



Taiho and Lung Therapeutics Enter into an Exclusive License Agreement in Japan for LTI-01, Treatment for Loculated Pleural Effusions

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Taiho Pharmaceutical Co., Ltd. ("Taiho") and Lung Therapeutics, Inc. ("Lung Tx") announced today an exclusive license agreement of LTI-01, a recombinant human single-chain urokinase plasminogen activator, currently under development by Lung Tx for loculated pleural effusions, for the territory of Japan.

Under the terms of the agreement, Taiho will obtain the rights for the development and commercialization of LTI-01 in Japan. Lung Tx will receive an upfront payment, milestone, and royalty payments based on product sales.

Loculated pleural effusion (LPE) is a condition in which fluid is trapped within the pleural cavity due to fibrinous adhesions, leading to pain, shortness of breath and possibly sepsis. There currently are no approved drug treatment options for this condition. LTI-01 is anticipated to promote drainage in LPE patients by lysis of fibrinous scar tissue in the pleural cavity.

"We are delighted to announce this new collaboration with Lung Tx for LTI-01," said Masayuki Kobayashi, President and Representative Director of Taiho. "Bringing together two companies' expertise and strengths, we believe we can further contribute to patients' QOL by providing a solution to an unmet medical need in the respiratory field."

"LTI-01 has the potential to be the first and only approved therapeutic for loculated pleural effusion patients," stated Brian Windsor, CEO of Lung Tx. "We are honored to partner with Taiho, a Japanese pharmaceutical company with a commitment to the respiratory field, for the development and commercialization of LTI-01 in Japan. Together, we intend to address a serious unmet medical need that affects thousands of patients each year. "

About LTI-01

LTI-01 is an injectable proenzyme, or zymogen, that enhances the fibrinolytic system and breaks down the fibrinous scar tissue which causes LPE. A Phase 2, randomized, placebo-controlled, double-blind, dose-ranging study in patients with infected, non-draining LPE is being conducted in the US¹. LTI-01 has received Orphan Drug Designation in the US and EU and Fast Track Designation in the US.

About Loculated Pleural Effusion (LPE)

Pleural Effusion is an accumulation of excessive fluid in the pleural cavity. Patients are typically treated by chest drainage to alleviate its symptoms such as dyspnea or chest pain. Loculated Pleural Effusion is a condition often associated with empyema or complicated parapneumonic pleural effusions, where the loculation of fluid occurs due to fibrinous adhesions and therefore, becomes difficult to drain.

Currently, the only approved treatments for an LPE are interventions such as chest tube drainage, and if unsuccessful, a surgical procedure. LPE is closely associated with pleural infection, and there are an estimated 80,000 new cases of pleural infection in the UK and US each year².

1. <https://clinicaltrials.gov/ct2/show/NCT04159831>

2. Corcoran J, Robert H, Najib MR (2013) "New therapeutic approaches to pleural infection" *Curr Opin Infect Dis*, 26:196–20

About Lung Therapeutics Inc.

Headquartered in Austin, Texas, Lung Therapeutics, Inc. is a clinical stage biopharmaceutical company formed to leverage leading research in orphan, pulmonary indications for which there are unmet medical needs. The company is developing a proprietary pipeline of novel therapeutics with the potential to greatly improve outcomes over currently available treatments. The company's lead drug [LTI-01](#) has received Orphan Drug Designation in the US and EU and Fast Track Designation in the US. LTI-01 is currently in a Phase 2, randomized, placebo-controlled, double-blind, dose-ranging study evaluating LTI-01 in patients with infected, non-draining loculated pleural effusions. The company's second product candidate, [LTI-03](#), is in development for idiopathic pulmonary fibrosis. For more information, visit lungtx.com.

About Taiho Pharmaceutical Co., Ltd.

Taiho Pharmaceutical, a subsidiary of Otsuka Holdings Co., Ltd., is an R&D-driven specialty pharma company with a focus on oncology. Taiho Pharmaceutical also has development programs in allergy and immunology, urology and consumer healthcare products. Our corporate philosophy is simple: "We strive to improve human health and contribute to a society enriched by smiles." For more information about Taiho Pharmaceutical, please visit: <https://www.taiho.co.jp/en/>.