ASX RELEASE

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KEY ADVANCEMENT TOWARDS COMMENCEMENT OF PHASE 1 CLINICAL STUDY OF ORAL FORMULATIONS

Highlights

- PhytoTech Medical has submitted key documents to the Institutional Review Board (IRB or Helsinki Committee) and National Clinical Trial Committee in Israel to allow the Company to commence clinical studies with it's Tetrahyrocannabidiol (THC) and Cannabidiol (CBD) unique oral capsules
- Submission of Clinical Study Protocol and Investigative Brochure, signifies a key milestone indicating advanced development stage and readiness to initiate phase 1 clinical study
- Accomplishment of Phase 1 clinical study will be a key step in the Company objective to develop the oral capsule for relief of pain and spasticity in Multiple Sclerosis (MS) patients – which currently affects over 2.3 million people globally
- Following successful completion of the Phase 1 study, the succeeding Phase 2 study will already assess the drug's efficacy in MS patients
- Phase 1 of the Clinical study, which the Company expects will commence in Q4 2015, will focus on the two new oral THC and CBD formulations recently licensed from Yissum.
- Initial pre-clinical study results have indicated a potential high bioavailability of the formulations

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PhytoTech Medical Limited (ASX: PYL) (the "Company") is pleased to provide an update on the progress of its oral drug development.

On the 11 June 2015 the Company submitted two formal clinical documents, which, when approved, will allow it to begin its Phase 1 study of its two pro-nano-lipospheres Tetrahyrocannabidiol (THC) and Cannabidiol (CBD) formulations.

The Oral formulations

The two pro-nano-lipospheres formulations are intended to increase the oral bioavailability of THC:CBD having poor water solubility and thus limited bioavailability. The Company intends to continue the clinical development of only one of the formulations. The Company will select the formulation which is shown to have the highest performance.

Health Authority approvals

The documents submitted include a Clinical Study Protocol, which outlines the objectives, design, methodology, statistical considerations and organisation of the proposed clinical trial and ensures the safety of the trial subjects and integrity of the data collected, and an Investigator Brochure (IB), which is a comprehensive document intended to provide the investigator with the information necessary for the management of the study and its subjects throughout the clinical trial.

Ahead of any clinical trial there is a requirement to apply for and receive approval from an Institutional Review Board (IRB) and National Clinical Trial committees. The purpose of this review is to ensure that appropriate steps are taken to protect the rights and welfare of participants.

PhytoTech has already established and put in place the necessary agreements with the clinical site, and various contract organisations responsible for study monitoring, drug-capsule manufacturing, stability tests, pharmacokinetic assessment and bio-statistics in order for the study to commence as soon as possible following approval from the IRB and the committees.

The Phase 1 Study

The Phase 1 study will be a single-centre, randomised, crossover study to compare the safety, tolerability and pharmacokinetics in healthy volunteers of the two new oral THC and CBD formulations, when administered as single doses.

As part of the study objectives, the Company will select the optimal THC:CBD formulation for delivering THC and CBD, and advance it to a Phase 2 clinical study which will focus on the drug's capability to relieve pain and spasticity in Multiple Sclerosis (MS) patients, of which there are over 2.3 million worldwide (Source: National MS Society).

The Phase I study will be performed in Sourasky Medical Clinical Research Center, one of the largest and highly regarded clinical sites in Israel.

It has been designed to fulfil all the regulatory requirements needed for the New Drug Application (NDA) to the Food and Drug Administration (FDA).

The Phase 1 clinical study is planned to commence in Q4 2015 following IRB and the committees' approvals, and is expected to conclude after a 9-week period.

The Phase 2 Study

The Phase 2 study will assess the drug's capability to relieve pain and spasticity in Multiple Sclerosis (MS) patients in comparison to Sativex®, GW Pharma's leading buccal delivery CBD:THC product for the treatment of muscle spasticity in MS patients.

Upon a successful completion of the Phase 1 study, the Company expects to begin the Phase 2 study during 2016 and plans to complete such study during 2017. In parallel, the Company will continue to develop validated manufacturing and testing methods, will upgrade the production of the formulated capsule and will carry out long-term stability studies.

THC:CBD in the treatment of Multiple Sclerosis symptoms

Multiple Sclerosis is a disabling neurological lifelong condition affecting young adults. According to the National MS Society over 2.3 million people worldwide suffer from MS. The market for disease-modifying Multiple Sclerosis therapies is predicted to expand at an annual rate of 10% per year, reaching nearly US$21 billion in 2018 (Source: Decision Resources).

Spasticity is one of the most common and most disabling symptoms, affecting up to 84% of patients (World Health Organisation). One of the most successful treatments for Multiple Sclerosis pain and spasticity was found to be the use of a safe and tolerable combination of THC and CBD at a 1:1 ratio. The therapeutic rationale for the THC and CBD combination has been established, however an optimal oral dosage form is yet to be available due to the substantial "first pass" metabolic effect of the cannabinoids (THC and CBD) in the gastrointestinal tract leading to very limited oral bioavailability of ~6%.

Pre-clinical study results

Favourable pre-clinical studies with the Company's THC:CBD oral formulations have indicated a potentially high bioavailability when administered as an oral capsule.

Oral administration is regarded as the best route to deliver the drug due to the decreased variability in dosage, no delivery system side effects, decreased dosing frequency, longer shelf life, ability to store at room temperature storage and its low cost. Oral capsules administering medical cannabis as a treatment are therefore expected to have an increased compliance in comparison to the current non-oral delivery routes.

Boaz Wachtel, Managing Director, PhytoTech Medical Limited commented:

"We are extremely pleased to have accomplished the planned development studies and related activities towards execution of the Phase 1 clinical study. Importantly, the pre-clinical results of the formulations have been very encouraging.

"The submission of documents to the IRB and Clinical Trial Committees is a key milestone for PhytoTech and I am confident that we will receive the necessary approvals to allow us to commence the study later this year."

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About PhytoTech Medical Limited

PhytoTech Medical Limited is a medical cannabis company, which aims to commercialise Medical Grade Cannabis ("MGC") and high potential cannabis based therapeutics products to the rapidly growing international market with regulated medical cannabis laws. With research facilities located in Israel, a global leader in medical cannabis research, the Company is strategically positioned to become a key player in the global MGC market.

On 23 March 2015, the Company announced that it had entered into an agreement to acquire 100% of the issued capital of MMJ Bioscience Inc., a Canadian-based multinational vertically integrated MC company. Under the terms of the agreement, the two companies will combine in a "Merger of Equals" via a three-stage deal structure based on MMJ achieving key milestones. The combined group will form a vertically integrated MC company, which will be involved with the production, research and development and distribution of MC products.