Biogen Idec and Cardiokine Initiate Phase III Clinical Trial for Lixivaptan in Congestive Heart Failure Patients with Hyponatremia

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CAMBRIDGE, Mass. & PHILADELPHIA--(BUSINESS WIRE)--Biogen Idec (Nasdaq: BIIB) and Cardiokine, Inc. today announced the initiation of a Phase III multi-center, randomized, placebo controlled, double-blind study of lixivaptan for congestive heart failure patients who suffer from hyponatremia, which is an electrolyte disturbance marked by low sodium levels in the blood. The trial will compare treatment with lixivaptan to placebo in approximately 650 patients in the U.S. and Europe.

Lixivaptan is an oral vasopressin V_2 receptor antagonist that works by causing a decrease in renal water reabsorption (an increase in urine volume) and a decrease in urine osmolality. In prior clinical studies, lixivaptan-treated patients showed improvement in serum sodium concentrations, decreases in body weight, and increases in urine volume. The safety profile supports continued development.

THE BALANCE (**T**reatment of **H**yponatr**E**mia **BA**sed on **L**ixiv**A**ptan in **N**YHA Class III/IV **C**ardiac Patient **E**valuation) study is a multi-center, randomized, placebo controlled, double-blind study of lixivaptan, a selective V_2 vasopressin receptor antagonist. Hyponatremia is common in patients who have been hospitalized with worsening heart failure. The primary endpoint of the study is to evaluate the safety and effectiveness of lixivaptan, when compared to placebo, in increasing serum sodium from baseline in heart failure patients with hyponatremia.

“The effect of hyponatremia on congestive heart failure patients is substantial and there are limited treatment options available to these patients,” said lead investigator William Abraham, M.D., Professor of Internal Medicine and Director of the Division of Cardiovascular Medicine, Ohio State University Medical Center. “Lixivaptan shows the potential to correct serum sodium levels in these patients.”

Hyponatremia is a condition that can occur in isolation, but is most often a complication of another disease including heart failure. At least a quarter of patients with heart failure have hyponatremia and recent studies have demonstrated that low sodium levels are an independent predictor of worsening outcomes in heart failure patients. Hyponatremia can also occur in patients with cirrhosis or syndrome of inappropriate anti-diuretic hormone secretion (SIADH).

“We are excited to see lixivaptan enter into Phase III studies as it is Biogen Idec’s lead cardiology program,” said Barry Ticho, M.D., Ph.D, Vice President, Cardiology, Biogen Idec. “Lixivaptan has the potential to address significant unmet needs for heart failure patients as well as other clinical conditions associated with hyponatremia.”

“This multi-national study utilizes a novel design and addresses the needs of an important subset of the heart failure population,” said Cesare Orlandi, M.D. Senior Chief Medical Officer at Cardiokine, which is responsible for running the trial. “THE BALANCE study is the first of several planned trials for lixivaptan. We anticipate initiating pivotal studies in SIADH later this year.”

Under the terms of the collaboration, Biogen Idec and Cardiokine expect to jointly develop lixivaptan. Biogen Idec will be responsible for its global commercialization and Cardiokine will have an option for co-promotion in the US.

About Biogen Idec

Biogen Idec creates new standards of care in therapeutic areas with high unmet medical needs. Founded in 1978, Biogen Idec is a global leader in the discovery, development, manufacturing and commercialization of innovative therapies. Patients in more than 90 countries benefit from Biogen Idec's significant products that address diseases such as lymphoma, multiple sclerosis and rheumatoid arthritis. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

About Cardiokine

Headquartered in Philadelphia, Cardiokine, Inc. is a specialty pharmaceutical company focused on the development of pharmaceuticals for the treatment and prevention of heart failure and related cardiovascular indications. Additional information about Cardiokine is available at www.cardiokine.com.

Biogen Idec Safe Harbor

This press release contains forward-looking statements regarding lixivaptan. These statements are based on Biogen Idec’s current beliefs and expectations. The commercial potential of lixivaptan is subject to a number of risks and uncertainties, including the risk of meeting the end points in clinical trials, other unexpected delays or hurdles, and the uncertainty of obtaining regulatory approval. Drug development and commercialization involves a high degree of risk.

For more detailed information on the risks and uncertainties associated with Biogen Idec’s drug development and other activities, see Item 1A "Risk Factors" in Biogen Idec’s most recent Form 10-Q filing with the Securities and Exchange Commission. These forward looking statements speak only as of the date of this press release, and we assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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