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CymaBay Announces Study to Evaluate the Potential for GPR119 Agonists to Prevent Hypoglycemia in Type 1 Diabetes

The AdventHealth Translational Research Institute (TRI) in Orlando, FL to lead the study, funded by the Helmsley Charitable Trust, evaluating MBX-2982, a GPR119 agonist, for its ability to increase secretion of glucagon, a hormone that reverses low blood glucose levels (hypoglycemia) in individuals with type 1 diabetes (T1D)

NEWARK, Calif., Nov. 05, 2020 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ: CBAY), a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet need, today announced it will provide its proprietary investigational GPR119 agonist, MBX-2982, and will assist in regulatory filings for a clinical study to be conducted by the TRI. CymaBay wholly owns and retains all rights to MBX-2982. The objective of the study is to determine if GPR119 agonists have potential to prevent hypoglycemia for people living with T1D. The trial is funded by a nearly $1.2 million grant from The Leona M. and Harry B. Helmsley Charitable Trust (Helmsley).

Glucagon is a hormone secreted by the pancreas, that naturally reverses hypoglycemia by signaling the body to release stored glucose. This process is defective in individuals with insulin-dependent diabetes, such as T1D. If left uncorrected, hypoglycemia can lead to unconsciousness or death. Preventing episodes of hypoglycemia in persons with diabetes is an unmet medical need: according to the 2016 global HAT study of 27,000 people, 4 out of 5 individuals with T1D reported hypoglycemia, with a rate of severe hypoglycemia (requiring assistance of another person) of approximately 5 events per patient-year.

In recent preclinical studies, GPR119 agonists were shown to enhance glucagon secretion in response to low glucose levels, and were able to prevent hypoglycemia in animal models. To translate these findings, the TRI in Orlando, FL will test CymaBay's MBX-2982 in a Phase 2a proof-of-pharmacology study to determine whether the drug can enhance glucagon secretion during insulin-induced hypoglycemia in subjects with T1D.

Sujal Shah, President and CEO of CymaBay, stated, "We are grateful to be able to contribute to this effort to evaluate MBX-2982, an agonist of GPR119, for its potential to treat individuals at risk for insulin-induced hypoglycemia, one of the most challenging and potentially life threatening complications of insulin therapy in diabetes."

Richard Pratley, MD the Samuel E. Crockett Chair in Diabetes Research and Diabetes

Program Head at the TRI said, “Hypoglycemia is common among persons with T1D and is a barrier to achieving optimal glycemic control for many patients. This is a unique opportunity to explore whether a clinical-stage class of drugs can address a key unmet need in the management of T1D.”

Ben Williams, PhD, Program Officer in the Helmsley T1D Program, stated, “Preventing hypoglycemia is a major focus of the Helmsley T1D Program and we are happy to support efforts to show whether this class of drug might help improve the lives of people with T1D.”

Study start-up activities are underway and TRI and CymaBay will provide updates on study design, objectives and results throughout the study.

About MBX-2982
MBX-2982 is a once daily oral GPR119 agonist that has previously been studied in type 2 diabetes. It has a favorable profile in non-clinical toxicology studies in two species of six months duration. It appeared to be safe and well tolerated in five previous clinical studies with dosing in over 200 subjects with a duration of up to 28 days. CymaBay fully owns all rights to MBX-2982. GPR119 is a G protein-coupled receptor that is expressed in pancreatic islets and the gastrointestinal tract. Pre-clinical studies conducted by CymaBay and others show that GPR119 agonists can stimulate glucose-dependent insulin secretion and release of incretin hormones such as GLP-1, and thus may preserve beta cell health. Previously, MBX-2982 was evaluated for treating type 2 diabetes mellitus (T2DM) due to its action to stimulate insulin secretion in a glucose dependent manner.

About Hypoglycemia in Diabetes
Insulin-induced hypoglycemia in diabetes is a significant limiting factor in achieving the desired glucose control and is the cause of significant morbidity. This can be a common, unpredictable and dangerous side effect of treatment, especially in diabetics using insulin. Type1 and advanced type 2 diabetics have compromised physiological defenses against falling plasma glucose concentrations that are the result of the pathophysiology of defective glucose counter regulation - the mechanisms that normally prevent or rapidly correct hypoglycemia. As the duration of the disease progresses, the glucose counterregulatory mechanisms opposing hypoglycemia in diabetics becomes impaired. Hypoglycemia, and its perceived risk, is an obstacle to achieving glucose control treatment goals. Many patients are fearful of dangerous hypoglycemic episodes and can become conservative in their use of insulin preventing the achievement of adequate glucose control. Currently there are no therapies restoring the natural physiologic response to changes in glucose levels in order to prevent or at least to blunt hypoglycemic episodes.

About CymaBay
CymaBay Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet medical need.

Cautionary Statements
The statements in this press release regarding expected or potential future events or results, including the potential benefits MBX-2982 as well as plans to evaluate MBX-2982, are forward looking statements that are subject to risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of risks and uncertainties, which include, without limitation, risks related to: the success, cost and timing of product development activities for MBX-2982,

including clinical trials. Additional risks relating to CymaBay are contained in CymaBay's filings with the Securities and Exchange Commission, including without limitation its most recent Annual Report on Form 10-Q and other documents subsequently filed with or furnished to the Securities and Exchange Commission. CymaBay disclaims any obligation to update these forward-looking statements except as required by law.

For additional information about CymaBay visit www.cymabay.com.

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