

# Samumed And United Therapeutics Announce North American License Agreement For Samumed's IPF Drug Candidate

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SAN DIEGO and SILVER SPRING, Md., Sept. 17, 2018 /PRNewswire/ -- Samumed LLC has entered an exclusive license agreement with United Therapeutics Corporation (Nasdaq: UTHR) for North American rights to Samumed's SM04646, being developed for the treatment of idiopathic pulmonary fibrosis (IPF). Deal terms include \$10 million up-front, plus up to \$340 million in developmental milestones and up to low double-digit royalties.

"We are excited to partner with United Therapeutics because of its culture of integrity, level of commitment, and expertise in pulmonology and drug-device combinations. We look forward to delivering what could be a first-in-class, disease-modifying treatment option for IPF patients," commented Osman Kibar, Ph.D., Chief Executive Officer of Samumed.

SM04646, a Wnt pathway inhibitor, is currently undergoing a phase 1 clinical trial. Under the terms of the agreement, United Therapeutics' subsidiary, Lung Biotechnology PBC, will conduct and fund all further development, regulatory and commercialization activities in the U.S. and Canada. Samumed retains development and commercialization rights for all markets outside of North America.

"I've been impressed with Samumed's exhaustive work on the pleiotropic Wnt pathway from the time I met Dr. Kibar at this year's Cura Foundation conference on regenerative medicine, held at the Vatican," said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of Lung Biotechnology PBC. "Our months of due diligence have energized our belief in SM04646's fibrosis-modulating properties, and hence unique potential for addressing IPF."

#### About SM04646

SM04646 is a small-molecule Wnt signaling pathway inhibitor currently being developed for the treatment of IPF. Preclinical data on SM04646 has demonstrated anti-fibrotic properties in numerous *in vitro* and *in vivo* studies, including a bleomycin-induced model of pulmonary fibrosis where aerosolized SM04646 significantly reduced fibrosis in the lungs compared with vehicle. A phase 1 study of SM04646 assessing the safety of the molecule is currently ongoing. FDA has granted orphan drug designation for SM04646 for the treatment of IPF. Additional information on Samumed's SM04646 IPF program can be found here: <a href="https://www.samumed.com/pipeline/detail.aspx?id=19">https://www.samumed.com/pipeline/detail.aspx?id=19</a>

### **About Lung Biotechnology PBC**

Lung Biotechnology PBC is a public benefit corporation addressing the acute national shortage of transplantable lungs and other organs with a variety of technologies that either delay the need for such organs or expand the supply. Lung Biotechnology is the first public benefit corporation subsidiary of a public biotechnology or pharmaceutical company. [uthr-g]

## **About United Therapeutics**

United Therapeutics is a biotechnology company focused on the development and commercialization of innovative products to address the unmet medical needs of patients with chronic and life-threatening conditions.

#### **About Samumed**

Samumed's small-molecule drug platform is harnessing the innate restorative power of the Wnt pathway to reverse the course of severe and prevalent diseases. Samumed's clinical pipeline can be found here: <a href="https://www.samumed.com/pipeline/default.aspx">https://www.samumed.com/pipeline/default.aspx</a>

# Forward-looking Statements

Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, among others, statements regarding the development of SM08686 for treatment of IPF. These forward-looking statements are subject to certain risks and uncertainties, such as those described in United Therapeutics' periodic and other reports filed with the Securities and Exchange Commission that could cause actual results to differ materially from anticipated results. In addition, the forward-looking statements in this press release are qualified by the cautionary statements, cautionary language and risk factors set forth in United Therapeutics' periodic reports and documents filed with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. United Therapeutics and Samumed are providing this information as of September 17, 2018, and assume no obligation to update or revise the information contained in this press release whether as a result of new information, future events or any other reason.

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