



Zafgen Presented Full Results of Phase 2 Clinical Trial for ZGN-1061 at the American Diabetes Association's 79th Scientific Sessions

June 10, 2019

Delivered comprehensive oral presentation on both cohorts of the clinical trial, including previously announced results for second cohort evaluating doses up to 1.8 mg

Company also presented data demonstrating that treatment with ZGN-1061 improves measures of insulin sensitivity and beta-cell function

BOSTON, June 10, 2019 (GLOBE NEWSWIRE) -- Zafgen, Inc. (Nasdaq:ZFGN), a clinical-stage biopharmaceutical company leveraging its proprietary knowledge of MetAP2 systems biology to develop novel therapies for patients affected by a range of metabolic diseases, today announced that the Company presented the full results of its Phase 2 clinical trial for ZGN-1061 in an oral presentation at the American Diabetes Association's 79th Scientific Sessions. Zafgen also presented a poster on data demonstrating that treatment with ZGN-1061 improved measures of glycemic control, including insulin sensitivity and beta-cell function.

Zafgen [previously announced](#) positive results from its Phase 2 clinical trial conducted outside the U.S., including data for the second cohort that included doses up to 1.8 mg, in January 2019. The clinical trial met all of its primary objectives at the 1.8 mg dose, which included glycemic control, or change in A1C, and safety and tolerability. The 12-week data demonstrated that treatment with the 1.8 mg dose of ZGN-1061 produced substantially more improvement in A1C versus placebo than the 0.9 mg dose versus placebo. Progressive and notable reduction in body weight also occurred in patients treated with the 1.8 mg dose. The data showed a favorable safety and tolerability profile for ZGN-1061, with no treatment-related serious adverse events and no cardiovascular (CV) safety signals observed in the trial.

The Phase 2 clinical trial also examined the effects of ZGN-1061 on other markers of glycemic control. In data presented during the poster session, patients who participated in a mixed-meal tolerance test demonstrated significant improvements in postprandial glucose excursion with ZGN-1061 ($p < 0.001$ for both the 0.9 and 1.8 mg doses) and a trend for improvement in insulin levels from baseline to Week 12. ZGN-1061 also demonstrated improvement in beta-cell function and insulin sensitivity in an exploratory combined analysis of 0.9+1.8 mg ZGN-1061 ($p = 0.02$ and $p = 0.07$) using a modeling approach. These data suggest improved glycemic control with ZGN-1061 may be driven by changes in insulin sensitivity and beta-cell function in this population of patients with advanced diabetes.

The poster will be available on the Company's [website](#).

About Zafgen

Zafgen (Nasdaq:ZFGN) is a clinical-stage biopharmaceutical company leveraging its proprietary MetAP2 biology platform to develop novel therapies for patients affected by complex metabolic diseases. Zafgen has pioneered the study of MetAP2 inhibitors in both common and rare metabolic disorders. Learn more at www.zafgen.com.

Safe Harbor Statement

Various statements in this release concerning Zafgen's future expectations, plans and prospects, including without limitation, Zafgen's expectations regarding the development and use of ZGN-1061 as a treatment for metabolic diseases, nonclinical or clinical options to resolve the clinical hold concerning ZGN-1061, and Zafgen's expectations with respect to the timing and success of its nonclinical studies and clinical trials of ZGN-1061 and its other product candidates, and Zafgen's expectations regarding the length of its cash runway, may constitute forward-looking statements for the purposes of the safe harbor provisions of 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, ZGN-1258, ZGN-1345 and its other product candidates and to differentiate them from first generation MetAP2 inhibitors, such as belorabin, the nonclinical and clinical results for ZGN-1061, ZGN-1258, ZGN-1345 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 nonclinical studies and clinical trials of its product candidates, Zafgen's ability to successfully engage with the FDA concerning the clinical hold on a clinical trial of ZGN-1061 and to design and conduct a nonclinical study or clinical trial demonstrating sufficient data to exclude cardiovascular risk to an acceptable degree and demonstrating the risk is reasonable to type 2 diabetes or other indications, Zafgen's ability to overcome the full clinical hold placed on ZGN-1061 by the FDA and obtain regulatory approval, Zafgen's ability to continue to evaluate ZGN-1258 and to advance the program in nonclinical and clinical development, 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 ability to attract and retain personnel, Zafgen's dependence on third parties for development, manufacture, marketing, sales and distribution of product candidates, and unexpected expenditures, as well as those risks more fully discussed in the section entitled "Risk Factors" in Zafgen's most recent Annual Report on Form 10-K 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, including without limitation Zafgen's Quarterly Reports on Form 10-Q. 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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The Zafgen logo consists of the word "Zafgen" in a light blue, sans-serif font. The letter "Z" is significantly larger than the other letters and has a unique, rounded shape. A small trademark symbol (TM) is located at the top right of the letter "n".

Source: Zafgen, Inc.