Aqualung Therapeutics Corporation Receives A $2.3 Million National Institute Of Health (NIH) Fast-Track Award To Develop A Novel Therapeutic Antibody For Patients With Radiation-Induced Lung Injury

TUCSON, AZ / ACCESSWIRE / June 2, 2020 / Aqualung Therapeutics, an early-stage biotech company developing immune-focused therapeutic antibodies for patients suffering from acute and chronic disorders characterized by systemic inflammation, has been awarded a three year NIH FAST-TRACK AWARD (R42 HL152888-01) which will support mid- and late-stage development of a therapeutic to treat patients who undergo radiotherapy for treatment of lung & esophageal cancers and are at risk for developing Radiation-Induced Lung Injury (RILI).

The initial stage of this NIH STTR Award involves the final selection of the lead eNAMPT-neutralizing humanized therapeutic mAb between two candidates, ALT-100 and ALT-200; with selection utilizing *in vitro* and preclinical *in vivo* models of Radiation Induced Lung Injury (RILI). The second STTR stage supports completion of pharmacokinetic/ pharmacodynamic and toxicology studies with the lead mAb ALT-100/ALT-200 candidate in appropriate animal models, and submission of an FDA IND application.

The development of radiation-induced lung injury (RILI) is a potentially fatal toxicity in cancer patients undergoing thoracic radiotherapy for lung or esophageal cancers, or in individuals exposed to ionizing radiation (IR) from a nuclear incident. Aqualung scientists identified nicotinamide phosphoribosyltransferase (NAMPT) as a novel upstream immune-based therapeutic target in the development of RILI and have generated a humanized monoclonal therapeutic antibody mAb, ALT-100, which is designed to suppress the systemic inflammatory cascades and prevent radiation pneumonitis and radiation-induced lung fibrosis.

"There are currently no FDA-approved therapies for patients who experience Radiation-Induced Lung Injury and we believe our pre-clinical evidence is compelling and supports the advancement of ALT-100/ALT-200 as a potential therapy for patients with thoracic cancer and potentially for individuals accidentally exposed in a nuclear incident. We are confident that ALT-100/ALT-200 will reduce the severity of potentially fatal radiation pneumonitis and radiation fibrosis. This aligns with our principle of finding cures for conditions of significant unmet medical needs that are driven by runaway inflammation" states Joe GN Garcia MD, CEO of Aqualung Therapeutics.

Pulmonary radiation injury manifests in approximately 8 percent of patients who receive thoracic radiation. However, reports of the incidence of symptomatic radiation pneumonitis ranges from 1-34 percent of patients who receive thoracic radiation for malignancy. Additionally, without FDA-approved therapies for this condition, it is also important to have a viable therapeutic available to treat patients who may be exposed to a nuclear incident as part of our national and

global state of preparedness. The Aqualung team is prepared to execute and achieve all the milestones associated with this STTR grant.

"Unchecked inflammation is a major contributor to many disease states and at Aqualung, we believe eNAMPT plays a central role in promoting this inflammatory cascade. This STTR grant, the second large NIH-funded award supporting a focus on a mAb that neutralizes eNAMPT, provides Aqualung the needed financial resources to immediately validate our target therapeutic in additional models and then initiate all IND-enabling studies", states Stan Miele, President & Chief Business Officer of Aqualung Therapeutics. The grant allows Aqualung to initiate early clinical development with non-dilutive capital.

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) and other key proteins expressed in both acute and chronic inflammatory diseases. Aqualung Therapeutics is developing eNamptor™, a Next Gen platform comprised of : i) ALT 100/200, humanized eNAMPT-neutralizing monoclonal antibodies; 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, prostate cancer, pulmonary hypertension, and both pulmonary and hepatic fibrosis (NASH). These conditions all exhibit a significant unmet medical need with significant morbidity and mortality. For additional information about the company, please visit *www.aqualungtherapeutics.com.*

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