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Zafgen Announces Initiation of Phase 2a Clinical Development with Beloranib in Obesity

CAMBRIDGE, Mass., Nov. 6, 2012 /PRNewswire/ -- Zafgen, Inc., a leading biopharmaceutical company dedicated to addressing the unmet needs of severely obese patients, today announced that it has initiated Phase 2a clinical testing of beloranib. This milestone follows the completion of three consecutive Phase 1b studies demonstrating rapid weight loss, reductions in body fat, improvements in cardiovascular risk factors and encouraging tolerability.

Beloranib, a novel therapy for obesity that utilizes a unique mechanism of action targeting methionine aminopeptidase 2 (MetAP2), is in development to assess its potential to safely and rapidly reduce body weight by restoring balance between the production and utilization of fat.

"This transition to larger and longer clinical trials is a significant milestone for Zafgen and for patients who suffer from severe obesity," Thomas Hughes, Ph.D., president and CEO of Zafgen, said. "We are looking forward to learning more about the safety and efficacy of treatment with beloranib over a longer period of time. Given the consistent and rapid weight loss we have observed with beloranib in previous studies, there appears to be significant potential to help severely obese patients, whose options are currently limited, to achieve a healthier weight and improve risk factors associated with type 2 diabetes and cardiovascular disease."

The first Phase 2a clinical trial will evaluate weight loss, safety and pharmacokinetics of beloranib administered twice a week. Obese men and women with and without type 2 diabetes will receive subcutaneous injections for 12 weeks at eight participating centers. The trial design is a randomized, double-blind, placebo-controlled study evaluating a range of doses in approximately 150 patients.

"Early results from clinical trials studying beloranib's effects on body weight and cardiovascular risk markers in obese patients have been very encouraging," Steven R. Smith, M.D., scientific director of the Florida HospitalSanford Burnham Translational Research Institute for Metabolism and Diabetes[1], said. "This new trial will evaluate how the effects of this novel therapy extend with longer treatment in patients with type 2 diabetes, an important obesity-related co-morbid condition, and will be an important scientific milestone in shaping its use in the treatment of obesity and its related conditions."

Results from the next clinical development phase are anticipated to be available in June 2013. For more information about the study, visit ClinicalTrials.gov.

About Fat Metabolism
Research continues to show that obese and lean individuals metabolize fat differently. Studies indicate that once a person becomes obese, the body undergoes certain metabolic changes and is "programmed" to create and store more fat, making it much more difficult to reduce body weight. These metabolic adaptations that take place in obese people impair the normal release and breakdown of fatty acids from adipose tissue. Simultaneously, the body becomes much more efficient in diverting calories from food and storing them as fat.

About Beloranib
Beloranib is the first compound in its class that works by targeting a key enzyme called MetAP2 that controls the production and utilization of fatty acids. Inhibitors of MetAP2 reduce the production of new fatty acid molecules by the liver and help to convert stored fats into useful energy. Beloranib is being developed as a twice-weekly