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press release

Novo Nordisk to acquire ocedurenone for uncontrolled hypertension from KBP Biosciences

Bagsværd, Denmark and Singapore, 16 October 2023 – Novo Nordisk A/S and KBP Biosciences PTE., Ltd. today announced that Novo Nordisk has agreed to acquire ocedurenone for uncontrolled hypertension with potential application in cardiovascular and kidney disease from KBP Biosciences for up to 1.3 billion US dollars.

Ocedurenone is an orally administered, small molecule, non-steroidal mineralocorticoid receptor antagonist (nsMRA) that is currently being examined in the phase 3 trial CLARION-CKD in patients with uncontrolled hypertension and advanced chronic kidney disease (CKD). Uncontrolled hypertension is when a person's blood pressure remains high despite taking two or more blood pressure-lowering treatments.

"Hypertension is a leading risk factor for cardiovascular events, heart failure, chronic kidney disease and premature death," said Martin Holst Lange, executive vice president and head of Development at Novo Nordisk. "With its expected benefit-risk profile, ocedurenone has best-in-class potential in treating uncontrolled hypertension and could help address a major unmet medical need in people living with cardiovascular disease and chronic kidney disease."

"We are delighted to pass the ocedurenone torch to Novo Nordisk, a global leader in management of chronic diseases. We believe this transition could unlock the full potential of ocedurenone and benefit more patients with cardiovascular and kidney disease worldwide," said Dr. Zhenhua Huang, founder and chairman of KBP Biosciences. "The transition is an exciting inflection point in the discovery, research and development work on ocedurenone carried out by KBP, a young player still establishing itself in the global pharmaceutical industry," added Dr. Fred Yang, chief development officer of KBP Biosciences.

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To date, ocedurenone has been investigated in nine clinical trials including the BLOCK-CKD Phase 2b trial. The BLOCK-CKD trial met its primary endpoint with ocedurenone demonstrating a clinically meaningful and statistically significant improvement in systolic blood pressure (SBP) from baseline to day 84 in patients with stage 3b/4 CKD and uncontrolled hypertension. There were no reports of severe hyperkalemia or acute kidney injury with ocedurenone in the trial[1].

The CLARION-CKD phase 3 trial has been initiated in the US, Europe and Asia with the first patient dosed at the end of 2021 and will continue as planned with a total of more than 600 patients expected to be randomised by more than 150 sites. Novo Nordisk expects to initiate phase 3 trials in additional cardiovascular and kidney disease indications in the coming years, aiming to maximise the full potential of ocedurenone.

"We look forward to adding ocedurenone to our pipeline as it will complement our current development programmes in cardiovascular disease and chronic kidney disease," said Camilla Sylvest, executive vice president, Commercial Strategy & Corporate Affairs at Novo Nordisk. "This deal is closely aligned with our strategic focus on expanding from our core in diabetes into other serious chronic diseases, including through novel drug modalities, to help many more patients living with unmet medical needs."

The closing of the acquisition is subject to receipt of applicable regulatory approvals and other customary conditions and is expected to happen before the end of 2023.

The transaction will not impact Novo Nordisk's previously communicated operating profit outlook for 2023 or the ongoing share buy-back programme. Novo Nordisk will fund the acquisition from financial reserves.

KBP Biosciences was represented by Goodwin Procter LLP and Novo Nordisk was represented by Covington & Burling LLP in this transaction.

About hypertension

Hypertension, also referred to as high blood pressure, is when a person's blood pressure, the force of blood flowing through the blood vessels, is consistently too high. An estimated 1.28 billion adults aged 30–79 years worldwide have hypertension, two-thirds living in low- and middle-income countries. An estimated 46% of adults with hypertension are unaware that they have the condition and less than half of adults (42%) with hypertension are diagnosed and treated. Approximately 1 in 5 adults (21%) with hypertension have it under control[2]. There is a significant unmet need in the treatment of hypertension, with a strong association with the risk of cardiorenal events[3] [4]. Despite advances in diagnosis and treatment over the last decades, hypertension was the leading cause of premature death (almost 10 million) in 2015 and has increased by 40% since 1990[5].

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About ocedurenone

Ocedurenone is a third-generation, non-steroidal, mineralocorticoid receptor antagonist (MRA) with a unique pharmacokinetic (PK) profile characterised by a long half-life and high mineralocorticoid receptor (MR) affinity. Certain MRAs have shown benefits in people with hypertension or heart failure, as well as cardiorenal benefits in patients with chronic kidney disease (CKD) and type 2 diabetes[6]. Patients with cardiovascular disease, CKD or diabetes are at greater risk for hyperkalemia (elevated potassium in the blood), an electrolyte abnormality that can cause muscle weakness, paralysis, cardiac arrhythmias, and sudden cardiac death. Renin-angiotensin-aldosterone system (RAAS) inhibitors, a group of drugs that includes MRAs, are known to further increase the risk of hyperkalemia. Based on clinical studies conducted to date, ocedurenone has the potential to have favorable efficacy (blood pressure reductions) and tolerability (lower risk of hyperkalemia)[1].

About CLARION-CKD

CLARION-CKD is a multicenter, double-blind, placebo-controlled, randomised phase 3 study of ocedurenone for uncontrolled hypertension in patients with advanced chronic kidney disease (CKD). CLARION-CKD follows the same inclusion criteria as the phase 2b BLOCK-CKD study which achieved its primary endpoint with clinical and statistical significance. For the CLARION-CKD trial, a total of more than 600 patients will be randomised by more than 150 sites. The CLARION-CKD study has been initiated in the United States, Europe, Asia and the first patient was dosed at the end of 2021.

About KBP Biosciences

KBP Biosciences is a global, clinical-stage biotechnology company, headquartered in Singapore, focused on discovering, developing, and commercializing innovative small-molecule therapeutics for the treatment of serious cardiorenal and infectious diseases with large unmet medical needs. KBP Biosciences' pipeline includes four novel drug candidates, two currently in clinical development covering multiple indications. CLARION-CKD, the global Phase 3 clinical trial of Ocedurenone (KBP-5074), is being conducted in patients with advanced CKD and uncontrolled hypertension. For more information about KBP Biosciences, please visit the company website at https://www.kbpbiosciences.com/

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat serious chronic diseases, built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 59,000 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, Facebook, X, LinkedIn and YouTube.

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