Avolynt Announces Completion of Phase 2b BRID Study of SGLT2 Inhibitor Remogliflozin-Etabonate

Top-line results to be available in the fourth quarter of 2016

RESEARCH TRIANGLE PARK, N.C., August 9, 2016 – Avolynt, Inc. ("Avolynt"), a privately held biotech company focused on the development of therapeutics for metabolic diseases, announced today that the phase 2b clinical trial of biphasic remogliflozin etabonate ("remogliflozin") has successfully completed last patient last visit.

The biphasic remogliflozin etabonate in diabetic subjects (BRID) study, a randomized, double blind dose-ranging study was conducted at twenty sites across the United States. Three doses of remogliflozin, plus placebo, were administered to 191 patients with type 2 diabetes. The primary endpoint is reduction in HbA1c. More information about the BRID Study may be found at clintrials.gov (NCT02537470).

"The BRID study is an important step in the development path for remogliflozin," said principal investigator Dr. Joel Neutel. "This study generated tremendous interest amongst our clinical sites with significant anticipation for the results."

Remogliflozin is a highly selective SGLT2 inhibitor being developed for type 2 diabetes and nonalcoholic steatohepatitis ("NASH"). Unlike other SGLT2 inhibitors, remogliflozin has a differentiated chemistry that provides a substantial anti-oxidant effect and allows for the avoidance of overnight inhibition of SGLT2. Overnight inhibition of SGLT2 is thought to lead to increases in LDL-cholesterol (LDL-c) and increased incidence of urogenital infections (Sykes, et al., Diab Obes Met. 17:94-101, 2015). The anti-oxidant properties of remogliflozin allow for a reduction in oxidative stress in the liver and in combination with its strong ability to improve insulin sensitivity, makes remogliflozin an ideal candidate for the treatment of NASH.

Subjects included in the study were male and female, 18-80 years old, diagnosed with type 2 diabetes and with HbA1c ranging from 7-10.5%.

"By concluding the trial, we have reached an exciting milestone in completing proof of concept of our hypothesis for a best-in-class SGLT2 inhibitor," said Avolynt Chief Scientific Officer Dr. William Wilkison. "We are looking forward to reviewing the results as the study was designed to test some of the conventional thinking around the SGLT2 mechanism and we will also obtain important data on the ability of remogliflozin to impact NASH."

About Remogliflozin
Remogliflozin is a selective SGLT2 inhibitor and potent anti-oxidant in clinical development for NASH and type 2 diabetes. Remogliflozin has been dosed in over 800 patients in greater than twenty clinical trials. In previous phase 2b clinical studies, remogliflozin demonstrated HbA1c lowering greater than 1% with few adverse events. Low incidence rates of genitourinary infections and little or no increases in LDL-c, common side effects commonly associated with SGLT2 inhibitors, were also observed.

Remogliflozin has also demonstrated strong improvements in both insulin sensitivity and beta cell function as well as reductions in liver enzymes and oxidative stress. The REIN study, a global pivotal study of remogliflozin in patients with histologically confirmed NASH, is anticipated to initiate in late 2016.

About Avolynt, Inc.
Avolynt is a privately owned drug development company based in Research Triangle Park, North Carolina. Avolynt's mission is to improve the lives of patients suffering from dysfunctions related to human metabolism. The Avolynt team has significant discovery and development experience across the metabolic syndrome, including diabetes, obesity, and nonalcoholic steatohepatitis (NASH). The Company is developing a novel SGLT2 inhibitor for the treatment of NASH and type 2 diabetes. Avolynt, through its wholly owned subsidiary BHV Pharma, holds an exclusive license to remogliflozin-etabonate for the global territory outside of Japan, Korea, and Taiwan. For more information about Avolynt, visit www.avolynt.com.

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