Aqualung Therapeutics Corpopration

AQUALUNG THERAPEUTICS TARGETING RUNAWAY INFLAMMATION

## AQUALUNG THERAPEUTIC'S ALT-100 MONOCONAL AN-TIBODY CITED AS A NOVEL THERAPEUTIC FOR LUNG FIBROSIS

TUCSON, AZ/Accesswire/April 4, 2022/ Aqualung Therapeutics, an early-stage immunotherapeutics biotech company developing an anti-inflammatory therapeutic platform for unchecked inflammation has published another study touting the effectiveness of its anti-inflammatory ALT-100 monoclonal antibody (mAb). A study reported in the March issue of the *American Journal of Respiratory and Cell Molecular Biology (AJRCMB)* (Alexander N. Garcia MD, PhD lead author) highlights the capacity of the eNAMPT-neutralizing ALT-100 mAb to reduce ionizing radiation-induced murine lung fibrosis. The ALT-100 mAb targets eNAMPT, a novel upstream protein first identified by Aqualung scientists and subsequently shown to act as a master regulator of unchecked inflammation. This study demonstrated that the eNAMPT-neutralizing ALT-100 robustly dampens the eNAMPT/TLR4 inflammatory cascade which results in significant reduction in the severity of murine radiation-induced inflammatory lung injury and fibrosis. These findings were strongly corroborated by accompanying histologic, biochemical and genomics studies.

Although the study targeted radiation-induced lung fibrosis which is a common complication of radiotherapy for the  $\sim$ 150,000 subjects who receive radiation for lung cancer annually, the study complements other Aqualung reports that highlights the potential for ALT-100 mAb to serve as a novel anti-fibrosis therapeutic in subjects with fibrosis of other organs such as the heart, GI tract and the liver. Current concepts of organ injury and fibrosis implicate the critical contribution of unregulated inflammation to the severity of organ fibrosis.

The study's findings have garnered the attention of lung fibrosis experts including Ivan Rosas MD, a Johns Hopkins-trained physician scientist and expert in lung fibrosis, who is the Director of Pulmonary and Critical Care Medicine at Baylor University Medical Center. In the same *AJRCMB* issue, Drs Rosas and I. Tsoyi published an editorial evaluating the Garcia study and highlighting the significance of ALT-100 mAb efficacy in the radiation model. Dr. Rosas commented that "The intimate

interplay between fibrotic pathways and inflammatory pathways is well established. The study by Garcia and the Aqualung team using a lung radiation mouse model, strongly supports eNAMPT as a key, highly druggable target to reduce eN-AMPT/TLR4-driven inflammatory cascades involved in tissue fibrosis. Additional recent reports by this group highlight the mechanism of action for ALT-100 mAb is via dampening of eNAMPT/TLR4-driven inflammatory pathways that may also directly affect fibroblast- myofibroblasts conversion, a key event in fibrosis induction. While additional studies are warranted using complementary models of lung fibrosis and possibly in large animals, ALT-100 appears to be a potentially effective strategy to attenuate inflammation and the severity of fibrosis in the lung and other organs as well."

"This marks the 7<sup>th</sup> peer reviewed publication for Aqualung therapeutics over the last 12 months utilizing our humanized therapeutic mAb ALT-100 in diverse preclinical models such as prostate cancer, pulmonary hypertension, and ARDS", states Stan Miele, President and CBO Aqualung Therapeutics. "We are proud of this publication and the accompanying editorial by Drs. Rosas and Tsoyi as it further validates the strong science surrounding the novel targeting of eNAMPT and highlights the potential for ALT-100 as an anti-inflammatory, anti-fibrotic strategy. Our company is built upon a strong scientific foundation and is focused on finding solutions to numerous unmet medical needs such as lung fibrosis. With our INDenabling preclinical studies successfully completed and GMP ALT-100 available, we are poised for IND submission in May 2022. Aqualung will be entering human clinical trials for the lead indication of Acute Respiratory Distress Syndrome (ARDS) and Ventilator-Induced Lung Injury (VILI) in June 2022 and continuing development in chronic indications such as pulmonary fibrosis in parallel."

## **About Aqualung Therapeutics Corporation**

Aqualung is an early-stage biotech company developing immune-focused therapeutic antibodies for patients suffering from disorders characterized by acute and chronic lung and systemic inflammation. Founded in 2016 and led by a physician scientist, Aqualung's science-driven approaches led them to the identification of nicotinamide phosphoribosyltransferase (NAMPT) as a contributor to severe inflammatory diseases. Aqualung Therapeutics is developing eNamptor<sup>™</sup>, a Next Gen platform comprised of: i) ALT 100 mAb, a humanized eNAMPT-neutralizing monoclonal antibody; ii) eNAMPT-Plex, a plasma-based biomarker panel comprised of cytokines, including eNAMPT, which predicts ARDS mortality; and iii) *NAMPT*-Gene, a genotyping assay that identifies individuals at increased risk for ARDS death. The pipeline of ALT is designed to target a range of diseases, including ARDS, ventilator- and radiation-induced lung injury, chorioamnionitis, prostate cancer, pulmonary hypertension, and other significant unmet medical needs with significant morbidity and mortality including organ fibrosis (cardiac, pulmonary, hepatic fibrosis or NASH, bowel). For additional information about the company, please visit <u>www.aqualungtherapeutics.com.</u>

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