



UCB
News

UCB enters into collaboration with Roche to develop antibody treatment for people living with Alzheimer's Disease

- UCB to provide to Roche and Genentech exclusive, world-wide license to UCB's UCB0107, an innovative anti-Tau antibody treatment
- UCB will receive an initial upfront payment and, after positive completion of proof-of-concept in Alzheimer's Disease, is eligible to receive further potential payments with a total potential consideration approaching US \$2 billion upon receipt of certain regulatory approvals and satisfying certain milestones.
- UCB to fund and perform initial proof-of-concept study in Alzheimer's Disease. Upon completion and availability of results, Genentech has the right to proceed with clinical development or return full rights back to UCB.

Brussels (Belgium) 29 July 2020 – 7:00 (CEST) - UCB today announced an agreement to enter into a world-wide, exclusive license agreement with Roche and Genentech, a member of the Roche Group, for the global development and commercialization of UCB0107 in Alzheimer's Disease (AD). The transaction remains subject to obtaining antitrust clearance and other customary closing conditions.

Charl van Zyl, Executive Vice President UCB and Head of Neurology said: "We are excited that Roche and Genentech, with their deep and wide-ranging expertise, capacity and know-how in Alzheimer's Disease, will collaborate with UCB on UCB0107 with a shared ambition to offer people living with Alzheimer's Disease a new treatment option. Our science driven, patient centric development approach, and leading experience in neurological diseases provides a uniquely holistic view towards the unmet needs and the potential for an effective anti-Tau antibody in the treatment of neurodegenerative diseases like Alzheimer's Disease and progressive supranuclear palsy. In-line with our ongoing and longstanding commitment to the neurodegeneration community, this partnership represents an important step in the potential development of this exciting new medicine."

James Sabry, Global Head of Roche Pharma Partnering said: "In Alzheimer's Disease, we are continuing to explore new molecules that address the key pathways of this complex disease. We are pleased to embark on this journey together with UCB to help expand our efforts on tau. Our commitment remains strong on exploring multiple approaches with the hope that our research and development, including this collaboration with UCB, will lead to a disease-modifying medicine that could positively impact millions of people with Alzheimer's Disease."

UCB0107 is an investigational monoclonal antibody drug being developed by UCB as a potential treatment for patients with tauopathies such as progressive supranuclear palsy (PSP) and Alzheimer's Disease.

UCB will provide an exclusive, world-wide license to Roche and Genentech to develop and commercialize UCB0107 in AD. In return, UCB will receive an initial upfront payment of US \$120 million. UCB will fund and perform a proof-of-concept study in AD and, upon availability of the results of that study, Genentech has the right to progress with the development or return full rights back to UCB. After Genentech's decision to proceed with further clinical development, UCB will be eligible to receive further potential cost reimbursement, development and sales milestone payments as well as royalties with a total potential consideration approaching US \$2 billion upon receipt of certain regulatory approvals and satisfying certain clinical and sales milestones.

This license agreement does not impact UCB's 2020 financial outlook.

UCB continues to develop UCB0107 in progressive supranuclear palsy (PSP), with a confirmatory phase 3 study due to commence in Q2 2021.

About UCB0107

UCB0107 is a recombinant, humanized, full-length IgG4 monoclonal antibody, targeting a central Tau epitope, which is being developed to block/reduce the spread of Tau pathology.

Tau is a microtubule-associated protein expressed in the central nervous system, which supports the assembly and stabilization of neuronal microtubules.¹ In tauopathies, Tau becomes pathogenic, forming tangles, which cause cell damage and ultimately neuronal death.^{1,2,3} It is hypothesised that the spread of Tau protein from neuron to neuron underpins disease progression in tauopathies⁴ providing the rationale for antibody therapies.

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 more than 7 500 people in approximately 40 countries, UCB generated revenue of € 4.9 billion in 2019. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

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Forward looking statements UCB

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’ 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 time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future.

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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