

Appili Therapeutics Announces Issuance of Patent for ATI-1701 Biodefense Vaccine Candidate to Protect Against Tularemia and Provides Update on Bridge Loan

Patent coverage provides drug market exclusivity through at least 2039

Pre-IND meeting with the FDA granted to discuss ATI-1701's regulatory, CMC, toxicology, and Phase 1 strategies

HALIFAX, Nova Scotia--(BUSINESS WIRE)--December 15, 2023--Appili Therapeutics Inc. (TSX:APLI; OTCQB: APLIF) (the "Company" or "Appili"), a biopharmaceutical company focused on drug development for infectious diseases and biodefense, today announced that the United States Patent and Trademark Office ("USPTO") has published patent claims for ATI-1701 under the U.S. Application No. **16/982,322** filed on **September 18, 2020** and titled "*A Method for Lyophilizing Live Vaccine Strains of Francisella Tularensis*". The patent covers the composition and preparation methods for the vaccine through 2039.

This patent was issued to our partners, the National Research Council of Canada ("NRC") and protects against the unauthorized use of methods claimed to lyophilize *Francisella tularensis* strains, including Appili's proprietary live vaccine strain ATI-1701. Appili licensed the biodefense vaccine candidate ATI-1701 from NRC in December 2017. The license agreement with NRC grants Appili exclusive worldwide rights to develop and commercialize ATI-1701. The new patent protects additional manufacturing methods for the final drug product.

"This patent protects an improvement in the method of lyophilizing *F. tularensis* live vaccine strains, such as the *Ft ΔclpB* mutant (ATI-1701). The patent also protects a special media which preserves the viability of the vaccine in a manner which is clinically useful and allows long-term storage," said Don Cilla, Pharm.D., M.B.A., President and Chief Executive Officer of Appili Therapeutics. "This patent strengthens ATI-1701's position and the new methods are expected to allow Appili to further develop a valuable vaccine that is urgently needed on the market."

Appili's development program ATI-1701, for the prevention of tularemia, has received awards totaling US\$14 million from the U.S. Air Force Academy ("USAFA"). This year, as ATI-1701 early-stage development activities and regulatory activities progressed, the Company successfully completed a knowledge transfer and executed a technology transfer to the Phase 1 Contract Manufacturing Organization ("CMO"). Appili expects the ATI-1701 CMO to successfully produce engineering batches and GMP batches in 2024.

Additionally, Appili was granted a pre-IND meeting with the FDA to discuss ATI-1701's regulatory, CMC, toxicology, and Phase 1 strategies and expects to receive feedback in early 2024. The goal of the ATI-1701 program is to evaluate the immunogenicity, efficacy, and safety of the ATI-1701 vaccine and ultimately submit a Biological License Application.

The Company also announced that the Company and Bloom Burton & Co. (“Bloom Burton”) have agreed to amend the terms of the existing \$300,000 bridge loan (the “Bridge Loan”) advanced to the Company by Bloom Burton in June 2023. Under the amended terms, the Bridge Loan will now mature on March 31, 2024, subject to acceleration in connection with certain corporate events.

About ATI-1701

ATI-1701 is the Company’s potential first-in-class vaccine candidate for the prevention of infection with *F. tularensis*, the causative agent of tularemia and a top-priority biothreat. Appili is developing ATI-1701 as a vaccine to combat *F. 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 at least 1,000-fold more infectious than anthrax, experts consider the aerosolized form to have a high potential for use in a bioterrorism attack.

Appili secured a US\$14M funding commitment for ATI-1701 from USAFA, who is working in partnership with the Defense Threat Reduction Agency. These funds along with other potential funding sources, are anticipated to continue to advance the ATI-1701 program toward an IND submission to the FDA in 2025.

About Appili Therapeutics

Appili Therapeutics is a biopharmaceutical company that is purposefully built, portfolio-driven, and people-focused to fulfill its mission of solving life-threatening infectious diseases. 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 an FDA approved ready-made suspension of metronidazole for the treatment of antimicrobial infections, a vaccine candidate to eliminate a serious biological weapon threat, and a topical antiparasitic for the treatment of a disfiguring disease. 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 proposed development plans for ATI-1701. 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 FDA application and approval process for ATI-1701. 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 New Drug Application for ATI-1701 may ultimately not be approved by the FDA, 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.sedarplus.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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