



Zafgen Initiates Phase 2 Clinical Trial for ZGN-1061 in Patients with Type 2 Diabetes

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-Company Expects to Report Interim Data from ZAF-1061-201 in First Half of 2018-

BOSTON, Sept. 12, 2017 (GLOBE NEWSWIRE) -- Zafgen, Inc. (Nasdaq:ZFGN), today announced initiation of ZAF-1061-201, the Company's Phase 2 clinical trial evaluating ZGN-1061 in patients with type 2 diabetes. The primary objectives of this trial are to assess glycemic control as well as safety and tolerability. ZGN-1061 is the Company's second-generation MetAP2 inhibitor.

"The initiation and commencement of patient dosing in this Phase 2 clinical trial represents a milestone in our ZGN-1061 development program, as we further evaluate ZGN-1061 in patients who face numerous challenges associated with managing their type 2 diabetes," said Thomas Hughes, Ph.D., President and Chief Executive Officer of Zafgen. "ZGN-1061 has the potential to drive improvements across a number of metabolic endpoints which are not fully addressed by current diabetes treatments, and we look forward to sharing progress on enrollment of the clinical trial and reporting interim data in the first half of next year."

The randomized, placebo-controlled Phase 2 clinical trial will evaluate three doses of ZGN-1061 for 12 weeks. The clinical trial will enroll approximately 120 patients with type 2 diabetes who are overweight or obese (BMI \geq 27) across 23 study sites in Australia and New Zealand. Patients will be randomized to either placebo or one of three ZGN-1061 dosing arms, 0.05 mg, 0.3 mg and 0.9 mg, which will be administered by subcutaneous injection every three days. In addition to the primary objectives of assessing glycemic control and safety and tolerability, the Company will evaluate the effects of ZGN-1061 on multiple metabolic measures and cardiovascular risk factors, including body weight, plasma lipid fractions, and inflammation. The protocol provides for an interim analysis, expected in the first half of 2018, which will evaluate all patients who have completed the 12-week treatment period at the time of the analysis.

"We expect that this clinical trial will provide us with initial insights on how ZGN-1061 could positively impact glycemic control and other metabolic endpoints in this difficult-to-treat patient population, and help identify an optimal dose range for use in later-stage clinical trials," stated Dennis Kim, M.D., Chief Medical Officer. "We have been very encouraged with the clinical profile for ZGN-1061, which in a Phase 1 clinical trial demonstrated a favorable safety and pharmacokinetic profile as well as early efficacy signals consistent with MetAP2 inhibition."

Previously Reported Data for ZGN-1061

Earlier this year, Zafgen presented the data from the Phase 1 clinical trial of ZGN-1061 showing that ZGN-1061 treatment causes improvements across multiple metabolic measures and demonstrates rapid drug absorption and clearance, with no evidence of prothrombotic effects.

In the clinical trial, ZGN-1061 was safe and well-tolerated, with no serious adverse events (SAEs) and no severe adverse events (AEs). There were no AEs leading to early withdrawal from the clinical trial.

On average, patients treated with ZGN-1061 for four weeks lost weight relative to placebo-treated patients (-4.6 lbs, -2.2 lbs, and -3.8 lbs for 0.2 mg, 0.6 mg, and 1.8 mg, respectively vs. -0.51 lbs for placebo). Body weight loss was steady and progressive during treatment with ZGN-1061 and rebounded post-treatment, supporting a drug effect. ZGN-1061 produced improvements in waist circumference relative to placebo and resulted in a trend for reduced food intake relative to placebo. The clinical trial demonstrated trends for reductions in LDL-cholesterol, and high-sensitivity C-reactive protein (hsCRP). Notably, there were greater reductions in mean LDL-cholesterol and hsCRP in ZGN-1061-treated patients with abnormally elevated LDL or hsCRP at baseline. Additionally, the clinical trial showed a trend for reductions in leptin and increases in adiponectin with ZGN-1061 compared to placebo, reflective of favorable changes in adipose function and signaling.

About ZGN-1061

ZGN-1061 is a fumagillin-class, injectable small molecule second generation MetAP2 inhibitor that was advanced into development due to its unique properties that maximize impact on metabolic parameters relevant to the treatment of type 2 diabetes and other related metabolic disorders. In preclinical studies, ZGN-1061 has demonstrated promising efficacy in animal models of type 2 diabetes and obesity, with an improved pharmacokinetic profile and safety margin relative to previous molecules in the MetAP2 inhibitor class. As demonstrated clinically for MetAP2 inhibitors, ZGN-1061 is anticipated to improve glycemic control while also helping to restore balance to fat metabolism, enabling calories to once again be used as a productive energy source, leading to improved metabolic control and long-term weight loss. Zafgen recently completed its first Phase 1 clinical trial of ZGN-1061, and is in Phase 2 clinical testing in patients with type 2 diabetes who are overweight or obese. Zafgen holds exclusive worldwide rights for the development and commercialization of ZGN-1061.

About Zafgen

Zafgen (Nasdaq:ZFGN) is a biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by metabolic diseases including type 2 diabetes and obesity. Zafgen is focused on developing novel therapeutics that treat the underlying biological mechanisms of metabolic diseases through the MetAP2 pathway. Zafgen has pioneered the study of MetAP2 inhibitors in both common and rare forms of obesity, and in patients affected by type 2 diabetes. Zafgen's lead product candidate is ZGN-1061, which is a novel, first-in-class, subcutaneous injection. Zafgen aspires to improve the lives of patients through targeted treatments and has assembled a team accomplished in bringing therapies to patients affected by 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 the use of ZGN-1061 and other MetAP2 inhibitors as treatments for metabolic diseases including type 2 diabetes and obesity, ZGN-1061's improved safety margin, including as it relates to prothrombotic characteristics, compared to first generation MetAP2 inhibitors, such as over beloranib, and Zafgen's expectations with respect to the timing and success of its preclinical studies and clinical trials of ZGN-1061 and its other product candidates, 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 ZGN-1061 and its other product candidates and to differentiate ZGN-1061 and its other product candidates from first generation MetAP2 inhibitors, such as beloranib, the preclinical and clinical results for ZGN-1061 and its other product candidates, which may not support further development and marketing approval, actions of regulatory agencies, which may affect the initiation, timing and progress of preclinical studies and clinical trials of its product candidates, Zafgen's ability to obtain, maintain and protect 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 when needed, Zafgen's dependence on third parties for development, manufacture, marketing, sales and distribution of product candidates, 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.

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