

SAMUMED RECEIVES ORPHAN DRUG DESIGNATION FROM FDA FOR SM04646 AS A TREATMENT FOR IDIOPATHIC PULMONARY FIBROSIS (IPF)

San Diego, CA—July 24, 2017—Samumed announced that the U.S. Food and Drug Administration (FDA) has granted SM04646, a novel small molecule Wnt pathway inhibitor, an Orphan Drug Designation (ODD) for IPF: <http://bit.ly/2gStpOf>

“The FDA’s decision to grant an ODD to SM04646 for IPF is another important milestone in the development of SM04646,” said Dr. Yusuf Yazici, Samumed’s Chief Medical Officer. “IPF is a chronic, progressive, fibrotic disorder that causes deteriorating lung function and severe dyspnea in patients and ultimately ends in fatality. Early trials demonstrate the therapeutic potential of SM04646 to help address the unmet medical need of individuals with IPF.”

The ODD is granted by the FDA to investigational drugs that are intended for the treatment of rare diseases that affect fewer than 200,000 people in the US and where the sponsor has established a medically plausible basis for the use of the drug for the rare disease or condition. Orphan drug designation provides tax incentives, exemption from the FDA user fee, and/or FDA assistance in clinical trial design and potential market exclusivity for seven years following approval.

SM04646 is administered locally via a nebulizer and has the potential to be used as a monotherapy or in combination with currently approved oral medications – Esbriet® (pirfenidone) and/or Ofev® (nintedanib).

Samumed recently announced the successful completion of a Phase I study in healthy subjects, in which SM04646 appeared safe and well tolerated: <http://bit.ly/2tp4Jin>. Samumed recently presented results of preclinical studies of SM04646, which 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 in the lungs: <http://bit.ly/2uuWDsC>.

About Idiopathic Pulmonary Fibrosis (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 is associated with several pulmonary and non-pulmonary conditions including lung cancer,



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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.

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