

Executive Summary

The Company - Innovene is an early stage therapeutics company based in New York City. The company is developing a new class of therapeutics derived from plant compounds targeting the human papillomavirus (HPV) infection and HPV associated cancers. The lead program (C-HPV 001) will examine the clinical efficacy of TriCurin in women with chronic cervical HPV infection,

The Problem - HPV is the most common sexually transmitted disease and the most frequent cancer-causing virus both in men and women. HPV also causes skin and external genital warts. In the US 1.8 million women have chronic cervical HPV which leads to 270,000 new cases of cervical pre-cancers each year. Currently, there is no medication available to treat cancer causing HPV infections. As a standard practice, physicians recommend a "watch and wait" approach, following patients with oncogenic HPV infections to see if they develop precancers, which are then treated with ablative or surgical procedures. These procedures have been shown to increase future pregnancy complications. While HPV vaccines can reduce rates of HPV infection among teenagers and young adults, they are not therapeutic for patients chronically infected. Furthermore, attempts to develop a synthetic antiviral have not been successful. HPV remains one of largest unmet medical needs causing a significant amount of morbidity, mortality and billions of dollars in health care costs.

Our Solution - TriCurin inhibits the expression of the viral oncoproteins E6 & E7, which are essential for the proliferation of HPV-infected cells and HPV (+) cancers. TriCurin disrupts the virus replicative cycle before pre-cancerous conditions become malignant. TriCurin has shown to be non-toxic to healthy tissue.

TriCurin will be made available in different product formulations to address various unmet medical needs. Innovene's lead product, TriCurin intravaginal cream, will target cervical HPV infection and cervical precancers. TriCurin topical cream will be used to treat skin and genital warts. TriCurin medicinal lollipop is for the prevention and treatment of oral HPV infection and TriCurin injectable is for direct intensive intra-tumor treatment of HPV positive cancers.

Product Development and Timeline - Innovene's first clinical development program with intravaginal TriCurin cream in women with chronic HPV infection can begin early 2018. The study is expected to obtain safety, tolerability and clinical efficacy data in 12 months. Upon completion, we will initiate a Phase II randomized placebo controlled clinical trial that will require 24 months to complete.

Way Forward - With sufficient funding to complete Phase I & II trials for cervical HPV infection showing clinical efficacy, Innovene will be uniquely positioned to develop TriCurin as stand-alone therapy or combination treatment. Currently, the HPV vaccines are not effective in preventing disease if patients are already infected; as a result the vaccines are not indicated for women over 26 years old. However, an anti-HPV treatment could be followed by HPV vaccination for women 26 years and above and establish a strategy for treatment and long lasting prevention. Subsequent to testing in cervical disease, Innovene will also begin testing TriCurin in other HPV infected sites, such as the skin warts & oral cavity.

Innovene will endeavor to partner with existing biotech or pharmaceutical companies that are focused on women's health products, transdermal technologies, and/ or HPV diagnostics, to further commercialize Innovene's product portfolio. Innovene is currently pursuing strategies that include direct investment, licensing or sale of one or more products, merger/acquisition or strategic partnership with other companies.

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