

# BIO WORLD<sup>®</sup> TODAY

TUESDAY  
SEPTEMBER 9, 2008

THE DAILY BIOTECHNOLOGY NEWSPAPER

VOLUME 19, No. 175  
SPECIAL REPRINT

## Somnus' Lead Drug, SKP-1041 Targeting Sleep Maintenance

By Jennifer Boggs  
Assistant Managing Editor

While the insomnia drug market has been dominated by blockbuster agents such as Ambien and Lunesta, both of which aim to help patients fall asleep, recently founded specialty pharma firm Somnus Therapeutics Inc. is developing a nonbenzodiazepine hypnotic agent specifically designed for sleep maintenance.

The Bedminster, N.J.-based firm – named for the Roman god of sleep – licensed rights to the product, SKP-1041, from SkyePharma plc shortly after being founded in mid-2007 by CEO Gary Cupit and venture capital firm Care Capital, of Princeton, N.J.

“One of the biggest problems with existing sleep drugs is that you need a long enough duration of sleep to avoid the sleep hangover,” Cupit told *BioWorld Today*.

Drugs like Ambien (zolpidem, Sanofi-Aventis Group) and Lunesta (eszopiclone, Sepracor Inc.) have been successful in treating insomnia but generally require about eight hours of sleep time. That means they work for patients who have trouble getting to sleep. But people who have trouble maintaining sleep could benefit from a product that is short-acting, he said.

“Our goal is sleep maintenance,” Cupit added. “We’re aiming specifically for the segment of the insomnia market that has trouble maintaining sleep.”

SKP-1041, a GABA receptor modulator, is designed as a controlled-release formulation using London-based SkyePharma’s Geoclock technology, which formulates tablets that have an active drug inside an outer layer for a predetermined release rate. Somnus hopes to show in clinical testing that SKP-1041, taken as a single oral dose at the start of patient’s sleep cycle, will allow for a full period of sleep without a sleep hangover upon waking. “That’s what we’re trying to prove in our Phase I,” Cupit said.

The company aims to finish up that trial by the end of the year and, pending positive results, will move to the next phase of testing. Somnus anticipates taking the product through Phase II proof of concept on its own, and then seeking a big pharma partner. “Although,” Cupit said, “investors are encouraged by the data so far, so they might be willing to fund a bit more,” allowing the company to partner the program later in a higher value deal.

To date, Somnus’ funding has come solely from Care Capital. Though the company has not disclosed the exact amount raised to date, Cupit said Somnus brought in enough funds to purchase SKP-1041 from SkyePharma for \$4 million, with “sufficient capital to fund operations for the first 18 months.”

Beyond the \$4 million payment, the deal with SkyePharma calls for milestone payments, including up to \$11 million payable during the development phase – mainly on product approval – and up to \$20 million in sales-related milestones.

Right now, Somnus is pursuing SKP-1041 only in sleep maintenance, though it’s possible the drug might have potential in other indications, such as shift work insomnia or jet lag, Cupit said.

Beyond that first product, the company plans to look for additional assets in the area of central nervous system disorders like pain, sleep or even depression.

Somnus currently is staffed by seven people, including the rest of the executive management team: Chief Medical Officer Mary Osbakken, Chief Regulatory Officer Christine Blumhardt, Chief Business Officer Linda Hogan, Chief Financial Officer Daniel Cabo and Anne McCormick, director of clinical project management. ■

©2008. Reprinted With Permission From BioWorld<sup>®</sup> Today, Atlanta, Georgia.