Zafgen Announces Regulatory Update on ZGN-1061

May 30, 2019

Received FDA Type A meeting minutes related to previously announced clinical hold

FDA acknowledged newly developed in vitro *assays of human plasma coagulation and tissue factor expression qualitatively differentiate ZGN-1061*

Company is working with FDA to translate in vitro *data and confirm relevant safety margins in an* in vivo *model*

Additionally, Zafgen is exploring a second IND for ZGN-1061 in a population with higher unmet medical need

BOSTON, May 30, 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 the receipt of minutes from its Type A meeting with the U.S. Food and Drug Administration (FDA) regarding the clinical hold for ZGN-1061.

Zafgen provided key new data in advance of the meeting, including newly developed *in vitro* assays of human plasma coagulation using endothelial cells and assessment of tissue factor expression with endothelial cells, and other supportive new assays. The Company is working with FDA to gain alignment on an *in vivo* animal model to confirm relevant safety margins as a next step toward resolving the clinical hold. Zafgen will be prepared to rapidly implement the agreed upon work.

“The Type A meeting with the FDA for ZGN-1061 was marked by constructive dialogue and progress driven by the important new data that the team worked diligently to provide to inform the discussion. This effort for Zafgen was led by highly experienced members of our team, Dr. Priya Singhal, our new Head of R&D, and Lisa Percival, our Vice President of Regulatory,” said Jeffrey Hatfield, Chief Executive Officer. “We believe the new *in vitro* data generated was encouraging, and the FDA was helpful with guidance regarding data needed to move forward in type 2 diabetes.”

Additionally, the Company is evaluating serious, rare disease indications that have few or no approved therapies in which ZGN-1061 could potentially benefit patients. The FDA was supportive of Zafgen seeking guidance on a second investigational new drug application (IND) for ZGN-1061, as appropriate.

Zafgen will provide an update on development plans by the end of the third quarter of 2019.

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 beloranib, 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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