UCB News

UCB Announces Bepranemab Phase 2a Study Results Accepted for Late-Breaking Presentation at Clinical Trials on Alzheimer's Disease (CTAD) 2024 Meeting

- Bepranemab - an investigational anti-tau antibody - targeting the mid-region of the tau protein is being studied to assess its potential to delay Alzheimer's disease progression[1]
- Late-breaking Phase 2a study TOGETHER (AH0003) results include all relevant clinical and imaging data[1]
- Late-breaking symposium will take place on 31 October 2024[2]
- UCB has regained all global rights to bepranemab from Roche and Genentech

Brussels, Belgium – 22 October 2024 – 7.00AM CEST – UCB today announced that the results of its double-blind TOGETHER (AH0003) Phase 2a study of bepranemab - an investigational anti-tau antibody - in people living with prodromal to mild Alzheimer's Disease (AD), have been accepted for presentation in a late-breaking symposium at the 2024 Clinical Trials on Alzheimer's Disease (CTAD) Meeting.[2] The CTAD meeting will take place in Madrid, Spain, October 29 – November 1, 2024.

The presentation will highlight primary and key secondary results from the Phase 2a study, including clinical, safety, and imaging endpoints. This acceptance underscores UCB's commitment to addressing the urgent need for new treatment options for Alzheimer's disease.

"We are pleased to have our innovative research program recognized by the CTAD committee and look forward to sharing the encouraging results of the TOGETHER study with the scientific community. These new data represent an important step in building a rigorous body of evidence evaluating bepranemab as an investigational treatment option, for people living with early Alzheimer's disease," said Alistair Henry, Chief Scientific Officer, UCB.

TOGETHER is a Phase 2a, global, multicenter, participant- and investigator-blind, placebo-controlled, parallel-group study designed to investigate the efficacy, safety and tolerability of bepranemab (two dose levels) – administered intravenously every 4 weeks – versus placebo in participants with prodromal (40% of study population) or mild (60% of study population) Alzheimer's disease over an 80-week treatment period, followed by a 48-week open-label extension period, and a 16-week safety follow-up period. [1]

Details of the late-breaking symposium:

- Title: Results from TOGETHER, a double-blind, placebo-controlled Phase 2 study evaluating efficacy, safety and tolerability of bepranemab in prodromal–mild Alzheimer's disease
- Presenters: Martin Citron, PhD (UCB Pharma); Matthew E Barton, PhD (UCB Pharma); Randall J Bateman, MD (Washington University School of Medicine, St Louis, MO, USA)
- Date/Time: October 31, 5:10pm CET

The CTAD meeting is one of the leading forums for the latest developments in clinical trials for Alzheimer's disease and other dementias. Attendees include experts from across the pharmaceutical, biotechnology, and medical communities who share a common goal of advancing treatment for Alzheimer's disease.

UCB also announced today that the company has regained all global rights to bepranemab following termination of a Collaboration Agreement with Genentech, a member of the Roche Group, and Roche. In July 2020, UCB entered a worldwide, exclusive license agreement with Roche and Genentech, for the global development, manufacturing, and commercialization of bepranemab in Alzheimer's disease.[3]

For more information, visit https://www.ucb.com/clinical-studies/Clinical-Trials?studyId=AH0003 or for the official CTAD program visit PROGRAM_CTAD2024_WEB October 14.pdf (ctad-alzheimer.com).

This release discusses investigational uses of an agent in development and is not intended to convey conclusions about efficacy or safety. There is no guarantee that any investigational uses of such product will successfully complete clinical development or gain health authority approval.

About bepranemab

Bepranemab is a recombinant, humanised, full-length immunoglobulin G4 monoclonal antibody (mAb) that specifically targets human tau protein.[4,5] Bepranemab targets a central region of tau (amino acids 235–250), near to the microtubule binding region (MTBR). [4,6] The rationale of this approach is that a mid-region antibody will more potently interfere with cell-to-cell propagation of pathogenic, aggregated tau than antibodies that target other regions of tau (ie., the N-terminus).[4,6,7]

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About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With approximately 9,000 people in approximately 40

countries, the company generated revenue of €5.3 billion in 2023. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

Forward looking statements

This press release may contain forward-looking statements including, without limitation, statements containing the words "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will", "continue" and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to differ materially from those that may be expressed or implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: the global spread and impact of COVID-19, changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring and retention of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, will progress to product approval or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products, which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB's efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

Given these uncertainties, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular

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UCB is providing this information, including forward-looking statements, only as of the date of this press release and it does not reflect any potential impact from the evolving COVID-19 pandemic, unless indicated otherwise. UCB is following the worldwide developments diligently to assess the financial significance of this pandemic to UCB. UCB expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

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References:

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