samumed

Media Contact:
Chrissy Randall
crandall@brunswickgroup.com
202-393-7337

SAMUMED SUCCESSFULLY COMPLETED PHASE I STUDY FOR POTENTIAL TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS

Promising Preclinical Results Presented at American Thoracic Society Annual Meeting

San Diego, CA—July 17, 2017—Samumed, a leader in tissue regeneration, today announced the successful completion of a Phase I clinical trial in healthy subjects for its potential treatment of Idiopathic Pulmonary Fibrosis (IPF), a chronic, usually fatal, fibrotic disorder of the lungs. The study results supported the continuation of the program into future studies in IPF patients. There were no serious adverse events or dose limiting toxicities observed in any of the four treatment groups, and Samumed's treatment appeared safe and well-tolerated at all dose levels studied. A detailed analysis, including safety and pK results, will be presented at future medical conferences.

Samumed's investigational drug is a nebulized inhalation solution of its novel small molecule compound SM04646. The study, conducted in Australia, was an open-label Phase I trial studying the safety and tolerability of a single inhalation of SM04646 in 17 healthy male and female subjects, between the ages of 18 and 50. SM04646 was tested with four ascending dose levels in four different treatment groups to determine the maximum tolerated dose (*e.g.*, the maximum dose that can be inhaled by a healthy subject without causing a strong cough response). Study details can be reviewed at: http://bit.ly/2tX6eFC

In May, Samumed presented promising data from its preclinical studies of SM04646 at the American Thoracic Society Annual Meeting in Washington, D.C. The presentation can be reviewed at: http://bit.ly/2tYNgQg. As presented, SM04646, demonstrated anti-fibrotic properties in numerous *in vitro* and *in vivo* studies, including a bleomycin-induced model of pulmonary fibrosis where aerosolized SM04646 reduced fibrosis-like changes in the lungs compared to sham treatment. SM04646 has shown greater antifibrotic activity *in vitro* when compared to pirfenidone and nintedanib by demonstrating greater inhibition of fibrotic gene expression in both normal human lung fibroblasts stimulated through TGF-β1 (a cellular pathway through which fibrosis is triggered in human tissue) and IPF human lung fibroblasts.

About IPF

Idiopathic pulmonary fibrosis (IPF) is a chronic, progressive, fibrotic disorder that typically affects adults over the age of 40. It is the most common interstitial lung disease seen by pulmonologists. In the U.S., the prevalence of IPF for women ranges from 13.2-27.9 per 100,000 and for men ranges from 20.2-63.0 per 100,000. Patients with IPF experience slow, rapid, or mixed clinical course of deteriorating lung function and severe dyspnea, which ultimately ends in fatality. The median survival is estimated to be between 2.5 and 3.5 years after diagnosis. IPF

samumed

Media Contact:
Chrissy Randall
crandall@brunswickgroup.com
202-393-7337

is associated with several pulmonary and non-pulmonary conditions including lung cancer, depression, emphysema, gastroesophageal reflux disease, and cardiovascular disease. Currently there is no cure for IPF, and the therapeutic options remain limited.

About Samumed, LLC

Based in San Diego, CA, Samumed (www.samumed.com) is a pharmaceutical platform company focused on advancing regenerative medicine and oncology applications through research and innovation. Samumed has discovered new targets and biological processes in the Wnt pathway, allowing the team to develop small molecule drugs that potentially address numerous degenerative conditions as well as many forms of cancer.

####