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Zealand Pharma announces Boehringer Ingelheim's survodutide is the first glucagon/GLP-1 dual agonist to demonstrate a favorable cardiovascular safety profile in global Phase 3 SYNCHRONIZE-CVOT trial with significant cardiometabolic benefits

- SYNCHRONIZE-CVOT met its primary endpoint demonstrating the safety of survodutide in terms of major adverse cardiovascular events compared with placebo in people with obesity and established cardiovascular disease (CVD), chronic kidney disease, and/or at least two weight-related complications or risk factors for CVD.[1]
- Survodutide also demonstrated meaningful improvements across multiple cardiometabolic measures, including significant reductions in systolic blood pressure and waist circumference at 72 weeks vs placebo.[1]
- These results were presented today at the American Heart Association Scientific Sessions and simultaneously published in The Lancet.[2]

Copenhagen, Denmark, November 9, 2026 – Zealand Pharma A/S (Nasdaq: ZEAL) (CVR-no. 20045078), a biotechnology company transforming metabolic health so millions millions can live without limits, today announced that Boehringer Ingelheim has reported positive results from the Phase 3 SYNCHRONIZE-CVOT trial, the first and only global cardiovascular safety trial of a glucagon/GLP-1 dual agonist to date. The trial met its primary endpoint using both the treatment-regimen* and supplementary secondary estimands†. The trial demonstrated that survodutide (BI 456906) did not increase the risk of major adverse cardiovascular events (5P-MACE: cardiovascular death, non-fatal MI, non-fatal stroke, coronary revascularization, or heart failure events) compared to placebo (HR 0.89 [95% CI: 0.67-1.18]; p<0.0001 for non-inferiority using the treatment-regimen estimand) in adults living with obesity or overweight with established cardiovascular disease (CVD), chronic kidney disease, and/or at least two weight-related complications or risk factors for CVD.[1] Obesity is a chronic, complex metabolic disease with impacts extending far beyond the scale.[3] Obesity is closely linked to metabolic dysfunction, increased cardiometabolic risk and with that to overall metabolic health.[3,4,5] Full results from SYNCHRONIZE-CVOT were presented today at the American Heart Association's (AHA) Scientific Sessions 2026 in Chicago, Illinois and simultaneously published in The Lancet.[2] An additional publication focused on achievement of cardiometabolic treatment targets will also be presented at AHA.[6]

Key secondary endpoint results showed that survodutide did not increase the risk of cardiovascular death, non-fatal stroke or non-fatal MI (3P-MACE) compared to placebo

(HR 0.84 [95%CI: 0.60-1.18]; p<0.0001 for non-inferiority using the treatment -regimen estimand).[1]

“With the SYNCHRONIZE-CVOT results reported today by Boehringer Ingelheim, the registrational Phase 3 SYNCHRONIZE program for survodutide in overweight and obesity is now complete. Collectively, the results of SYNCHRONIZE-1, SYNCHRONIZE-2, SYNCHRONIZE-MASLD and SYNCHRONIZE-CVOT provide us with further confidence that dual glucagon/GLP-1 can significantly reduce body weight, improve glycemic control, reduce liver fat and favorably affects cardiovascular risk factors,” said David Kendall, MD, Chief Medical Officer of Zealand Pharma. “These data confirm that targeting the metabolic function via dual agonism provides broad cardiometabolic improvements, including reductions in systolic blood pressure and waist circumference, which taken together serve as key indicators of reduced visceral fat and improved cardiometabolic health. We are pleased to see Boehringer Ingelheim are moving forward with global regulatory submissions in obesity.”

Additional key secondary endpoints showed survodutide improved several cardiometabolic health markers. A reduction in systolic blood pressure by up to 6.68 mmHg was seen using the supplementary secondary estimand compared with 1.76 mmHg in those receiving placebo (P= 0.0001), at 72 weeks.[1] Cardiovascular disease represents a leading cause of mortality and morbidity in people living with obesity.[7] For those receiving survodutide, a reduction in waist circumference of up to 11.96 cm was seen using the supplementary secondary estimand vs 2.74 cm with placebo. This reduction of waist circumference serves as a clinical marker closely linked to visceral fat and cardiometabolic risk.[5] Secondary endpoint results showed survodutide delivered meaningful weight loss of up to 13.7% at Week 72 using the supplementary secondary estimand in a population at elevated cardiovascular risk including individuals with T2D versus 2.0% in the placebo arm.[1] Significant reductions were seen in additional metabolic health biomarkers such as the inflammatory marker high sensitivity C-reactive protein (hs-CRP) and triglycerides versus placebo, that are predictors of cardiovascular risk.[2,8]Together, these findings demonstrate improvements across several dimensions of cardiometabolic health while establishing cardiovascular safety consistent with placebo.

