Avolynt, Inc. Announces Positive Topline Data for Phase 2b BRID Study of SGLT2 Remogliflozin

RESEARCH TRIANGLE PARK, N.C., December 19, 2016 -- Avolynt Inc. ("Avolynt"), a privately held biotech company focused on the development of therapeutics for metabolic diseases, announced today topline results of the twelve-week phase 2b clinical trial of biphasic remogliflozin etabonate. The Biphasic Remogliflozin etabonate In Diabetic subjects (BRID) study was a double blind, dose ranging study conducted at twenty sites across the United States. Three doses of remogliflozin, plus placebo, were administered to 191 randomized patients with type 2 diabetes. More information about the BRID Study (NCT02537470) may be found on ClinicalTrials.gov clinicaltrials.gov/ct2/show/NCT02537470.

All three doses examined caused statistically significant decreases in placebo-adjusted HbA1c ranging from 0.44% to 0.6% with p values $\leq$0.02. Additional efficacy measurements included decreases by all three doses in body weight and fasting plasma glucose. Of particular interest was a large decrease in placebo-adjusted systolic (-2.4 to -5.6 mmHg) and diastolic (-1.7 to -3.7 mmHg) blood pressure. NAFLD fibrosis scores were also decreased from baseline (-0.14 and -0.36) in two of the three remogliflozin treatment groups and with a greater percentage of subjects treated with remogliflozin showing improvement when compared to placebo. The decreases were comparable to those seen in FLINT and GOLDEN at 24 weeks and 52 weeks respectively.

Equally important to the efficacy data, biphasic remogliflozin demonstrated excellent results for safety and tolerability. Biphasic remogliflozin did not increase LDL-c after 12 weeks of dosing, a common side effect of SGLT2 inhibition. Urogenital infections were also very low compared to other published results of clinical studies of SGLT2 inhibitors. Remogliflozin was generally well tolerated with few adverse events and no drug related significant adverse events.

"The results of the BRID study are very encouraging on multiple fronts," said Avolynt Chief Scientific Officer Dr. William Wilkison. "In addition to strong efficacy, we are particularly excited about the cardiovascular related results we see with LDL cholesterol and blood pressure, in addition to a positive effect on NAFLD fibrosis biomarker scores."

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 significant HbA1c lowering 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 adaptive study of remogliflozin in patients with histologically confirmed NASH, is anticipated to initiate in 2017.

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 from Kissei Pharmaceutical Co., Ltd., Japan, to remogliflozin- etabonate for the global territory outside of Japan, Korea, and Taiwan. Libbs Farmaceutica, Brazil, licensee of rights to remogliflozin in Latin America, provided financial support for the BRID study. For more information about Avolynt, visit www.avolynt.com.

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