

## galleon pharmaceuticals

### Galleon Pharmaceuticals Demonstrates Successful Clinical Proof-of-Concept for Lead Product from Sleep Apnea Drug-Discovery Platform

Horsham, PA—April 11, 2013—Galleon Pharmaceuticals announced today a clinically significant outcome in a clinical proof-of-concept study evaluating the ability of its lead investigational drug, GAL-021, to successfully regulate respiratory drive, a key requirement to prevent respiratory complications in high-risk surgical patients. This is the first time a drug has been shown to regulate and protect respiratory drive from drug-induced respiratory depression. In this study, intravenous GAL-021 was able to reverse respiratory depression under challenging conditions including high doses of opioids and elevated carbon-dioxide levels, which can be particularly problematic for post-surgical and sleep apnea patients. The Company is actively seeking funding to advance this promising candidate into a broad Phase II program.

“These findings are exciting and represent an important advance in the treatment of respiratory depression,” said Albert Dahan, M.D., Ph.D., Principal Study Investigator and Professor of Anesthesiology at the Leiden University Medical Center, Netherlands. “For the first time, we have shown that a drug can reverse opioid-induced respiratory depression without affecting analgesia. This has the potential to be a major advance for physicians and hospitals that care for high-risk surgical patients, such as those with sleep apnea, obesity or recent opioid use.”

In the double-blinded, placebo-controlled crossover study, 12 people with both normal and elevated carbon-dioxide levels were given alfentanil, a potent opioid analgesic drug commonly used during surgery. Then two dose-levels of alfentanil and two dose-levels of GAL-021 were administered. In this study, GAL-021 successfully protected against the opioid-induced respiratory depression while not affecting analgesia. The dose-dependent protective effect of GAL-021 was statistically and clinically significant at both low and high doses of alfentanil. GAL-021 was well-tolerated with side effects that did not differ from placebo.

“Impaired respiratory drive worsens sleep apnea and Galleon’s research into drug candidates to treat this condition is very exciting,” said Sigrid Veasey, M.D., Associate Professor of Medicine at University of Pennsylvania’s Center for Sleep and Circadian Neurobiology. “The demonstration that Galleon’s first clinical candidate can regulate respiratory drive is an important milestone for the oral drug candidates that may have utility for sleep apnea patients seeking an alternative to mask-based positive-pressure machines.”

Galleon’s drugs work through a novel mechanism of action allowing creation of both oral and intravenous products for a variety of clinical uses including: post-surgical care of high-risk patients, chronic pain patients using opioids and sleep apnea.

“This important study confirms our preclinical findings and provides the basis for Galleon to progress into Phase II to develop a drug that may prevent costly respiratory complications in high-risk surgical patients, such as those with sleep apnea,” said James F. McLeod, M.D., Galleon’s Senior Vice President, Clinical Research and Development, and Chief Medical Officer. “Demonstrating GAL-021’s effectiveness under these conditions clinically validates the drug’s target and is a key indicator for additional potential drug candidates in Galleon’s sleep apnea drug-discovery platform. Further, these data provide a strong foundation for our oral product GAL-160, which is intended for chronic sleep apnea in outpatients. We believe this class of Galleon drugs has the potential to address important unmet medical needs for patients with a variety of respiratory conditions including apneas of multiple etiologies.”

#### About Sleep Apnea and Related Breathing-Control Disorders

The normal breathing control system regulates the frequency and depth of breathing through a series of receptors feeding information to the control center in the brain. A wide variety of factors can impair breathing control including certain drugs, age, obesity, alcohol and concomitant diseases. Sleep apnea is among the most common breathing control disorder and affects about 20 million patients in the United States alone. Many of these patients are undiagnosed. Sleep apnea is an independent risk factor for cardiovascular disease, as patients stop breathing many times throughout sleep thereby increasing the risk for hypertension, heart attack, stroke, diabetes and excessive daytime sleepiness. Recent scientific advances have identified causes of sleep apnea that may be appropriate strategies for drug treatment. Two of these causes are decreased respiratory drive and upper airway collapse. An effective pharmaceutical product would offer an alternative to currently available positive-pressure machines, surgery and dental devices.

Anesthetics, opioid analgesics and sedatives are well-known to impair breathing control. Galleon estimates that there are 23 million surgeries performed every year which require anesthesia and pain control, with an estimated 35-40% of those being done in high-risk patients such as those with sleep apnea, chronic opioid use and obesity. Sleep apnea patients are especially sensitive to the effects of anesthetics, sedatives and analgesics. A drug that protects against drug-induced respiratory depression may improve patient safety, enable better pain control and decrease costs.

### **About Galleon Pharmaceuticals**

Galleon is the first company to build a drug discovery and development platform that focuses on the pharmaceutical treatment of sleep apnea and related breathing-control disorders. The company's proprietary platform incorporates recent advances in neurobiology, molecular physiology, respiratory medicine and medicinal chemistry. The Company has developed proprietary models of sleep apnea and breathing control that enable a multi-dimensional analysis of the primary causes of sleep apnea and related conditions. For more information, please visit [www.galleonpharma.com](http://www.galleonpharma.com).

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