"For people living with obesity, the clinical challenge extends beyond weight to the profound, often unrecognized effects of obesity, on cardiovascular and metabolic health,” said Dr. Biykem Bozkurt, M.D., Ph.D., Principal Investigator of the SYNCHRONIZE-CVOT trial. “We are looking at novel therapeutic approaches that do not merely reduce body weight but can also improve metabolic dysfunction while maintaining cardiovascular safety. Combined with the breadth of evidence from the SYNCHRONIZE program, these data help give us confidence in how we could manage obesity and related cardiometabolic risk.”

Obesity is a chronic, complex metabolic disease that can contribute to metabolic dysfunction, which can develop silently and progressively increase the likelihood of cardiometabolic conditions such as T2D, cardiovascular disease, chronic kidney disease and metabolic dysfunction-associated steatotic liver disease (MASLD) or early metabolic dysfunction-associated steatohepatitis (MASH).[3,4,5,9] Survodutide's dual glucagon/GLP-1 receptor agonist mechanism is designed to address this with the GLP-1 receptor agonism helping to regulate appetite and energy intake, while it's glucagon receptor agonism is associated with effects on energy expenditure and liver metabolism[10,11,12,13] By addressing these interconnected factors, survodutide may have the potential to deliver benefits that extend beyond weight loss to broader metabolic health. Survodutide has not been approved for use, and its efficacy and safety have not been established. Based on the totality of evidence generated across the SYNCHRONIZE program, we are moving forward with global regulatory submissions in obesity.

"The SYNCHRONIZE-CVOT trial findings represent an important milestone for survodutide clinical development as this is the first time we have demonstrated survodutide safety with respect to major adverse cardiovascular events", said Shashank Deshpande, Chairman of the Board of Managing Directors and Head of Human Pharma, Boehringer Ingelheim. "Together with the growing body of evidence from the SYNCHRONIZE program, these results strengthen our confidence in the potential of survodutide's dual-agonist approach to address underlying metabolic dysfunction and improve broader metabolic health beyond body weight alone. We remain committed to building evidence across interconnected metabolic diseases through our broader global clinical development program."

As expected with GLP-1-based therapies, the most commonly reported adverse events for survodutide were gastrointestinal (GI) events, which were mostly mild to moderate in severity, with nausea, vomiting, diarrhea, and constipation the most common compared to placebo.[1] The treatment discontinuation rates due to GI adverse events were 19.3% and 20.8% in people who received 3.6mg and 6.0mg doses of survodutide respectively compared to 1.9% on the placebo arm. These results are consistent with those from other SYNCHRONIZE trials.[1]

Discontinuations usually occurred during the dose escalation phase, as the initial study protocol allowed limited flexibility to manage adverse events through slower titration, dose adjustment, or longer temporary interruption.[1] This resulted in discontinuation in situations where patients might otherwise have continued treatment. Upcoming Phase 3b studies, including SYNCHRONIZE-START, SYNCHRONIZE-HERA, and ELEVATE-LIVER, as well as the Phase 3 SYNCHRONIZE-T2D trial, allow for more flexible, patient-centered titration strategies from the start to better reflect real-world use and support tolerability.[14,15,16,17]

In addition to the SYNCHRONIZE program, survodutide is being studied in two global Phase 3 clinical trials LIVERAGE and LIVERAGE-Cirrhosis investigating the efficacy and safety of survodutide in adults with MASH and fibrosis stages 2 or 3 and in those with compensated MASH cirrhosis (fibrosis stage 4).[18,19]

This company announcement discloses inside information pursuant to Article 17 of the Market Abuse Regulation (EU) No 596/2014.

