

[Hummingbird Bioscience Announces First Patient Dosed in Phase 1 Clinical Trial of HMBD-001 in Advanced HER3-Expressing Solid Malignancies](#)

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HMBD-001 is an anti-HER3 monoclonal antibody with a highly differentiated mechanism of action designed to block all forms of HER3 activation

Houston, TX, and Singapore, December 6, 2021 - [Hummingbird Bioscience](#), (“Highlight”), an innovative clinical-stage biotech company focused on developing precision therapies against hard-to-drug targets in cancer and autoimmune disease, and Cancer Research UK, the world’s leading cancer charity, today announced that the first patient has been dosed in a Phase 1 clinical trial of HMBD-001 for the treatment of patients with advanced HER3-expressing solid malignancies ([NCT05057013](#)).

The Phase 1 clinical trial in the United Kingdom is being sponsored and managed by Cancer Research UK’s Centre for Drug Development and led by Chief Investigator, Professor Johann De Bono at the Royal Marsden Hospital and The Institute of Cancer Research, London. The trial intends to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and explore preliminary evidence of HMBD-001 activity in patients with advanced HER3-expressing solid malignancies, including NRG1 fusion-driven cancers.

HMBD-001 is the first of Hummingbird Bioscience’s deep pipeline of antibody drug candidates to enter clinical trials. Rationally developed using Hummingbird Bioscience’s proprietary Rational Antibody Discovery (RAD) platform, HMBD-001 is the only reported anti-HER3 antibody in clinical development that uses a highly differentiated mechanism of action designed to block the formation of all active HER3 dimers, regardless of NRG1 ligand binding or HER2/EGFR overexpression.

“Dosing of the first patient in the clinical trial of HMBD-001, Hummingbird’s most advanced program, marks the beginning of a potentially transformative approach to treating HER3-driven cancers,” said **Dr. Jerome Boyd-Kirkup, Chief Scientific Officer, Hummingbird Bioscience**. *“I am immensely proud of the teamwork that has brought our differentiated program to this point. Hummingbird Bioscience is dedicated to discovering and developing important medicines for cancer and autoimmune disease with our unique Rational Antibody Discovery platform.”*

“This significant milestone brings us a step closer to provide a much-needed and highly differentiated therapy for patients with HER3-driven cancers,” said **Dr. Eric Rowinsky, Chief Medical Officer, Hummingbird Bioscience**. *“We are pleased to partner with Cancer Research UK for this trial, and we look forward to advancing the clinical development of HMBD-001 for cancer patients.”*

Dr. Nigel Blackburn, Director of Cancer Research UK's Centre for Drug Development, said, *"We are thrilled to be working with Hummingbird Bioscience to advance its novel drug candidate into clinical trials. Although HER3 was discovered over 30 years ago, no therapies able to block its cancer-promoting action have been approved. Hummingbird Bioscience has taken fresh aim at a difficult drug target and has come up with a novel, potentially transformative antibody for cancer patients who desperately need new treatments."*

Initial data from the Phase 1 dose escalation is expected in the second half of 2022.

About HMBD-001

HMBD-001 is a clinical-stage IgG1 antibody designed to target HER3. Discovered using our proprietary RAD platform, HMBD-001 is now in development for the treatment of multiple solid tumors. 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, independent of the process leading to such dimerization. In preclinical models evaluating HMBD-001, we have observed superior affinity and more potently inhibited tumor growth compared to other existing anti-HER3 antibodies. Our near-term development plan for HMBD-001 focuses on four priority, high-value indications with strong scientific rationale and supporting preclinical data: NRG1 fusion-driven cancers, metastatic castrate resistant prostate cancer (mCRPC), metastatic colorectal cancer (mCRC), and squamous cell carcinoma of the head and neck (SCCHN).

About Hummingbird Bioscience

Hummingbird Bioscience is a clinical-stage biotechnology company with a proprietary Rational Antibody Discovery (RAD) platform, developing a broad pipeline of novel, precision therapeutics for the treatment of cancer and autoimmune disease.

We are focused on targets with significant biological validation and disease association that have not been drugged, or are inadequately drugged to date, which we refer to as "hard targets". Our RAD platform uses data-driven computational and systems biology with the goal of selecting promising protein targets that are associated with dysregulated biology and clinical disease, enabling us to develop antibodies that bind to specific epitopes and have the potential to be advantageous against these targets. We believe our platform has the potential to unlock novel mechanisms of action, making previously undruggable protein targets druggable, offering a significant potential opportunity to benefit patients.

For more information, please visit www.hummingbirdbioscience.com, and follow Hummingbird Bioscience on [LinkedIn](#) and [Twitter](#).

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About Cancer Research UK's Centre for Drug Development

Highlight Therapeutics, formerly known as Bioncotech Therapeutics, is a private, clinical-stage company dedicated to unlocking the full potential of immuno-oncology. Our lead drug candidate BO-112 is a best-in-class RNA-based therapy which has been demonstrated to initiate a powerful immune response, leveraging a unique multi-target approach to turn 'cold' tumors 'hot' and therefore visible to the immune system. It has the potential to rescue patients who are resistant to current checkpoint inhibitor therapy, a very large market opportunity. BO-112 is currently being investigated in a range of clinical trials as a monotherapy and in combination with checkpoint inhibitors. In addition to in-house research, Highlight Therapeutics has a number of external collaborators, including Merck & Co and UCLA.

For more information, please visit www.highlighttherapeutics.com

About Cima Universidad de Navarra

Cancer Research UK has an impressive record of developing novel treatments for cancer. The [Cancer Research UK Centre for Drug Development](#) has been pioneering the development of new cancer treatments for 25 years, taking over 140 potential new anti-cancer agents into clinical trials in patients. It currently has a portfolio of 21 new anti-cancer agents in preclinical development, Phase I or early Phase II clinical trials. Six of these new agents have made it to market including temozolomide for brain cancer, abiraterone for prostate cancer and rucaparib for ovarian cancer. Two other drugs are in late development Phase III trials.

About Cancer Research UK

- Cancer Research UK is the world's leading cancer charity dedicated to saving lives through research.
- Cancer Research UK's pioneering work into the prevention, diagnosis and treatment of cancer has helped save millions of lives.
- Cancer Research UK receives no government funding for its life-saving research. Every step it makes towards beating cancer relies on every donation made.
- Cancer Research UK has been at the heart of the progress that has already seen survival in the UK double in the last 40 years.
- Today, 2 in 4 people survive their cancer for at least 10 years. Cancer Research UK's ambition is to accelerate progress so that by 2034, 3 in 4 people will survive their cancer for at least 10 years.
- Cancer Research UK supports research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses.
- Together with its partners and supporters, Cancer Research UK's vision is to bring forward the day when all cancers are cured.

For further information about Cancer Research UK's work or to find out how to support the charity,

please call 0300 123 1022 or visit www.cancerresearchuk.org. Follow us on [Twitter](#) and [Facebook](#).

Source: Hummingbird Bioscience