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Zafgen Appoints Global Head of Medical Affairs and Global Head of Regulatory

BOSTON, May 27, 2015 (GLOBE NEWSWIRE) -- Zafgen, Inc., a biopharmaceutical company dedicated to significantly improving the health and well-being of patients affected by obesity and complex metabolic disorders, today announced the appointments of Nerissa Kreher, M.D., M.S., M.B.A., as Global Head of Medical Affairs, and Kevin P. Malobisky, Ph.D., M.S., R.A.C., as Global Head of Regulatory.

"We are very excited to welcome Nerissa and Kevin to our team at Zafgen," said Thomas Hughes, Ph.D., Chief Executive Officer of Zafgen. "Nerissa's experience as a pediatric endocrinologist and her leadership in clinical development and medical affairs in the orphan drug arena and Kevin's extensive development experience, including his previous regulatory leadership work with an obesity drug and several orphan-designated early phase programs, will prove invaluable as we continue to advance the development of beloranib and ultimately bring it to market."

Dr. Kreher is a physician and board certified pediatric endocrinologist with deep academic, clinical research and biotechnology industry experience that includes both Medical Affairs and Clinical Development in start-up environments and within large biotechnology companies. She has a proven ability to build and develop Medical Affairs teams.

Most recently, Dr. Kreher was the Global Clinical Development Lead, Neonatology, at Shire. Previously, she held several roles at Alexion Pharmaceuticals and Enobia Pharma, where she became the Executive Medical Director, Medical Affairs Franchise Lead, Metabolic Diseases, and was responsible for the global medical affairs metabolic disease program. Prior to that, Dr. Kreher was Medical Director, Medical Affairs, at Genzyme, responsible for U.S. Medical Affairs for Endocrinology. She began her career in the industry as Director of U.S. Medical Affairs, Endocrinology, at EMD Serono.

Dr. Kreher is a member of several professional organizations, including the Endocrine Society, and the recipient of a number of awards and honors. She received a B.A. from the University of North Carolina, Chapel Hill; her M.D. from East Carolina University School of Medicine; her M.S. in Clinical Research from Indiana University; and an Executive M.B.A. from Northeastern University.

Dr. Malobisky is a seasoned global regulatory affairs professional with 25 years of laboratory, clinical, and regulatory development expertise spanning devices, biologics, and small molecules. He has held leadership roles at the country, region, and global levels, developing and implementing strategies to support both early and late-phase biologic and small molecule compounds across multiple therapeutic areas including obesity and orphan indications, as well as supporting marketed products across North America.

Most recently, Dr. Malobisky was a Senior Regulatory Consultant working with the Harte Group. Prior to that, he spent 14 years with Sanofi, where he held positions of increasing seniority in Regulatory Affairs and ultimately served as Associate Vice President, Global Regulatory Affairs, a position comprised of two roles: Regional Head, United States and Canada, and Global Head, Fibrosis & Cardiovascular. In addition, Dr. Malobisky represented Sanofi at PhRMA by serving on the Regulatory Affairs Coordination Committee and leading multiple industry initiatives and pilot programs.

Dr. Malobisky is a current member of several professional societies including the Regulatory Affairs Professional Society (RAPS) and the Drug Information Association (DIA), and has extensive experience as an instructor and speaker. He earned his Master of Science degree in Quality Assurance and Regulatory Affairs from Temple University School of Pharmacy, and his Ph.D. in Organization and Management from Capella University School of Business and Technology.

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. 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 HIAO, Prader-Willi syndrome, and severe obesity in the general population, its expectations with respect to the timing and success of its clinical trials, the expected requirements and timing of 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 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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