



PhaseBio Pharmaceuticals Announces Positive Clinical Results with its Once Weekly GLP-1 analogue, Glymera™ for the Treatment of Hyperglycemia in Patients with Type 2 Diabetes

MALVERN, PA – (November 15, 2011 - Business Wire) – [PhaseBio Pharmaceuticals, Inc.](#), announced today positive results from its Phase I/IIa single and multiple ascending dose clinical study with [Glymera™](#), a recombinant glucagon-like peptide-1 (GLP-1) analogue for the treatment of hyperglycemia in patients with type 2 diabetes. In a dose dependent manner, Glymera™ demonstrated highly statistically significant reductions in fasting glucose glycemic load following meal tolerance testing, and average daily glucose measured through continuous glucose monitoring following 4 weeks of dosing.

“Currently approved GLP-1 analogues in the US need to be given at least once a day. Our intent was to develop a long acting product that would provide full 24/7 coverage and we are extremely pleased to have such robust results this early in the development of Glymera™ that supports a weekly dosing regimen and plan to aggressively move Glymera™ through the development process” said [Lynne Georgopoulos, Senior Vice President Clinical Development at PhaseBio.](#)

The Phase I/IIa study was a multicenter, randomized, double-blind, placebo-controlled single and 4-week multiple (once weekly dosing) ascending dose study (NCT 01236404) conducted at three study centers in the United States. The purpose of the study was to assess the safety, tolerability and PK profile and to evaluate PD effects through measurement of fasting glucose, metabolic response to a liquid meal challenge, and change in average daily glucose measured through continuous glucose monitoring (CGM) before and after dosing in selected subjects receiving multiple doses of Glymera™. A total of 80 subjects with screening HbA1c between 6 and 9% on a background of one oral anti-diabetic drug (OAD), or between 6 and 8.5% when taking up to two OADs, discontinued OAD during a minimum 2 week run-in period prior to dosing.

Overall Glymera™ was well tolerated. The most common adverse event was a dose dependent transient and mild nausea. The slow controlled rate of absorption and long half-life directly correlates to a favorable GI tolerability displayed both in preclinical studies and in this clinical study.

“The magnitude of the reductions in fasting plasma glucose as well as average glucose from continuous glucose monitoring are expected to translate into a substantial decrease in HbA1c” said [Dr. Poul Strange, MD, PhD, President Integrated Medical Development and Chief Medical Advisor to PhaseBio’s Metabolic and Endocrinology Program.](#) Dr. Strange went on to say, “Because PhaseBio’s ELP technology is able to closely control the absorption profile, Glymera™ has the potential to show less nausea than what has been reported with other GLP-1 analogues as the onset of nausea appears to be related to the rapid release of GLP-1 agonist into the circulation”.

“This study provides a robust validation of the safety and mechanism of action of the ELP technology platform. Moreover, the clinical findings are consistent with our goal of using ELP technology to bring highly differentiated products to the market and we look forward to the successful development of Glymera™ and other products currently in our development pipeline” said [Craig Rosen, Chief Scientific Officer and Chairman of the Board, PhaseBio Pharmaceuticals.](#)

About PhaseBio

PhaseBio Pharmaceuticals is a clinical-stage biopharmaceutical company developing novel drugs to treat diabetes, metabolic and cardiovascular disease. The company uses elastin-like biopolymers (ELP's) to increase the half-life, bioavailability, efficacy and ease of administration of therapeutic drugs and to reduce their side effects. ELPs have been engineered to control the rate of absorption into the circulation which results in a steady state pharmacokinetic profile exhibiting a unique combination of slow absorption and prolonged half-life providing an optimal drug exposure. The company's lead development candidates are Glymera™, a GLP-1 analogue for type 2 diabetes and obesity, and Vasomera™, a vasoactive intestinal peptide (VIP), currently in preclinical development for chronic heart failure and hypertension. PhaseBio is a privately owned company with headquarters and research laboratories in Malvern, Pennsylvania.

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