About obesity and overweight

More than one billion people around the world are living with obesity today (1 in 8 of us) - and by 2030, that number could be more than double what it was in 2010.[20] Overweight and obesity are complex chronic conditions involving abnormal or excessive fat accumulation that present a risk to a person's overall health.[21]

About survodutide (BI 456906)

Survodutide is a glucagon/GLP-1 receptor dual agonist that activates both the glucagon and GLP-1 receptors, which play a role in controlling metabolic functions.[12,22,23] Survodutide is an investigational agent and has not been approved for use; its efficacy and safety has not been established. It is being evaluated in a robust Phase 3 clinical development program, including the SYNCHRONIZE studies for people living with overweight or obesity, and the LIVERAGE studies for people living with MASH and fibrosis.[17,18,19,24,25,26,27,28,29]

Survodutide has potential to treat adults with non-cirrhotic MASH and moderate or advanced fibrosis (stages 2 or 3) and has been recognized by the U.S. FDA, which granted it:

- Fast Track designation in May 2021 and;[30]
- Breakthrough Therapy designation in September 2024.[31]

Survodutide's potential to treat adults with MASH and fibrosis has also been recognized by:

- the European Medicines Agency (EMA), through acceptance to its PRIME scheme in November 2023 and;[32]
- the Center for Drug Evaluation of China's National Medical Products Administration (NMPA) which granted it Breakthrough Therapy designation in June 2024 and;
- the Taiwan Food and Drug Administration which granted it Breakthrough Designation in September 2024.

Survodutide is licensed to Boehringer Ingelheim from Zealand Pharma, with Boehringer solely responsible for development and commercialization globally. Survodutide is part of Boehringer Ingelheim's research and development portfolio in the cardiovascular, renal and metabolic disease areas.

About the SYNCHRONIZE-CVOT trial (NCT06077864)

SYNCHRONIZE-CVOT is a Phase 3, double-blind, placebo-controlled event driven cardiovascular safety study of survodutide among 5530 adults living with obesity or overweight with established cardiovascular disease (CVD) or chronic kidney disease, and/or at least two weight-related complications or risk factors for CVD.[27] Participants received a weekly injection of survodutide at either a 3.6 mg or 6.0 mg dose, or placebo. The primary endpoint of the trial is the time to first occurrence of any of the adjudicated components of the composite endpoint consisting of: CV death, non-fatal stroke, non-fatal MI, ischaemia related coronary revascularisation, or HFE (to demonstrate non-inferiority).[27]

There are 27 secondary and key secondary endpoints, including:[27]

- Time to first occurrence of any of the adjudicated components of 3P-MACE (CV death, non-fatal stroke, or non-fatal MI)
- Absolute change in systolic blood pressure (SBP)
- Absolute change in waist circumference
- Percentage change in body weight

About the SYNCHRONIZE program

Survodutide has been evaluated in three other global Phase 3 studies for people living with overweight or obesity.

- SYNCHRONIZE-1 enrolled adults without type 2 diabetes.[24]
- SYNCHRONIZE-MASLD enrolled adults at risk of MASLD with a confirmed or presumed diagnosis of MASH.[26]
- SYNCHRONIZE-2 enrolled adults with type 2 diabetes.[25]

Survodutide is also explored in two Phase 3 in-market trials:

- SYNCHRONIZE-JP in Japan and SYNCHRONIZE-CN in China are exploring survodutide for sub-populations of people living with obesity. SYNCHRONIZE-JP explores the relative change in liver fat and body composition parameters from

baseline to Week 76 when treated with survodutide versus placebo, as a secondary endpoint.[28,29]

As part of the broader evidence program, a set of Phase 3b studies are being advanced to address key unmet needs in people living with obesity and real-world care, including:

- SYNCHRONIZE-HERA will evaluate survodutide in women's health.[15]
- ELEVATE-LIVER will assess the impact of survodutide in the preservation of cardiac function and structure in people living with metabolic dysfunction-associated steatotic liver disease (MASLD) or early metabolic dysfunction-associated steatohepatitis (MASH).[16]
- SYNCHRONIZE-START will examine real-world titration approaches, including treatment initiation and switching from GLP-1 RAs, with a focus on tolerability[14]

