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PhytoTech Therapeutics Phase 2 Clinical Trial Update

Results from the first 10 patients in the Phase 2 clinical trial in children with treatment-resistant epilepsy now available

Highlights:

- PTL's Phase 2 open label clinical trial is aimed at measuring safety and efficacy of Satipharm CBD capsules for reducing seizure frequency in children with refractory, or treatment-resistant epilepsy.
- Satipharm CBD capsules are a proprietary oral formulation developed using the Gelpell-CBD™ product technology.
- Satipharm CBD capsules reduced monthly seizure frequency in the treatment-resistant children when added to current medications. The treatment was generally well tolerated, with a safety profile consistent with prior experience.
- Promising evidence of efficacy has been reported. In 6 patients a reduction of 59-91% in mean monthly seizure frequency was observed following 12 weeks of treatment.
- The median reduction was -79.5% in the 12-week treatment period compared to the 4-week observation period.

MMJ PhytoTech Limited (ASX: MMJ) ("MMJ" or "the Company") is pleased to advise that it has received results from the first 10 patients who participated in the Phase 2 clinical trial undertaken by MMJ's wholly-owned, Israeli-based subsidiary PhytoTech Therapeutics Ltd ("PTL").

Importantly, the initial results received to date indicate that Satipharm AG's ("Satipharm") capsules significantly reduce monthly seizure frequency when added to current medications, with strong evidence of efficacy reported.

PTL's near-term focus is on recruiting the final patients required for the Phase 2 trial, in the next few weeks, with the study expected to be completed by mid-2018. The full results for the entire patient cohort would then be published shortly thereafter.

Phase 2 Clinical Trial Background

The Phase 2 trial is an open-label, single-center clinical study, designed to evaluate the safety, tolerability and efficacy of the Satipharm CBD capsules as an adjunctive treatment to 15 children with treatment-resistant epilepsy, aged 2-15 years.

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The study comprised of 3 periods: observation (4 weeks), dose-titration and treatment (12 weeks), and follow-up (2 weeks). Patients were eligible to participate in the study if they had tried at least four prior anti-epileptic drugs (AEDs), including one trial of a combination of two AEDs, without successful seizure control. Daily doses were limited to 25mg/kg or 450 mg, whichever is lower.

Eight patients completed the study, while two patients were discontinued due to worsening seizures. Following 12 weeks of treatment, 6 of the 8 patients were rated as “very much improved/improved” in overall condition on the Caregiver Global Impression of Improvement scale and 7/8 patients were rated as “very much reduced/reduced” on Caregiver Global Impression of Seizures Severity scale. In these patients the mean monthly seizure frequency reduction was 59-91% after the 12-week treatment period, compared to the 4-week observation period.

One patient had a small response (12% reduction in seizures). For one patient, the critical data is missing from the later part of the diary (last 5 weeks) as it was destroyed in a fire, therefore, the daily seizure count is missing. The median reduction was -79.5% in the 12-week treatment period compared to the 4-week observation period.

Treatment with the capsules was generally safe and well tolerated. No serious adverse events were observed. A total of 20 treatment related adverse events (1.5% of total administrations) were reported, from 1.5% of administrations (20 out of total of 1329 administrations). Most adverse events were mild, a few were moderate, and all transient.

Satipharm CBD Capsules Background

Satipharm CBD capsules utilise a proprietary formulation developed using the Gelpell-CBD™ product technology. These capsules are produced under an exclusive contract manufacturing arrangement with Gelpell AG. The capsules contain organically derived, highly purified cannabidiol, (CBD), a non-psychoactive cannabinoid. The capsules are currently available in dosage units of 10, 50 and 100 mg CBD in Europe and Australia.

Refractory Epilepsy in Children Background

Severe childhood epilepsies are characterised by frequent seizures, neurodevelopmental delays and impaired quality of life. Approximately one third of patients with epilepsy are resistant to treatment, meaning they do not respond to drug therapy and continue to experience seizures. This can be the result of the drug therapy failing to control the seizures, or patients not being able to tolerate the related side effects. A number of currently available epilepsy drugs have been found to have significant side effects including the impairment of a patient’s motor skills and cognitive abilities.

The incidence of refractory epilepsy remains high despite the influx of many new antiepileptic drugs (AEDs) over the past 10 to 15 years. It is estimated that approximately 100,000 children in North America suffer from treatment resistant epilepsy, causing uncontrollable seizures.

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MMJ's Managing Director, Andreas Gedeon, commented:

"Notwithstanding the small number of patients treated to date, these results compare very favourably to other similar studies of cannabidiol, including those published by GW Pharmaceuticals.

"Importantly, these stark reductions in the number of seizures, in these very difficult to treat patients, have the potential to be a life-altering event for these patients and their families.

"The completion of this Phase 2 clinical trial, which has been earmarked for the middle of 2018, is a major step towards the commercial development of our Satipharm CBD capsules and we look forward to providing further updates on progress in due course."

MMJ wishes to caution investors that the study conducted by PTL had a limited sample size and duration. Definitive conclusions with respect to the efficacy of Satipharm CBD capsules cannot be drawn from the results described herein. Statements with regards to the application of Satipharm CBD capsules are based on this preliminary study, and any application or result of use of Satipharm CBD capsules may not be realized, or realized in the manner described herein.

– ENDS –

For media and investor inquiries please contact:

Andreas Gedeon
Managing Director
+1 (250) 713 6302
agedeon@mmj.ca

Released through Sam Burns, Six Degrees Investor Relations, M: +61 400 164 067



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

About MMJ PhytoTech Limited

In October 2017, MMJ PhytoTech Limited (ASX. MMJ) announced its strategy to become an incubator for strategic investments across regulated jurisdictions globally covering the entire cannabis value chain.

Following the successful listing of United Greeneries Holdings Ltd ("United Greeneries") and Satipharm AG ("Satipharm") on the TSX-V through Harvest One Cannabis Inc. (TSX-V: HVST), MMJ has focused on the identification of a number of independent strategic investment opportunities that have the potential to deliver significant value to the Company's shareholders.

MMJ is actively pursuing early stage opportunities with the ability to deliver significant future revenue and the opportunity to provide dramatic global synergistic value as regulatory frameworks in key international markets continue to evolve. MMJ is targeting the full range of emerging cannabis-related



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sectors including healthcare products, technology, infrastructure, logistics, processing, cultivation, equipment, R&D, hemp food products and retail.

MMJ currently holds an equity stake of 53,333,333 shares in Harvest One, 100% ownership of Israeli-based R&D division PhytoTech Therapeutics Limited (“PTL”) and strategic holdings in e-Sense Lab Limited (ASX: ESE) and private Canadian-based company WeedMe Inc.