Appili Therapeutics ATI-1701 Biodefense Vaccine Secures ~US$14 Million of Funding from the U.S. Department of Defense in Partnership with the U.S. Air Force Academy

Dr. Armand Balboni appointed as Chair of the Board and moves to the U.S. Air Force Academy to take over as Principal Investigator for the ATI-1701 program; and Dr. Don Cilla promoted to President and Chief Executive Officer of Appili

HALIFAX, Nova Scotia--(BUSINESS WIRE)--November 14, 2022--Appili Therapeutics Inc. (TSX: APLI; OTCQX: APLIF) (the "Company" or "Appili"), a biopharmaceutical company focused on drug development for infectious diseases and biodefense, today announced that the U.S. Department of Defense ("DOD"), via the Joint Science and Technology Office of the Defense Threat Reduction Agency ("DTRA") in partnership with the U.S. Air Force Academy ("USAFA"), will provide at least US$14 million in funding over two years to fund the development of ATI-1701. ATI-1701 is a potential first-in-class vaccine candidate for the prevention of infection with aerosolized *Francisella tularensis,* a top-priority biothreat.

Appili is expected to partner with USAFA to advance the program. This revised funding represents a 40% increase over the originally anticipated DTRA funding for this program, as announced in February 2022. With DTRA's additional support, work on ATI-1701 is expected to include nonclinical, manufacturing, and regulatory activities to prepare for an Investigational New Drug ("IND") application to the United States Food and Drug Administration ("FDA"). If approved by the FDA, ATI-1701 may be eligible for a Priority Review Voucher.

"We are excited to announce the funding from DTRA in partnership with USAFA for Appili's ATI-1701 as it will help in addressing an urgent risk to public health. This funding is expected to strengthen Appili's foundation in infectious disease and biodefense," said Dr. Don Cilla, Pharm.D., M.B.A., Appili's President and CEO.

About ATI-1701 and DTRA Contract

Appili owns the commercial rights to, and is developing, ATI-1701 as a vaccine to prevent *Francisella tularensis*, which has been classified as a Category A pathogen by the U.S. National Institutes of Health due to its high rates of infectiousness and ability to cause lethal pneumonia and systemic infection. As the transmission of *Francisella tularensis in the* aerosolized form can be more infectious than anthrax, it is considered to be a high bioterrorism threat.

Earlier this year, Appili announced positive one-year results from its preclinical study evaluating the efficacy of biodefense vaccine candidate ATI-1701 in a lethal animal model of tularemia. A one-year survival rate of 29% (n = 2/7) was reported in the ATI-1701 vaccinated cohort, compared to 0% (n = 0/5) in mock vaccinated controls. The positive data built on previously reported efficacy results observed at 28- and 90-day challenge timepoints where there was 100% survival of ATI-1701 vaccinated animals at the 90-day challenge timepoint. These data position ATI-1701 to potentially become the first approved vaccine for the prevention of tularemia. The study was funded by DTRA and conducted by MRIGlobal.

The DTRA funding will initially be advanced to USAFA, as the prime contractor under the supervision of Dr. Balboni as principal investigator. As noted above, Appili is expected to partner with USAFA, subject to negotiating definitive documentation governing the terms of such engagement.

The expected total program funding amount is ~US$14 million, with a portion of the funding subject to future U.S. federal budget approval. This funding is expected to advance the ATI-1701 program to an IND submission to the FDA in 2024.

Appili Leadership Transition

As part of today's announcement, Dr. Armand Balboni has been appointed as Chair of the Board of Directors of Appili and will continue providing oversight and guidance to Appili's overall portfolio, with a specific focus on the ATI-1701 Program for which he will serve as Principal Investigator. Dr. Balboni will be returning to the Department of Defense as a LT. Colonel, faculty member and Director of the Life Sciences Research Center at USAFA.

Don Cilla, Pharm.D., M.B.A., who has served as Appili's Chief Development Officer for two years, has been promoted to the position of President and Chief Executive Officer of Appili. Dr. Cilla has over 35 years of experience in the pharmaceutical industry, serving in key leadership roles across research and development in pharmaceutical, biotech and generic drug companies. In prior roles, Dr. Cilla led and participated in the global development of more than 40 products, of which six products are clinically and commercially successful.

