Olink participates in one of the largest proteomics studies enabling new treatment options for patients with heart failure

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UPPSALA, Sweden, Dec. 02, 2021 (GLOBE NEWSWIRE) -- Olink Holding AB (publ) (“Olink”) (Nasdaq: OLK), today announced that its project with Boehringer Ingelheim, assessing the potential utility of protein biomarkers in the empagliflozin EMPEROR studies, recently entered the data analysis phase.

Empagliflozin, approved in the US under the tradename JARDIANCE, is a product used to lower blood sugar in patients with type 2 diabetes, and also to reduce the risk of cardiovascular death in those with type 2 diabetes who have known cardiovascular disease. JARDIANCE is also under Priority Review at the US FDA as a potential new treatment to reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure independent of left ventricular ejection fraction. The sNDA is based on results from the EMPEROR-Preserved Phase 3 trial, in which Jardiance was associated with a 21% relative risk reduction for the composite primary endpoint of cardiovascular death or hospitalization for heart failure in adults with heart failure with LVEF over 40% compared with placebo. Results were independent of ejection fraction or diabetes status.

“While the beneficial cardiovascular and renal effects of SGLT-2 inhibitors have been demonstrated in multiple clinical trials, the precise molecular mechanism of those effects is not well understood,” **said Jon Heimer, Chief Executive Officer of Olink Proteomics**. “Analyses like these may be among the first to demonstrate the future of drug development, when biomarker based informed decisions bring us all closer to precision medicine.”

Olink believes this effort represents one of the largest proteomics analysis directed at an approved drug, and that it could provide a better understanding of human biology, drug pharmacodynamic effects, and may also identify biomarkers allowing for better patient stratification. The analysis is being led by Boehringer Ingelheim and Prof Faiez Zannad, one of the principal investigators of the EMPEROR studies, and is being conducted with the Olink® Explore platform.

“It is hoped that these analyses by Boehringer Ingelheim and Olink become a model for future pharma-diagnostics companies best use of clinical trial data and samples to help understand the molecular basis of drug benefits, precisely in the clinical setting of the intended use of the drug." said **Prof Faiez Zannad, one of the principal investigators of the EMPEROR studies**.

The analyses will collect and measure circulating protein biomarkers in 1,500 blood samples from EMPEROR-Reduced and 1,500 blood samples from EMPEROR-Preserved in an effort to reveal a potential mode of action and the underlying biology in patients with heart failure. Sample collection, and proteomic analyses and data delivery occurred during the third quarter of 2021, with analyses now ongoing. It is expected that the results of these analyses will be communicated by Boehringer Ingelheim at a later date.

About the Emperor Studies
The EMPEROR (EMPagliflozin outcomE tRial in patients with chrOnic heaRt failure) studies in chronic heart failure, were conducted in patients with and without diabetes, and were two Phase 3, randomized, double-blind trials that investigated once-daily empagliflozin compared to placebo in adults with chronic HFrEF (heart failure with reduced ejection fraction) or HFpEF (heart failure with preserved ejection fraction).

EMPEROR-Preserved was a Phase 3 international, randomized, double-blind trial that enrolled 5,988 adults with and without type 2 diabetes. All participants had heart failure (New York Heart Association [NYHA] functional class II, III or IV) and LVEF over 40%; 4,005 (67%) had HFpEF (LVEF of at least 50%), and 1,983 (33%) had mildly reduced LVEF (greater than 40% but less than 50%). Participants were randomized to once-daily Jardiance 10 mg (n=2997) or placebo (n=2991), on top of treatment with guideline-directed heart failure therapy. Median follow-up time was 26.2 months. The composite primary endpoint was defined as time to first event of cardiovascular death or hospitalization for heart failure. In this study, empagliflozin reduced the combined risk of cardiovascular death or hospitalization for heart failure in patients with heart failure with preserved ejection fraction, regardless of the presence or absence of diabetes.

EMPEROR-Reduced was a Phase 3 international, randomized, double-blind trial that enrolled 3,730 patients with NYHA class II, III, or IV heart failure and an ejection fraction of 40% or less. Study participants received empagliflozin (10 mg once daily) or placebo, in addition to recommended therapy. The primary outcome was a composite of cardiovascular death or hospitalization for heart failure. Overall, in this trial empagliflozin was associated with a lower combined risk of cardiovascular death or hospitalization for heart failure than placebo, and with a slower progressive decline in renal function in patients with chronic heart failure and a reduced ejection fraction, regardless of the presence or absence of diabetes.

About Olink
Olink Holding AB (Nasdaq: OLK) is a company dedicated to accelerating proteomics together with the scientific community, across multiple disease areas to enable new discoveries and improve the lives of patients. Olink provides a platform of products and services which are deployed across major biopharmaceutical companies and leading clinical and academic institutions to deepen the understanding of real-time human biology and drive 21st century healthcare through actionable and impactful science. The company was founded in 2016 and is well established across Europe, North America and Asia. Olink is headquartered in Uppsala, Sweden.

Use of forward-looking statements
This press release contains forward-looking statements that are based on management’s beliefs and assumptions and on information currently available to management. All statements contained in this release other than statements of historical fact are forward-looking statements, including statements regarding our 2021 revenue outlook, our ability to develop, commercialize and achieve market acceptance of our current and planned products and services, our research and development efforts, and other matters regarding our business strategies, use of capital, results of operations and financial position, and plans and objectives for future operations. In some cases, you can identify forward-looking statements by the words “may,”

“will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “ongoing” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks, uncertainties and other factors are described under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Registration Statement on Form F-1, as amended (File No. 333-257842) and elsewhere in the documents we file with the Securities and Exchange Commission from time to time. We caution you that forward-looking statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. As a result, the forward-looking statements may not prove to be accurate. The forward-looking statements in this press release represent our views as of the date hereof. We undertake no obligation to update any forward-looking statements for any reason, except as required by law.

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