

Appili Therapeutics Enters Commercial Agreement With Saptalis Pharmaceuticals for Anticipated Launch of ATI-1501 Antibiotic Candidate in the U.S.

NDA filing expected within 18 months for liquid metronidazole to support the growing number of patients who cannot tolerate current oral tablet formulation

HALIFAX, Nova Scotia--(BUSINESS WIRE)--December 3, 2019--Appili Therapeutics Inc. (TSXV: APLI) (the “Company” or “Appili”), a biopharmaceutical company focused on anti-infective drug development, today announced that it has entered into a commercialization agreement with Saptalis Pharmaceuticals LLC, a New York-based specialty pharmaceuticals company, on ATI-1501, Appili’s liquid suspension reformulation of the antibiotic metronidazole. Under the terms of the agreement, Appili is eligible to receive multiple milestone and royalty payments on the sale of ATI-1501 in the U.S. In addition, Saptalis will be responsible for overseeing the regulatory review, manufacturing and preparation for the anticipated commercialization of ATI-1501 in the U.S.

“Infectious diseases form the basis of some of the most urgent public health threats in today’s treatment landscape. Our approach to drug development is to identify overlooked infectious disease assets that address significant needs in the marketplace, and advance them through the drug development process,” said Dr. Armand Balboni, Chief Executive Officer, Appili Therapeutics. “Having completed clinical development for ATI-1501 at Appili, we are pleased to find a strong partner who can take the program through FDA review and market launch, upon regulatory approval. This agreement with Saptalis is a win for our shareholders, clinicians and patients seeking better treatment options.”

ATI-1501 is a proprietary, novel, taste-masked oral liquid formulation of metronidazole – a broad-spectrum and widely prescribed antibiotic used to treat parasitic and anaerobic bacterial infections.ⁱ Currently, oral metronidazole is only available as a solid tablet or capsule in the U.S. and Canada; no liquid oral dose forms are approved. The tablet’s bitter taste is so pronounced that it appears as an adverse event on the drug’s label. An increasing number of patients with dysphagia (difficulty swallowing) are unable to take the tablet and require it to be crushed into food. This process amplifies the pronounced bitter taste, which can negatively impact patients’ adherence to their prescription.

Appili began developing ATI-1501 to solve a significant and growing issue for patients who cannot tolerate the current tablet formulation of metronidazole.^{ii iii iv} Appili’s market research shows a potential for more than 600,000 patients in the U.S. who could benefit from the program, with additional potential upside beyond this core target market.

“We are excited to form a partnership with Appili on their ATI-1501 program, which is a good fit for Saptalis’ focus on developing difficult-to-formulate dosage forms and novel drug delivery approaches, including liquid suspensions,” said Polireddy Dondeti, PhD, Chief Executive Officer at Saptalis Pharmaceuticals, LLC. “We have a great team and a great facility here at Saptalis with the resources to efficiently manufacture the product to commercial scale, to complete regulatory review and, ultimately, to launch the antibiotic in a timely fashion.”

“Securing this agreement with Saptalis shortly after taking Appili public is an important milestone that demonstrates Appili’s ability to identify promising opportunities, develop and add value to those programs, and monetize those opportunities for the benefit of shareholders and patients,” continued Dr. Balboni. “We look forward to executing on additional opportunities to tackle serious public health challenges and generate shareholder value as we strive to do well by doing good.”

Stock Option Grant

The Company granted 1,995,000 stock options under Appili’ Stock Option Plan to the Company’s employees, officers, directors and investor relations consultant. The stock options will be exercisable at the closing price of the Appili common shares on Wednesday, December 4, 2020, and will have a term of ten years and will vest over a period of three years (over one year for the investor relations consultant).

About Appili Therapeutics

Appili Therapeutics Inc. was founded to advance the global fight against infectious disease by matching clearly defined patient needs with drug development programs that provide solutions to existing challenges patients, doctors, and society face in this challenging disease space. Appili has built a pipeline of assets designed to address a broad range of significant unmet medical needs in the infectious disease landscape. This diverse pipeline aims to address some of the most urgent threats in global public health. Appili acquired ATI-2307, a novel, broad spectrum, clinical stage antifungal, in development to address severe and difficult-to-treat invasive fungal infections. Via an in-licensing program, Appili acquired the rights to ATI-1701, a vaccine for tularemia, being developed to mitigate the risks of a very serious biological weapons threat. ATI-1503 is a drug discovery program aimed at generating negamycin analogue candidates, which are a novel class of antibiotics with broad-spectrum activity against Gram-negative superbugs. ATI-1501 employs Appili’s proprietary, taste-masked, oral-suspension technology with metronidazole for the growing number of patients with difficulty swallowing. Headquartered in Halifax, Nova Scotia, with offices in Toronto, Ontario, Appili is pursuing worldwide opportunities in collaboration with science and industry commercial partners, governments and government agencies. For more information, visit www.AppiliTherapeutics.com.

About Saptalis Pharmaceuticals LLC

Saptalis Pharmaceuticals, LLC (“Saptalis”) is a rapidly growing pharmaceutical company specialized in development, manufacturing and marketing of generic and branded products in liquid and semi-solid dosage forms. The Company is focused on development of complex formulations of sterile and non sterile medicines, including nanosuspensions and microemulsions. Saptalis’ goal is to build value through commercialization of selected branded and generic prescription products. In addition to the diverse pipeline of generic products, the Company is developing innovative products, such as improved formulations of existing medicines to address unmet patient needs.

Located in the Hauppauge Industrial Park on Long Island, NY, USA, Saptalis has fully equipped Research & Development Laboratories and state of the art commercial scale manufacturing

facility designed to meet FDA cGMP requirements. For more information, visit www.Saptalis.com.

Forward looking statements

This news release contains “forward-looking statements” which reflect the current expectations of the Company’s management future growth, results of operations, performance and business prospects and opportunities. 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 involve significant known and unknown risks, uncertainties and assumptions, including, without limitation, those listed in the annual information form of the Company dated July 3, 2019 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.

Neither the TSX Venture Exchange, nor its regulation services provider (as that term is defined in the policies of the exchange), accepts responsibility for the adequacy or accuracy of this release.

ⁱ IQVIATM 2014-2017 NPA, ‘metronidazole’; IQVIATM 2016-2017 CDM, ‘metronidazole’

ⁱⁱ Baguley (2012) Arch Dis Child: Prescribing for children - taste and palatability affect adherence to antibiotics: a review.

ⁱⁱⁱ Hoppe (1996) Pharmacoeconomics

^{iv} Boateng (2017) J Pharm Sci

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