently received growing external recognition. Selected from over 600 global applicants, Hummingbird Bioscience won the [Asia Pacific Trailblazer Award](#) at the Nebius AI Discovery Awards. The company was also [named one of three finalists](#) in the Fierce AI Innovation Awards in the Preclinical Development category, selected as a finalist for the [Scrip Awards](#) in the Best Use of AI in Drug Discovery & Preclinical Development category, and honored on the [NextGen Tech 30](#) list by Granite Asia.

About HMBD-001

HMBD-001 is a novel, potentially best-in-class clinical-stage IgG1 antibody designed to target HER3, discovered and developed with Hummingbird Bioscience's proprietary technologies. 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. Additionally, combining HMBD-001 with EGFR inhibition further improved anti-tumor activity in squamous non-small cell lung cancer models. HMBD-001 is currently in Phase II multi-regional clinical trials for advanced squamous cell cancers ([NCT05910827](#)).

About Hummingbird Bioscience

Hummingbird Bioscience is a clinical-stage biotherapeutics company integrating AI and rigorous experimental science to bring more precise, scientifically grounded medicines to patients faster. Its lab-in-the-loop AI Molecular Medicine platform, AIMM, draws on over a decade of proprietary experimental, translational, and clinical data, learning from every new data point to prioritize hypotheses, select targets and indications, and design and optimize biotherapeutics. By combining AI with biological expertise and wet-lab validation, Hummingbird Bioscience has advanced several programs from concept to clinic in as little as 12 months. Hummingbird Bioscience has engineered a deep pipeline with AIMM, including four programs in clinical trials and seven programs out-licensed or partnered. For more information, visit www.hummingbirdbioscience.com, and follow Hummingbird Bioscience on [LinkedIn](#), [X \(formerly Twitter\)](#), and [YouTube](#).

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