

Press Release



HPR Dr. Schaffler GmbH in cooperation with Zalicus announces positive results of Z944 Phase 1B Clinical Study in Pain

Efficacy Signals in Inflammatory and Neuropathic Pain Observed

Second U.S. Patent Issues for Z944 Providing Exclusivity to 2029

Munich, Germany – June 17th, 2014 – HPR Dr. Schaffler GmbH, a contract research organization, which conducts Phase 1 clinical trials in the field of CNS pain research, announced positive results of a Phase 1b clinical study for its customer Zalicus (Z944). Research object is a novel oral T-type calcium channel modulator in development for the treatment of pain. The Phase 1b study is an experimental clinical model utilizing Laser-Evoked-Potentials (LEP) to provide both objective and subjective assessments of the activity of Z944 in induced pain states. Based on these results, Zalicus is planning to advance a modified-release formulation of Z944 into Phase 2 clinical development in an appropriate pain indication in 2014. In addition, a second United States patent for Z944 (U.S. Patent number 8,569,344) covering methods of treating pain was issued on October 29, 2013, providing additional patent protection for Z944 in the United States until at least 2029.

“This is the first T-type calcium channel modulator to demonstrate clinical translation in pain, and these results are indicative of Z944’s potential activity in modulating pain signaling. We look forward to further evaluating a modified release formulation of Z944 in a relevant clinical pain syndrome in 2014,” commented Mark H.N. Corrigan, MD, President and CEO of Zalicus.

This exploratory, double-blind placebo-controlled, randomized cross-over, Phase 1b clinical study enrolled 16 healthy volunteers and was conducted in a single center in Germany. The primary objective of the study was to compare the analgesic/anti-hyperalgesic properties of three different single doses of Z944 in a model of inflammatory pain and in a model of chronic neuropathic pain as compared with placebo. Highlights of the results of the Z944 Phase 1b LEP study results include:

Statistically significant and meaningful reductions at each of the three doses compared to placebo of overall peak-to-peak (PtP) amplitude of LEPs in models of both inflammatory ($p \leq 0.0002$) and neuropathic ($p < 0.05$) pain.

Consistent trends in reduction of subjective pain scores compared to placebo using a visual analog scale in both pain models.

Meaningful trends in effects based on dose and concentration, providing important insights into the potential therapeutic window and effective plasma concentrations of Z944.

Z944 was generally well tolerated with dose dependent CNS side effects and no serious adverse events.

In this study, hypersensitivity to laser thermal stimulation was induced by UV light exposure as a model of inflammatory pain and by topical capsaicin as a model of neuropathic pain. Electrical voltage fluctuations evoked by laser thermal stimulation were quantified with vertex-Electroencephalography(EEG) in addition to a subject-reported pain score. Many currently approved and emerging pain drugs have been evaluated using the LEP model, providing the ability to benchmark the efficacy of Z944 against other therapies.

About Z944 and T-type Calcium Channels

Z944 is a novel, oral, state-dependent, selective T-type calcium channel modulator that has demonstrated efficacy in multiple preclinical inflammatory pain models and in a Phase 1b experimental model of pain. T-type calcium channels have been recognized as key targets for therapeutic intervention in a broad range of cell functions and have been implicated in pain signaling. Zalicus is planning to advance a modified release formulation of Z944 through further clinical development.

About HPR Dr. Schaffler GmbH

HPR Dr. Schaffler GmbH – a Contract Research Organization (CRO) – has built a successful name in pharmacodynamic research since 1976.

Since more than 35 years now, the founder of Human Pharmacodynamic Research, Dr. med. Klaus Schaffler, MD, has been specializing in the electrophysiology and pharmacology of the human central nervous system (CNS) – as well as in the field of human experimental pain research. During this development process, HPR Dr. Schaffler GmbH has issued over 175 presentations/ publications and has conducted more than 150 phase-I studies with quite different objectives.

HPR is focused on Phase-I clinical trials in human pharmacodynamics and in combined pd/pk approaches for national and international pharmaceutical companies. Hereby, HPR has elaborated – besides other CNS-research approaches in vigilance and psychomotorics – a special model, the “Laser-Pain-Algesimetry”, under consideration of different sensitized and non-sensitized states of the skin to examine and analyze the effect of analgesic and anti-inflammatory compounds in humans. This well-developed and validated method of pain measurement guarantees a highly objective and quantitative approach to investigate the efficacy of analgesics by examining brain responses to repetitive nociceptive stimuli via “Evoked Potentials” – recorded on-line in real-time from Vertex-EEG position.

This strong, unique and systematic methodological feature, together with flexible and creative study designs, as well as quick statistical data analysis and reporting, enables us to provide customers with outstanding examination and analysis of medication effects on CNS and pain processing – also based on an existing large data base of prior investigated analgesics and topicals in different compound groups and also based on a large scale of experimental and practical trial experience and competence in this field.

About Zalicus

Zalicus Inc. (Nasdaq Capital Market: ZLCS) is a biopharmaceutical company that discovers and develops novel treatments for patients suffering from pain. Zalicus has a portfolio of

proprietary clinical-stage product candidates targeting pain such as Z160 and Z944 and has entered into multiple revenue-generating collaborations with large pharmaceutical companies relating to other products, product candidates and drug discovery technologies. Zalicus applies its expertise in the discovery and development of selective ion channel modulators and its combination high throughput screening capabilities to discover innovative therapeutics for itself and its collaborators in the areas of pain, inflammation, oncology and infectious disease. To learn more about Zalicus, please visit www.zalicus.com.

Contacts:

HPR Dr.Schaffler GmbH

Heisenbergbogen 1
-Europa Forum I-
D-85609 Aschheim-Dornach (Munich) Germany

Telefon: +49-(0)89-99322-0

Telefax: +49-(0)89-99322-299

Email: info@hpr-cro.com

Website: www.hpr-cro.com

Registry Court District Court Munich HRB 187078

Registered Office Aschheim-Dornach (Munich)

Executive Board (CEO): Dr. med. Klaus Schaffler

Tax-No.: 143/147/30845

VAT-No.: DE272921450