



Galleon Pharmaceuticals Announces Publication of Proof-of-Concept Clinical Studies for GAL-021, Projected Use for the Emerging Perioperative Sleep Apnea Epidemic

By

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HORSHAM, Pa., Sep 02, 2014 (BUSINESS WIRE) -- Galleon Pharmaceuticals announced clinically and statistically significant ($p < 0.01$) results from a double-blind, placebo-controlled clinical proof-of-concept study of its lead investigational compound GAL-021 in normal volunteers. The data were published in the most recent issue of *Anesthesiology*.

The study sought to assess whether GAL-021 stimulated breathing in humans with respiratory depression induced by a potent opioid under conditions common after surgery. Researchers concluded that GAL-021 met or exceeded the study's pre-defined goals of maintaining both respiration and pain control under these conditions, and called for further clinical exploration of the drug's safety and efficacy.

GAL-021 is being developed to prevent respiratory complications in surgical patients, including those at higher risk due to sleep apnea. According to a recent report in the *New England Journal of Medicine*, 25 to 80 percent of surgical patients have sleep apnea predisposing them to the rapidly emerging perioperative sleep apnea epidemic. The combination of sleep apnea with respiratory depressant drugs such as opioids, sedatives and anesthetics is especially dangerous and complicates care of these patients.

"There is a high unmet need for an agent to help anesthesiologists and other professionals manage the growing numbers of respiratory related complications taking place post-surgery," said Albert Dahan, M.D., Ph.D., professor of anesthesiology at Leiden University Medical Center in Leiden, The Netherlands, and lead investigator for the study. "These new data reinforce our belief that GAL-021 may be an important option for patients and providers to help protect these patients' airways and restore breathing control. We also believe more studies are needed to confirm these initial findings."

An accompanying editorial to the two studies, written by Joseph F. Cotten, M.D., Ph.D, and an anesthesiologist at Massachusetts General Hospital, was also published in *Anesthesiology*. In the independent editorial, called "The Latest Pharmacologic Ventilator", he called GAL-021 a "promising new breathing stimulant compound", and said a drug minimizing opiate-induced respiratory depression "would have significant clinical utility." Dr. Cotten also called

for future studies addressing the potential of GAL-021 dosing and efficacy in humans.

The researchers used an opioid to simulate the respiratory depression that is common in the perioperative setting. Opioids serve as the most effective drugs for acute pain management in the perioperative setting, and are administered routinely. However, they cause respiratory depression, a significant contributor to respiratory complications in this setting.

GAL-021 is the first of a new class of chemoreceptor modulator compounds and is believed to work through a specific type of potassium channel. This mechanism gives GAL-021 the potential to correct respiratory depression from a variety of causes including drugs commonly used in surgery without decreasing the pain relieving benefit of opioids.

“We are extremely encouraged by the results of our first two studies of GAL-021 in humans. Our animal studies were very promising, but this publication takes our proprietary scientific platform to the next level,” said James C. Mannion, Ph.D., President, CEO and founder of Galleon. “In particular, the burden of post-surgery complications in this patient population on our healthcare system is significant. Each post-surgery patient with respiratory depression costs a hospital an average of an additional \$50,000 for more prolonged and intensive treatment. We believe GAL-021 has the potential to increase patient safety, improve surgical pain control and reduce hospital 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.

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