Appili Receives FDA and Health Canada Clearance to Begin Clinical Trials of its Antibiotic Oral Liquid Reformulation

For Immediate Release

HALIFAX, Nova Scotia – October 30, 2017 – Appili Therapeutics Inc. (the "Company" or "Appili"), an anti-infective drug development company, announced today that both the US Food and Drug Administration (FDA) and Health Canada have cleared its IND and CTA clinical investigation applications, respectively, to conduct a clinical trial of ATI-1501, a taste-masked antibiotic targeting anaerobic bacteria like *Clostridium difficile*. ATI-1501 has been optimized in an oral liquid suspension to provide patients who have difficulty swallowing with a more convenient alternative to the currently marketed metronidazole tablet.

Appili plans to conduct the ATI-1501 clinical study in Toronto, Ontario and will begin recruiting subjects in November 2017. The company expects to enroll approximately 40 healthy volunteers in this bioavailability study.

"Having both Health Canada and FDA authorization affirms our confidence in our regulatory and development strategy," said Kevin Sullivan CEO of Appili Therapeutics. "We're excited to take ATI-1501 into clinical trials because it brings us a step closer to offering physicians a new weapon to fight serious infections and improve patient compliance."

ATI-1501 fulfills an unmet market need for millions of people with swallowing difficulties who have been prescribed metronidazole. These individuals, primarily children and the elderly, are not completing their full course of metronidazole tablets because of the extreme bitter taste and difficulty swallowing tablets. Poor patient compliance is leading to the spread of infection, recurrent infections, and antibiotic resistance, which makes treatment more complicated and expensive. As the mainstay for treating anaerobic bacterial infections, IMS Health reports that over 9.5 million prescriptions of metronidazole tablets are issued in the US each year.

Appili's ATI-1501 oral liquid antibiotic candidate has been taste-masked to improve palatability and reduce issues with non-compliance. Once ingested, the well-studied and established antibiotic is designed to kill anaerobic bacteria by interfering with their DNA, which clears up the infection.

"We expect the completion of this clinical trial will set us up to file our new drug application in 2018 and advance our commercialization activities," said Jamie Doran, Vice President of Drug Development of Appili Therapeutics.

Appili's regulatory strategy involves registration using a 505(b)(2) pathway in the US, which is an abbreviated FDA pathway that allows the Company to reference safety and efficacy data of the original oral metronidazole tablet.

About Appili Therapeutics

Appili is dedicated to identifying, acquiring and advancing novel therapeutics for infectious disease. The Company has two anti-infective programs, ATI-1501 and ATI-1503, in its pipeline. ATI-1501 is a taste-masked treatment for anaerobic infections that has been granted orphan drug status by the FDA. Appili's second product, ATI-1503, is a novel antibiotic with broad potential to treat deadly Gram-negative infections. These drug-resistant infections have been identified by the US Centers for Disease

Control (CDC) and the World Health Organization as posing the highest threat to human health. For more information visit www.AppiliTherapeutics.com.

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