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Zafgen Announces Initiation of Phase 2b Trial of Beloranib in Severe Obesity

BOSTON, Dec. 15, 2014 (GLOBE NEWSWIRE) -- Zafgen, Inc. (Nasdaq:ZFGN), a biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by obesity and complex metabolic disorders, today announced that the Company has initiated a Phase 2b clinical trial with its lead product candidate, beloranib, in the treatment of patients with both severe obesity and type 2 diabetes.

The trial is a randomized, double-blind, placebo-controlled design in severely obese adults with a BMI between 30 and 60 kg/m^2, and type 2 diabetes. The trial will aim to demonstrate weight loss over a 6 - 12 month period, along with improvements in glycemic control, and is expected to enroll 150 patients at approximately 15 sites across Australia. Patients enrolled will be randomized to receive placebo, 1.2 mg or 1.8 mg of beloranib, twice weekly subcutaneous injections during the randomized treatment period of 12 months.

The primary efficacy endpoint is change in total body weight from baseline to the end of randomized treatment. Key secondary endpoints include changes in glycemic control, lipid parameters and inflammatory markers. Additional assessments include sense of hunger and quality of life impact for patients.

"We're very excited to announce the initiation of this Phase 2b trial of beloranib. The trial aims to determine the long-term impact of beloranib on body weight, and will provide us with the opportunity to assess the compound's potential to impact medically important comorbid conditions such as type 2 diabetes," said Dr. Thomas Hughes, Ph.D., Chief Executive Officer. "We are eager to explore beloranib in this high-risk population of severely obese patients, for whom type 2 diabetes is a common and life-altering comorbidity."

For more information about the trial, please visit www.clinicaltrials.gov.

About Beloranib

Beloranib is a novel, first-in-class injectable small molecule therapy with a unique mechanism of action that reduces hunger while stimulating the use of stored fat as an energy source. Beloranib is a potent inhibitor of MetAP2, an enzyme that modulates the activity of key cellular processes that control metabolism. MetAP2 inhibitors work, at least in part, by directing MetAP2 binding to cellular stress mediators, and, thus, reducing the tone of signals that drive lipid synthesis by the liver and fat storage throughout the body. In this manner, MetAP2 inhibition increases metabolism of fat as an energy source. Zafgen holds exclusive worldwide rights (exclusive of South Korea) for the development and commercialization of beloranib. Zafgen exclusively licensed beloranib from Chong Kun Dang (CKD) Pharmaceutical Corp. of South Korea.

About Severe Obesity

Severely obese people are among the most medically underserved populations globally, beyond reach of currently approved therapies and are at increased risk for serious health issues and premature death. According to the Centers for Disease Control and Prevention, more than one-third of U.S. adults are obese, and for those who are severely obese, getting to a healthier state is especially difficult because their bodies become "programmed" to create and store more fat. There currently are no approved medical therapies that fully address the biological mechanisms of obesity, and many patients are still beyond reach of meaningful treatment with current therapies.

About Zafgen

Zafgen (Nasdaq:ZFGN) is a biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by obesity and complex metabolic disorders. Zafgen is focused on developing novel therapeutics that treat the underlying biological mechanisms through the MetAP2 pathway. Beloranib, Zafgen's lead product candidate, is a novel, first-in-class, twice-weekly subcutaneous injection being developed for the treatment of multiple indications, including severe obesity in two rare diseases, Prader-Willi syndrome and obesity caused by hypothalamic injury, including craniopharyngioma-associated obesity; and severe obesity in the general population. Zafgen aspires to improve the lives of patients through targeted treatments and has assembled a team accomplished in bringing therapies to patients with both rare and prevalent metabolic diseases.

Safe Harbor Statement

Various statements in this release concerning Zafgen's future expectations, plans and prospects, including without limitation, Zafgen's expectations regarding beloranib as a treatment for PWS and other forms of severe obesity, including severely obese patients with type 2 diabetes, its expectations with respect to the timing and success of its clinical trials, the expected requirements and timing of additional clinical trials, and its plans regarding commercialization of beloranib may constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements can be identified by terminology such as "anticipate," "believe," "could," "could increase the likelihood," "estimate," "expect," "intend," "is planned," "may," "should," "will," "will enable," "would be expected," "look forward," "may provide," "would" or similar terms, variations of such terms or the negative of those terms. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including, without limitation, Zafgen's ability to successfully demonstrate the efficacy and safety of its product candidates, the pre-clinical and clinical results for its product candidates, which may not support further development, actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials, obtaining, maintaining and protecting intellectual property, Zafgen's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties, competition from others developing products for similar uses, Zafgen's ability to manage operating expenses, Zafgen's ability to obtain additional funding to support its business activities and establish and maintain strategic business alliances and new business initiatives, Zafgen's dependence on third parties for development, manufacture, marketing, sales and distribution of products, the outcome of litigation, and unexpected expenditures, as well as those risks more fully discussed in the section entitled "Risk Factors" in the final prospectus related to Zafgen's initial public offering filed with the Securities and Exchange Commission pursuant to Rule 424(b) of the Securities Act, as well as discussions of potential risks, uncertainties, and other important factors in Zafgen's subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Zafgen's views only as of today and should not be relied upon as representing its views as of any subsequent date. Zafgen explicitly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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