Additionally, SYNCHRONIZE-T2D will investigate the effect of survodutide on improving glycemic control in adults with T2D who are managing their condition with diet and exercise alone or in combination with diabetes medications, including insulin.[17]

About LIVERAGE and LIVERAGE-Cirrhosis

LIVERAGE and LIVERAGE-Cirrhosis are global Phase 3 clinical trials investigating the efficacy and safety of survodutide in adults with MASH and fibrosis stages 2 or 3 and in those with compensated MASH cirrhosis (fibrosis stage 4), respectively[18,19]

LIVERAGE will enroll approximately 1,800 adults, and LIVERAGE-Cirrhosis will enroll approximately 1,590 adults. In each trial, participants are randomized to receive weekly injections of either survodutide, reaching a maximum dose, or placebo[18,19]

About Boehringer Ingelheim

Boehringer Ingelheim is a biopharmaceutical company active in both human and animal health. As one of the industry's top investors in research and development, the company focuses on developing innovative therapies that can improve and extend lives in areas of high unmet medical need. Independent since its foundation in 1885, Boehringer takes a long-term perspective. Our approximately 54,300 employees serve over 130 markets to build a healthier tomorrow. Learn more at www.boehringer-ingelheim.com.

* The treatment-regimen estimand is the estimated treatment effect, regardless of whether the patient adheres to the treatment, discontinues, or initiates other therapies.

†The supplementary secondary estimand is the effect expected with continued treatment, assuming no intercurrent events. It is conceptually similar to the efficacy estimand used in the other SYNCHRONIZE trials.

About Zealand Pharma A/S

Zealand Pharma A/S (Nasdaq: ZEAL) is a biotechnology company focused on advancing medicines for obesity and metabolic health. Combining more than 25 years of peptide R&D expertise with a proprietary data platform that leverages advanced data driven and AI/ML approaches, Zealand Pharma aims to lead a new era in obesity and metabolic health.

To date, more than ten Zealand Pharma invented drug candidates have entered clinical development, of which two products have reached the market and three candidates are in late-stage development. The Company has collaborations with global pharmaceutical and biotechnology partners for research, development, and commercialization.

Founded in 1998, Zealand Pharma is headquartered in Copenhagen, Denmark, with a U.S. presence in Cambridge, Massachusetts. Learn more at www.zealandpharma.com.

Forward-looking Statements

This company announcement contains “forward-looking statements”, as that term is defined in the Private Securities Litigation Reform Act of 1995 in the United States, as amended, even though no longer listed in the United States this is used as a definition to provide Zealand Pharma’s expectations or forecasts of future events regarding the research, development, and commercialization of pharmaceutical products, the timing of the company’s clinical trials and the reporting of data therefrom and the company’s significant events and potential catalysts in 2026 and financial guidance for 2026. These forward-looking statements may be identified by words such as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “possible,” “potential,” “will,” “would”, and other words and terms of similar meaning. You should not place undue reliance on these statements, or the scientific data presented. The reader is cautioned not to rely on these forward-looking statements. Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions, which may cause actual results to differ materially from expectations set forth herein and may cause any or all of such forward-looking statements to be incorrect, and which include, but are not limited to, unexpected costs or delays in clinical trials and other development activities due to adverse safety events or otherwise; unexpected concerns that may arise from additional data, analysis or results obtained during clinical trials; our ability to successfully market both new and existing products; changes in reimbursement rules and governmental laws and related interpretation thereof; government-mandated or market-driven price decreases for our products; introduction of competing products; production problems; unexpected growth in costs and expenses; our ability to effect the strategic reorganization of our businesses in the manner planned; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; regulatory authorities may require additional

information or further studies, or may reject, fail to approve or may delay approval of our drug candidates or expansion of product labelling; failure to obtain regulatory approvals in other jurisdictions; exposure to product liability and other claims; interest rate and currency exchange rate fluctuations; unexpected contract breaches or terminations; inflationary pressures on the global economy; and political uncertainty. If any or all of such forward-looking statements prove to be incorrect, our actual results could differ materially and adversely from those anticipated or implied by such statements. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. All such forward-looking statements speak only as of the date of this press release/company announcement and are based on information available to Zealand Pharma as of the date of this release/announcement. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. Information concerning pharmaceuticals (including compounds under development) contained within this material is not intended as advertising or medical advice.

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