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Zafgen Completes Enrollment of Phase 2b Trial of Beloranib in Severe Obesity Complicated by Type 2 Diabetes

On Track to Report Interim Results in Late 2015 or Very Early 1Q16

BOSTON, Sept. 9, 2015 (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 it has completed enrollment of ZAF-203, a Phase 2b clinical trial of beloranib in the treatment of patients with both severe obesity and type 2 diabetes. The trial enrolled 152 patients across 16 sites in Australia.

ZAF-203 is a Phase 2b clinical trial designed to determine the long-term weight loss benefits of MetAP2 inhibitor treatment with beloranib in patients with severe obesity complicated by type 2 diabetes, which began randomized treatment in December 2014. The trial aims to demonstrate efficacy and safety over a 12 month period, with an interim six-month analysis. Patients in the study are randomized to receive twice weekly subcutaneous injections of placebo, 1.2 mg or 1.8 mg of beloranib during the treatment period of 12 months. The Company remains on track to release six-month interim data in a subset of 95 patients in late 2015 or very early 2016.

The baseline characteristics of the study population on average are as follows: 54 years of age, body mass index (BMI) of 40 kg/m^2, body weight of 115 kg, HbA1c of 8.3% and fasting glucose of 193 mg/dl, with 43% of the patients being female. "The baseline characteristics of patients in this trial meet our expectations. The population being studied is poorly controlled, at high risk of developing serious medical complications, and in need of improved therapies providing clinically significant weight loss and glycemic control," said Dr. Dennis Kim, Chief Medical Officer of Zafgen.

"We're very pleased to announce that we have completed enrollment for our Phase 2b study in this high risk population of obese patients complicated by type 2 diabetes inadequately controlled by other agents," said Dr. Thomas Hughes, Chief Executive Officer of Zafgen. "We look forward to seeing the impact of beloranib treatment on body weight and glycemic control, among other endpoints. This study provides our first view of the drug's potential to provide changes in the range of those seen following bariatric surgery."

The primary efficacy endpoint is change in total body weight at six months 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.

For more information about this 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 methionine aminopeptidase 2, or 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 (PWS) and hypothalamic injury-associated obesity (HIAO), including craniopharyngioma-associated obesity; and severe obesity in the general population. Zafgen is also developing ZGN-839, a liver-targeted MetAP2 inhibitor, for the treatment of nonalcoholic steatohepatitis, or NASH, and abdominal obesity, as well as second-generation MetAP2 inhibitors. 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, HIAO and other forms of severe obesity, including severe obesity in patients with type 2 diabetes, its expectations with respect to the timing and success of its clinical trials of beloranib and other product candidates, the expected requirements and timing of additional clinical trials and pre-clinical studies, 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 its 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 Zafgen's most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, 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.

CONTACT: Media/Investor Relations Contact:

FTI Consulting

Kimberly Ha

(212) 850-5612

kimberly.ha@fticonsulting.com

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