"I am delighted to be chosen for this tremendous opportunity to build on Appili's foundation and to renew our focus in infectious disease and biodefense treatments. We're grateful for this funding, which will advance ATI-1701 to the next stage of development" said Dr. Cilla.

In his new role as President and Chief Executive Officer, Dr. Cilla will also join Appili's Board of Directors. Additional Board changes include Ian Mortimer stepping down as Chair of the Board and Director and Dr. Theresa Matkovits being appointed as Lead Independent Director.

"I have forged a strong relationship with Don as the Chief Development Officer at Appili and I'm excited for Don to move into the Chief Executive Officer role given his tremendous track record in drug development," said Dr. Balboni. "I also want to extend my gratitude to Ian Mortimer for his years of service on our Board and as Board Chair, where we have benefited greatly from his leadership and guidance."

About ATI-1701

Appili is developing ATI-1701 as a vaccine to combat *Francisella tularensis*, which is classified by the U.S. National Institutes of Health (NIH) as a Category A pathogen, an organism that poses the highest risk to national security and public health. Estimated to be 1,000-fold more infectious than anthrax, experts consider the aerosolized form to have a high potential for use in a bioterrorism attack.

About Appili Therapeutics

Appili Therapeutics is an infectious disease biopharmaceutical company that is purposefully built, portfolio-driven, and people-focused to fulfill its mission of solving life-threatening infections. By systematically identifying urgent infections with unmet needs, Appili's goal is to strategically develop a pipeline of novel therapies to prevent deaths and improve lives. The Company is currently advancing a diverse range of anti-infectives, including a vaccine candidate to eliminate a serious biological weapon threat, a topical antiparasitic for the treatment of a disfiguring disease, and a novel easy to use, liquid oral formulation targeting parasitic and anaerobic infections. Led by a proven management team, Appili is at the epicenter of the global fight against infection. For more information, visit www.AppiliTherapeutics.com.

Forward-Looking Statements

This news release contains "forward-looking statements", including with respect to the anticipated funding amount, the anticipated timing of such funding, the Company's ongoing development plans and timeline with respect to ATI-1701 and the Company's expected cash runway. Wherever possible, words such as "may," "would," "could," "should," "will," "anticipate," "believe," "plan," "expect," "intend," "estimate," "potential for," and similar expressions have been used to identify these forward-looking statements.

Forward looking statements contained in this press release are provided in reliance on certain assumptions, including with respect to the satisfaction of all conditions precedent to the advancement of the full anticipated funding (including receipt by DTRA of any requisite U.S. federal budget approvals, general development plans with respect to ATI-1701, general access to data required to support regulatory submissions, expected PRV eligibility for ATI-1701, and the nature and scope of the services to be provided by Appili to USAFA with respect to advancing the ATI-1701 program). Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, the Company cannot give assurance that these expectations will prove to have been correct.

Forward looking statements involve significant known and unknown risks, uncertainties and assumptions, including, without limitation, the risk that the final conditions governing the funding and the relationship of between Appili and USAFA may not be satisfactory to the Company , the final funding amount may be different than that communicated herein (including as a result of the failure to secure the requisite US government budget approvals), receipt of funding may be delayed in the event that any remaining conditions are not satisfied in a timely manner, ATI-1701 may ultimately be determined not to be PRV eligible, other standard risks associated with governmental grants of this nature and the other risk factors listed in the annual information form of the Company dated June 23, 2022 and the other filings made by the Company with the Canadian securities regulatory authorities (which may be viewed at www.sedar.com). Should one or more of these risks or uncertainties materialize or should assumptions underlying the forward-looking statements prove incorrect, actual results, performance or achievements may vary materially from those expressed or implied by the forward-looking statements contained in this news release. These factors should be considered carefully, and prospective investors should not place undue reliance on the forward-looking

statements. The Company disclaims any intention or obligation to revise forward-looking statements whether as a result of new information, future developments or otherwise, except as required by law.

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