Sagene Pharmaceuticals Completes Successful Pre-IND Meeting with FDA for Dual-Action Erectile Dysfunction Drug

Oldsmar, FL, September 8, 2011 – Sagene Pharmaceuticals, Inc., a biopharmaceutical company focused on developing combinations of FDA-approved drugs to treat diseases associated with aging, has completed a pre-IND (Investigational New Drug) meeting with the Division of Reproductive and Urologic Products of the FDA to discuss the development plan for SPI-1972, a dual-action combination treatment for erectile dysfunction. The FDA addressed the Company's questions and provided guidance on the NDA requirements for the SPI-1972 development program. The FDA found the filing of an IND for SPI-1972 acceptable under the 505(b)(2) regulations as a combination product in which the active ingredients have been previously approved individually. The 505(b)(2) regulations provide an accelerated pathway for drug approval.

"The successful completion of our Pre-IND meeting is a step in the right direction towards the filing of the IND for our Erectile Dysfunction Program," said Sagene Chief Executive Officer and Founder Tom Thomas, MD, Ph.D. "The FDA's guidance has improved our development program and the acceptance of 505(b)2 application requirements means SPI-1972 could reach patients significantly faster."

SPI-1972 is an oral combination product consisting of selegiline, an FDA-approved MAO-B inhibitor, and a PDE-5 inhibitor, such as Viagra®, Cialis® or Levitra®. This patented combination is the only drug with dual actions targeting CNS and vascular tissue, increasing dopamine neurotransmission in the brain and enhancing the levels of NO (nitric oxide) and cGMP in target tissue. In animal studies, Sagene found that selegiline enhances the action and acts synergistically with PDE-5 inhibitors in healthy and diabetic models.

"Based upon our preclinical data, and the overall safety profile of both agents, we are excited by the prospects for this program and the potential to treat a large group of patients that do not adequately respond to current treatments for erectile dysfunction." commented Albert J. Azzaro, Ph.D., Acting Vice President of Research and Development for Sagene.

About Erectile Dysfunction

ED affects over 150 million men worldwide with cases expected to double in 10 years. Most men experience ED at some point in their lives, but 85% of cases

are undiagnosed. PDE-5 inhibitors (Viagra®, Levitra®, Cialis®) are the main treatment for ED and generated almost $4.3 billion of sales in 2010. However, up to 40% of men with ED do not respond adequately to PDE-5 monotherapy and patients become less responsive over time. Penile erection involves a physiological interaction between the CNS and the peripheral target tissue. PDE-5 inhibitors only target ED through actions on erectile tissue but have no impact on the CNS centers that regulate this function. The combination of selegiline and a PDE-5 inhibitor would impact both the CNS and peripheral tissue sites. Sagene's preclinical studies demonstrate that selegiline enhances the effects of PDE-5 inhibitors in erectile tissue at low doses. Accordingly, the combination of selegiline and a PDE-5 inhibitor is expected to address many of the current shortcomings of monotherapy.

About Sagene Pharmaceuticals, Inc.
Sagene Pharmaceuticals is a biopharmaceutical company developing novel applications for combinations of FDA-approved drugs to treat diseases associated with aging. Sagene has shown that selective MAO-B inhibitors, specifically selegiline (l-deprenyl), can reduce side effects and enhance efficacy in combination with current treatments for erectile dysfunction (ED), pulmonary arterial hypertension (PAH), pain/inflammation and cardiovascular diseases by targeting multiple disease pathways not typically addressed by currently approved drugs. These novel actions of selegiline have been patented by Sagene. The combination approach for treating diseases with FDA-approved drugs to improve their therapeutic effect, reduces development risk, time and costs by utilizing the 505(b)(2) NDA approval process. Sagene has assembled a team of experts experienced in drug development, clinical trials and regulatory affairs. Sagene has conducted preclinical studies showing proof of concept and the benefits of selegiline in laboratory animals and human platelets. The company is headquartered in Oldsmar, FL.

For more information about Sagene Pharmaceuticals, please visit the Company's website at www.sagenepharma.com.

For Further Information Contact:

Prem Thomas
CFO and Cofounder
Sagene Pharmaceuticals
+1 919 452 7317
prem@sagenepharma.com