

24 August 2015

## Phase I Clinical Study Approved, Expected to Commence Late 2015

### Highlights

- First Clinical Study ("Study") approval for MMJ PhytoTech Limited ("MMJ" or the "Company") and key milestone in implementation of the Company's 'Farm to Pharma' strategy
- Study to be conducted by MMJ subsidiary, PhytoTech Therapeutics and will focus on testing the safety and performance of its proprietary oral capsule formulations
- Approval received by all relevant bodies and allows Study to be conducted in Israel
- Initial stability studies have indicated an extended shelf life of the oral capsule formulation at room temperature, providing the potential to increase market share by lower product costs and increased patient compliance
- On track to commence Study by November 2015 with initial results expected by Q1 2016
- Company in advanced discussions with leading Good Manufacturing Practices ("GMP") manufacturer of soft gelatin capsules regarding upgrading and scaling production and testing methods of the formulated capsules
- Upon successful completion of Phase 1, Phase 2 Clinical Study will assess the capability of the oral capsule to relieve pain and spasticity related to Multiple Sclerosis ("MS") planned for H2 2016
- Company is well capitalized to fund further studies after recent oversubscribed A\$4.8m equity offering and expected revenues from CBD pill sales

**MMJ PhytoTech Limited (ASX:MMJ)** is pleased to announce that its subsidiary, PhytoTech Therapeutics, has received official National approval in Israel to commence a Phase I Clinical Study to assess the safety and performance of its proprietary oral capsule formulations.

On June 11 2015 PhytoTech Therapeutics advised that it had submitted a Clinical Study Protocol to all relevant parties. The Protocol outlined the objectives, design, methodology, statistical considerations and organisation of a clinical trial and an Investigator Brochure (IB), a comprehensive document providing the investigator with the insights necessary for the management of study conduct and its subjects throughout a clinical trial.

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Today, on 24 August 2015, PhytoTech Therapeutics received approval from all relevant parties including The Tel Aviv Sourasky Medical Centre Institutional Review Board (Helsinki Committee), Clinical Trial Department and the Medical Marijuana Unit at the Israeli Ministry of Health to begin the study.

### **Study to Commence in November 2015, Initial Studies Encouraging**

PhytoTech Therapeutics intends to commence the study by November 2015, with initial results expected as early as Q1 2016.

On-going initial stability studies have been very encouraging and indicate the capsule formulations potential of a long shelf life, even when stored at room temperature. This indicates that the formulation excipient components are able to maintain the Tetrahydrocannabinol (THC) and Cannabidiol (CBD) integrity at various storage temperatures.

### **Potential for Superior Product**

The capsules have a clear advantage over smokeable products in that oral administration is much more controllable and user-friendly than smoking. Compared to other currently available orally administered products the capsules have several potential competitive advantages.

The ability to store the capsules for a long period of time at room temperature enables the product to remain stable during shipment and storage, resulting in a much lower product cost as the requirement for refrigeration is eliminated. This also increases patient compliance due to storage convenience at home or while traveling. Competing commercial products are required to be stored at 4°C, resulting in lower patient compliance due to product price and usage convenience.

The capsules pro-nanoparticle formulations result in increased bioavailability enabling efficient administration of the cannabinoids through the user-friendly oral route.

The formulations' characteristics are expected to significantly increase patient compliance and thereby become the preferred prescription choice, resulting in an increased market share.

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### Advanced Discussions with Supply Partners

In order to conduct the Phase 2 Clinical Study at the earliest time possible following the successful completion of the Phase 1 study, PhytoTech Therapeutics is in advanced discussions with a number of parties to supply the necessary Active Pharmaceutical Ingredients (APIs) and materials.

For the supply of the critical APIs PhytoTech Therapeutics is in discussions with Satipharm, its sister company based in Switzerland, for the supply of high quality, GMP THC and CBD purified extracts.

PhytoTech Therapeutics is also in final discussions with one of the leading GMP manufacturers worldwide of soft gelatin capsules for upgrading the production and testing methods of the formulated capsules.

Daphna Heffetz, CEO, PhytoTech Therapeutics commented:

*"Receiving National approvals to commence the Phase I Clinical Study is an important step towards our accelerated clinical development plan, which is aimed at marketing an oral capsule for the relief of pain and spasticity of Multiple Sclerosis patients. We're ahead of schedule and have made significant progress towards commencing both Phase I and 2 of the Study.*

*"We've been encouraged by the initial stability studies of the formulation, which has demonstrated elongated shelf life when stored at room temperature. This, as well as the high bioavailability of the capsules, provides us with a significant advantage above other medical cannabis based drugs in the market."*

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### About MMJ PhytoTech Limited

MMJ PhytoTech 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. The Company operates three subsidiaries with operations across the entire Medical Cannabis value chain, encompassing the Company's "Farm to Pharma" strategy.

Its **United Greeneries** subsidiary has growing facilities in Canada and is fully integrated with Agrichem Analytical, its quality control and testing laboratory. **Satipharm** has a number of key international distribution partnerships for the distribution of cannabinoid-based pharmaceutical, nutraceutical and wellness products.

Through its **PhytoTech Therapeutics** subsidiary in Israel the Company has an exclusive research and licensing agreement with Yissum, the prestigious Research Development and technology transfer Company of Hebrew University in Jerusalem, Israel, a global leader in medical cannabis research.

<http://www.mmjphytotech.com.au>