



News Release

Somnus Therapeutics Developing Medication to Prevent Middle-of-the-Night Awakening with No Adverse Effects on Next Day Performance

New Clinical Results Presented at SLEEP 2010 -- the Association of Professional Sleep Societies 24th Annual Meeting

San Antonio, TX (June 9, 2010): Many insomnia sufferers fall asleep readily but have trouble sleeping through the night. Middle-of-the-night (MOTN) awakening is an issue not well-addressed by currently available sleep medications, particularly agents that not only induce sleep immediately, but that can also leave users with unwanted next-day effects, such as sleepiness, as well as impaired motor function, memory and reaction time. Clinical research on SKP-1041, a delayed-release formulation of zaleplon, under development by Somnus Therapeutics, Inc, suggests that SKP-1041 may enable natural sleep induction and prevent MOTN awakening with no residual cognitive or motor effects.

Investigator David J. Greenblatt, MD, Professor and Chair, Department of Pharmacology & Experimental Therapeutics at Tufts University School of Medicine, said, "Recently completed preliminary studies demonstrate that SKP-1041 produces the desired delayed release of zaleplon, and reproducible systemic pharmacokinetics. In elderly subjects (65-73 years old), SKP-1041 produced peak plasma concentrations of zaleplon at 3-5 hours after administration, without evidence of impaired drug clearance, and with a pharmacokinetic profile consistent with that in younger subjects. More importantly, SKP-1041 demonstrated no next-day impairment as measured by a driving simulation and other tests of alertness, sleepiness and memory. In younger subjects (20-46 years old), the pharmacokinetic profile was similar, whether the drug was administered during the day or at night, an important consideration for those with rotating shift work schedules."

Gary Cupit, Chief Executive Officer of Somnus Therapeutics, said, "We made use of comprehensive tools to evaluate the effects of SKP-1041 in these Phase 1 studies. These included electroencephalography, a noise-induced insomnia model, as well as driving simulation and cognitive tests for next-day effects. These tools have already helped us fine-tune the dosing and delayed-release delivery throughout Phase 1. What's more, in our just-initiated Phase 2 studies, they will help us collect data applicable to target patients who have difficulty sleeping through the night and want to awaken refreshed from a restorative sleep and ready to face the day."

Two phase 1 studies (sponsored by Somnus Therapeutics) presented at SLEEP 2010 demonstrate activity of SKP-1041 in healthy subjects consistent with the targeted product profile. One study, conducted with 23 subjects 20-46 years of age, showed a comparable day vs night pharmacokinetic profile of SKP-1041 15mg, with no differences related to natural circadian rhythm. This would be important for shift workers who may need to sleep during daylight hours. This study also provided proof-of-concept for effective sleep maintenance by exposing subjects to simulated car and truck noises throughout the night. Polysomnographic results showed that arousal and wake after sleep onset (WASO) was significantly less during the time of peak plasma concentrations of SKP-1041 compared to placebo.

The second study of SKP-1041 15mg was conducted with 22 elderly subjects 65-73 years of age. Results showed a comparable pharmacokinetic profile to younger subjects. Importantly, these elderly subjects showed no next-day impairment of alertness as measured by a driving simulation test. Cognitive function as described by effect on immediate and working memory, memory consolidation, and subjective sleepiness were comparable with placebo. SKP-1041 was well-tolerated in both studies with no clinically significant adverse events.

Poster Presentations

[SLEEP 2010](#) - Association of Professional Sleep Societies 24th Annual Meeting, Wednesday June 9, 8am-12pm, Henry B. Gonzalez Convention Center, San Antonio, TX

Abstract #0658, Poster Board 130: Phase I, Randomized, Double-Blind, Placebo-Controlled, Crossover Study to Compare the Pharmacokinetics of a Single Oral Dose of a New Zaleplon Formulation (SKP-1041) and Open-Label Zaleplon in Healthy Elderly Subjects

Abstract #0659, Poster Board 131: Phase I, Randomized, Crossover Study to Compare the Day vs Night Pharmacokinetics of a Single Oral Dose of a New Zaleplon Formulation in Healthy Young Volunteers

About MOTN Awakening

The majority of people with insomnia can fall asleep naturally but have difficulty maintaining sleep throughout the night. Such insomnia is strongly associated with daytime fatigue and cognitive impairment and thus with reduced job productivity and safety. Data available in the last few years show a significant association with comorbidities, including obesity, mood disorders, and chronic pain, which may exacerbate and be exacerbated by nocturnal awakenings.

About Zaleplon

Zaleplon is a non-benzodiazepine agent with a short half-life (~1 hour), and little or no residual hypnotic effect upon awakening. It has been marketed since 2000 in Sonata[®], as a 5 mg and 10 mg immediate-release capsule for the treatment of sleep-onset insomnia. With a pharmacokinetic profile characterized by rapid absorption and elimination, zaleplon effectively induces sleep without unwanted residual effects, but because of its short half-life, is not routinely used for sleep maintenance.

About SKP-1041

SKP-1041 uses SkyePharma's Geoclock™ technology to delay and sustain the release of zaleplon after bedtime administration. It is designed to treat people who have difficulty maintaining sleep after falling asleep naturally by preventing middle-of-the-night awakening while avoiding residual effects.

In June 2007, Somnus entered into an exclusive license with SkyePharma for the worldwide development and commercialization of SKP-1041. Under the agreement, SkyePharma will formulate and manufacture the product and Somnus will seek a partner to develop and commercialize it.

About the Geoclock® controlled-release technology

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

About Somnus Therapeutics, Inc

Somnus, with offices in Bedminster, NJ, was founded in 2007 by Gary Cupit and [Care Capital](#) LLC, a life sciences venture capital firm. By leveraging a small team of experienced managers with an expert scientific advisory board, clinical research organizations and other outsourced services, Somnus can focus on accelerated clinical development of therapeutics for CNS markets. In February, 2010, Somnus completed a Series A preferred stock financing for approximately US\$15 million, led by [CTI Life Sciences Fund](#) with the participation of Care Capital. For more information please visit the Somnus Therapeutics web site at www.somnusthera.com.

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