



## Zafgen Announces Agreement with U.S. Food and Drug Administration on New Nonclinical Study Design for ZGN-1061

July 24, 2019

*Alignment reached on in vivo animal study design and protocol to translate work from novel in vitro assays and establish relevant safety margins*

*Topline data from the in vivo study expected by the end of 2019*

*Company has implemented measures to ensure the effective use of capital and extend cash runway*

BOSTON, July 24, 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 has reached agreement with the U.S. Food and Drug Administration (FDA) on an *in vivo* animal study design and protocol to establish relevant safety margins for ZGN-1061, its investigational MetAP2 inhibitor in development. The study is designed to translate the data from the Company's newly developed *in vitro* assays of human endothelial cells and assessment of tissue factor expression with endothelial cells, along with other supportive assays, as it works toward resolving the previously announced clinical hold. Topline data from the *in vivo* animal study are expected by the end of 2019.

"The *in vitro* assays we presented to the FDA reflect Zafgen's deep understanding of the significant difference of ZGN-1061 on endothelial cell biology as compared to our prior compound and we believe represent a truly sophisticated and optimized approach to evaluate important safety information about ZGN-1061," said Priya Singhal, M.D., M.P.H, Head of Research and Development. "We are working to rapidly implement the *in vivo* animal study, which aims to establish the relevance of the *in vitro* mechanism and safety margins. We appreciate the FDA's thorough feedback and continuing collaboration throughout this process."

Given the current status and expected timelines of Zafgen's development programs, the Company has implemented plans to reduce its operating expenses and prioritize key resources, with an immediate corporate restructuring as well as other strategies to preserve resources. This restructuring includes a workforce reduction of approximately 25%, in addition to other attrition in 2019. With these changes, Zafgen now expects its projected cash runway to last greater than two years, given its current operating plan.

"Since our constructive Type A meeting with the FDA earlier this year, we've been focused on gaining clarity on the path forward, reaching agreement on the *in vivo* study design and protocol, and preparing for strong initiation and execution of the study," said Jeffrey Hatfield, Chief Executive Officer. "As we move ahead with ZGN-1061 having accomplished these goals, we have also taken steps to ensure the effective use of capital as we look to the future. This includes the difficult but prudent decision to restructure at this time. We are deeply grateful for the entire team's dedication and many contributions."

### 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](http://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 and its other product candidates and to differentiate them from first generation MetAP2 inhibitors, such as beloranib, the nonclinical 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 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 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.

**Media/Investor Relations Contacts:**

Zafgen, Inc.

Patricia Allen

Chief Financial Officer

617-648-9792

*Media*

Krystle Gibbs

Ten Bridge Communications

[krystle@tenbridgecommunications.com](mailto:krystle@tenbridgecommunications.com)

508-479-6358

*Investors*

John Woolford

Westwicke

[john.woolford@westwicke.com](mailto:john.woolford@westwicke.com)

443-213-0506

The Zafgen logo is displayed in a light blue, sans-serif font. The letter 'Z' is stylized with a horizontal bar that extends to the left and then curves back to the right, creating a unique, modern look. The rest of the letters are in a clean, simple font.

Source: Zafgen, Inc.