



October 16, 2015

Zafgen Announces Partial Clinical Hold Affecting Beloranib Trials

Investor Conference Call Today, October 16th, at 8:30 a.m. E.T.

BOSTON, Oct. 16, 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 that it received verbal notice late yesterday from the U.S. Food and Drug Administration (FDA) that beloranib has been placed on partial clinical hold. This partial clinical hold impacts ongoing or planned clinical trials, including ZAF-311 and ZAF-312. A partial clinical hold is an order that the FDA issues to delay or suspend part of a sponsor's clinical work requested under its investigational new drug (IND) application.

As previously reported, Zafgen learned of a death in the ongoing Phase 3 bestPWS study (ZAF-311) of beloranib in Prader-Willi Syndrome (PWS). While the cause of death remains unknown, the patient's treatment assignment has been unblinded and it is now known that the patient was receiving beloranib. Due to previously reported thromboembolic events in ongoing and prior clinical trials of beloranib and the unknown nature of the death, the FDA gave verbal notice of a partial clinical hold to institute measures to ensure patient safety. Patients currently participating in the ZAF-311 study will be screened for existing thrombotic disease prior to receiving further study drug and regularly monitored through the completion of the study. Given that the study is near complete, at this time, the Company expects to report top-line results in the first quarter of 2016. Similar screening and monitoring is being considered for the ongoing Phase 2b study (ZAF-203) in patients with severe obesity complicated by type 2 diabetes. The Company now anticipates that the PWS Phase 3 clinical trial, ZAF-312, will be initiated after ZAF-311 is completed and a full assessment of the safety and efficacy of beloranib is performed by the FDA.

"Patient safety is our top priority, and we will work closely with the FDA to implement these measures to support the further development of beloranib," said Dr. Thomas Hughes, Chief Executive Officer of Zafgen.

Conference Call Information

Zafgen will host an investor conference call today, October 16, 2015 at 8:30 a.m., Eastern Time, to discuss today's announcement. Investors and other interested parties may participate by dialing (844) 824-7428 in the United States or (973) 500-2177 outside the United States and referencing conference ID number 63172382. The call will also be webcast live on the Company's website at <http://ir.zafgen.com/events.cfm>. You can access the replay for seven days by dialing (855) 859-2056 in the United States or (404) 537-3406 outside the United States and referencing conference ID number 63172382.

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 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 Pharmaceutical Corporation (CKD Pharma) of South Korea.

About Prader-Willi Syndrome (PWS)

Prader-Willi syndrome (PWS), the most common known genetic cause of life-threatening obesity, results in constant and unrelenting hunger that drives patients with PWS to engage in problematic hunger-related behaviors and to gain excessive weight. As a result, many of those affected with PWS become morbidly obese and suffer significant mortality. Currently, there is no cure for this disease. Although the cause of PWS is complex, it results from a deletion or loss of function of a cluster of genes on the 15th chromosome. PWS typically causes low muscle mass and function, short stature, incomplete sexual development, and a chronic feeling of hunger that, when coupled with a metabolism that utilizes drastically fewer calories than normal, can lead to excessive eating and life-threatening obesity. PWS occurs in males and females equally and in all races, with the same incidence around the world. Prevalence estimates have ranged from 1:8,000 to 1:50,000.

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 and obesity caused by hypothalamic injury, 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, including craniopharyngioma-associated obesity, 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 requirements for ongoing and planned clinical trials, and the need for 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 obtain a release of the partial clinical hold that the FDA placed on beloranib, the risk that the FDA may decide to elevate the partial clinical hold on beloranib to a full clinical hold, 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.

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