



News Release

Presented at SLEEP 2009: New Controlled-Release Formulations of Proven Drug Being Developed for Middle-of-the-Night Awakening

Advances in sleep research help speed Somnus Therapeutics' development of zaleplon-based sleep-maintenance treatment

Seattle, Washington, (June 8, 2009): Research sponsored by Somnus Therapeutics, Inc. demonstrates that new controlled-release formulations of a marketed insomnia medication have shown a pharmacodynamic profile indicative of a potential therapy addressing a frequent complaint of insomnia sufferers: preventing middle-of-the-night (MOTN) awakening without next-morning hangover.

Findings include specifically demonstrating that three controlled-release formulations produced maximum sedation 3 to 5 hours after administration with no residual effects observed after 8 hours. The studies applied technical advances in sleep monitoring to support clinical development and allow fine-tuning of dose and delivery during clinical studies, which may help bring an improved therapy to market more quickly and at a lower development cost.

The research, reported today at SLEEP 2009, the 23rd Annual Meeting of the Associated Professional Sleep Societies, LLC – a premier event for sleep research and sleep medicine professionals – was sponsored by Somnus Therapeutics, Inc. (“Somnus”), a private specialty pharmaceutical company that is developing controlled-release formulations of zaleplon to prevent MOTN awakening.

“In addition to measuring drug levels in blood plasma samples, we used 4-lead electroencephalography (EEG) and the Karolinska Drowsiness Test (KDT) to accurately determine the pharmacodynamics of these formulations,” said Remy Luthringer, PhD, head of the FORENAP Institute for Research in Neurosciences and Neuropsychiatry in Rouffach, France, a principal investigator in these studies. “All three formulations produced maximum sedation between 3 to 5 hours after administration with no residual effects seen 8 hours after administration.

“In another study, we applied the Multiple Sleep Latency Test (MSLT), a well-validated, standardized measure of physiologic sleep tendency, to evaluate the effects of daytime administration of the three formulations of zaleplon on the sleep tendency of healthy normal volunteers. We saw differing time courses of sleep-promoting activity one to four hours after administration that corresponded to plasma levels of the drug.”

Poster Presentations: Monday, June 8, 2009:

1. Pharmacodynamic Profile of Three Novel Release Formulations of Zaleplon versus Placebo and Marketed Zaleplon Measured by Electroencephalography and the Karolinska Drowsiness Test in Healthy Volunteers

2. Pharmacodynamic Profile of Three Novel Formulations of Zaleplon in Normal Volunteers as Evaluated by the Multiple Sleep Latency Test
3. Pharmacokinetic Profile of Single Oral Doses of Zaleplon in Three Novel Formulations in Normal Volunteers
4. Use of the Addiction Research Center Inventory (Sedation Subscale) and the Karolinska Sleepiness Scale to Evaluate Subjective Alertness After Single Oral Doses of Zaleplon in Three Novel Release Formulations
5. Relationship of Subjective and Objective Endpoints for Outcomes of a Phase I Trial of a Potential New Sleep Agent

About MOTN Awakening

A frequent and significant complaint of insomnia patients is middle-of-the-night (MOTN) awakening. Market research indicates that some two-thirds of insomnia sufferers find staying asleep a major problem. MOTN insomnia is strongly associated with daytime fatigue and cognitive impairment and thus with reduced job productivity and safety. A recent study showed a significant association with comorbidities, including obesity, mood disorders, and chronic pain, which may be exacerbated by nocturnal awakenings.

About Zaleplon

Zaleplon is a commercially available non-benzodiazepine agent with a very short half-life (1 hour), very little addiction potential, and little or no residual hypnotic effect upon waking. It is currently available (since 2000) as a 10 mg immediate-release capsule (Sonata®) for the treatment of insomnia. With a pharmacokinetic profile characterized by rapid absorption and rapid elimination, zaleplon is effective for sleep induction without unwanted residual effects, but because of its short half-life, it is not routinely used for sleep maintenance.

About the Geoclock® controlled release technology

The Geoclock® (SkyePharma, London, UK) delivery system is a unique technology that allows delivery of a drug over a preset time period by means of a chronotherapy-focused press-coated tablet with active drug loaded inside an outer tablet layer that is formulated to produce a pH-independent lag time prior to core drug delivery.

About Somnus Therapeutics

Somnus was founded in 2007 by Gary Cupit along with Care Capital, a life sciences venture capital firm based in Princeton, New Jersey. In June 2007, Somnus entered into an exclusive agreement with SkyePharma PLC for the worldwide development and commercialization of the sleep therapeutic, SKP-1041. Somnus is applying technical advances in formulation, controlled-release, and clinical testing to speed clinical development and reduce costs. SKP-1041 will begin phase II studies in the second half of 2009. For more information please visit the Somnus web site at www.somnusthera.com.

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