

**ASX RELEASE** 

24 July 2018

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PTL completes Phase 2 clinical trial

**MMJ PhytoTech Limited (ASX: MMJ) ("MMJ")** is pleased to announce results of the Phase 2 clinical trial ("the trial") undertaken by its wholly-owned subsidiary PhytoTech Therapeutics Ltd ("PTL"). As previously announced, PTL is to be sold by MMJ to Harvest One Cannabis Inc. (TSX-V:HVT), subject to MMJ shareholder approval.

## Key elements of the trial

- An open-label, single-centre clinical study to evaluate the safety, tolerability and efficacy of oral administration of the Satipharm CBD capsules as an adjunctive treatment to children suffering from refractory, or treatment-resistant epilepsy
- Comprised of 3 periods: observation (4 weeks), dose-titration and treatment (12 weeks) and follow-up (2 weeks)
- Patients were eligible to participate if they were between 2 and 15 years old, had tried at least four prior anti-epileptic drugs (AEDs), including one trial of a combination of two AEDs, without successful seizure control
- 16 patients were screened and started the CBD treatment. 11 patients completed the study. The mean age of the children participated in the study was 9.1 years (SD: 3.40 years). The mean dose in maintenance was 13.6 mg/kg (SD: 4.24 mg/kg). Patient adherence to treatment was very high (mean of 96%)

## Key findings of the trial

- Promising evidences of efficacy were demonstrated
- Satipharm's CBD capsules significantly reduced monthly seizure frequency in the treatmentresistant children when added to current medications. The median reduction was -82% in the 12-week treatment period compared to the 4-week observation period
- 9/16 patients (56%) who started the treatment had a reduction of at least 50% in total number of seizures during the entire treatment period, compared to observation
- Following 12 weeks of treatment, 8/11 patients (73%) were rated as "very much improved/improved" in overall condition on the Caregiver Global Impression of Improvement scale and 9/11 patients (82%) were rated as "very much reduced/reduced" on that scale
- Prof. Uri Kramer, Director of Pediatric Epilepsy Service, Tel Aviv Sourasky Medical Center and Principal Investigator of the trial commented that "Notwithstanding the small number of patients treated, the efficacy of Satipharm's CBD capsules as add-on therapy in the treatment of pediatric, intractable epilepsy has been shown. Moreover, these results compare favourably to other similar studies of cannabidiol, including those published by GW Pharmaceuticals. Importantly, the significant reductions in seizure frequency while demonstrating satisfactory safety and tolerability profile, in these very difficult to treat patients, have the potential to be a life-altering event for these patients and their families. I would be greatly interested in prescribing such standardized and clinically tested product as Satipharm's CBD"



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