# galleon pharmaceuticals

## Galleon Pharmaceuticals Reports Positive Results from Second Phase I Study of GAL-021 for Treatment of Respiratory Depression

Horsham, PA– September 20, 2012 – Galleon Pharmaceuticals, a leader in the development of novel medicines to treat breathing control disorders, today announced that results from a second Phase I clinical study of its investigational drug GAL-021 confirmed previous findings that the drug has dose-dependent effects on respiration. The purpose of the new study was to evaluate higher doses of GAL-021 to determine an appropriate dose range for future studies, including an upcoming Phase I proof-of-concept study utilizing conditions simulating post-operative patients who have impaired respiration.

The new study evaluated a single dose of GAL-021 in 18 healthy volunteers using higher doses of GAL-021 than the previous Phase I trial. The placebo-controlled, double-blind, crossover study confirmed the drug's positive effects, including improved minute ventilation (a capacity measure of air supplied to the lungs) and decreased end-tidal carbon dioxide levels (a measure of the effectiveness of alveolar gas exchange), demonstrating a clear dose response on these respiratory parameters. Side effects of the drug were generally mild to moderate At the highest dose in some subjects, the improved lung ventilation was sufficient to increase in minute ventilation by more than 50% and in parallel lower $CO_2$ levels more than 25%.

"This study confirmed our previous Phase I findings and establishes a clear dose range for future studies," said James F. McLeod, M.D., Galleon's senior vice president, clinical research and development, and chief medical officer. "We identified a maximum tolerated dose of the drug in healthy volunteers which produced hyperventilation and decreased $CO_2$ levels, and can now proceed with plans to evaluate the effects of GAL-021 in those with opioid-induced respiratory compromise. Our goal will be to demonstrate that GAL-021 can reduce or prevent respiratory depression associated with opioid use following surgery or other medical procedures."

GAL-021 is a proprietary small molecule delivered by intravenous administration to treat or prevent acute respiratory insufficiency in surgical and critical-care patients following the use of anesthetic, analgesic and sedative drugs individually or in combination. Galleon estimates there are 23 million surgeries performed every year which require anesthesia and pain control, with an estimated 35-40% of those being done in patients at higher risk for respiratory depression.

## About Galleon Pharmaceuticals

Galleon is the first pharmaceutical company to focus on the medical treatment of breathing-control disorders associated with surgical and procedural sedation, chronic pain management and sleep apnea. The company's product pipeline reflects recent advances in neurobiology, molecular physiology and respiratory medicine which have enabled the development of a unique drug-discovery platform and promising drug candidates that are now undergoing clinical trials. Galleon scientists apply sophisticated pharmacology, medicinal chemistry and drug-discovery tools to identify potential medical treatments for acute and chronic breathing-control conditions. This approach is unique among pharmaceutical companies and enables the rapid evaluation of multiple variables to establish a comprehensive profile of breathing-control activity. For more information, please visit www.galleonpharma.com.