CBD Integrated Data Presentation Clinical Safety & Efficacy Manufacturing & Labeling

> Pure Green, LLC Food and Drug Administration Silver Spring, Maryland 5.31.2019 Debra Kimless, MD Medical Director

Clinical Data

- 6 pilot clinical trials completed
- 3 multi-center clinical trials underway
- Now reporting ...
- Single center, mild-to-moderate undifferentiated pain,
 - male/female, ages 21-80, N=16
- Active ingredients: 5 mg CBD + 0.1 mg terpenes
- Wong Baker Faces Pain Rating Scale
- Statistically significant p<0.0001
- Clinically significant, mean pain reduction from 5/10 to 1/10 in <15 minutes
- Patients self-reported faster pain reduction than scoring system, lasting 4-6 hours, 2 patients more than 24 hours

Sublingual, Water Soluble CBD tablet CMC Data

Finished dosage form – oral, sublingual admin

250 mg, standard pharmaceutical excipients

- Unique CBD/Terpenes rendered water soluble
- Unique-leverages entourage effect
- Marketed formulation: 20 mg CBD + 0.1 mg terpenes
- Validated GMP production conditions

Clinical Advantages

- Pharmaceutically accurate dosage
- Ease of administration
- No smoking or vaping

CBD API CMC Data

- Exceeds USP purity standards
- Amber oil, 99.8% CBD
- Full quantitative and qualitative data analysis
- Extractive process: alcohol, followed by short path fractional distillation
- Full IQ/OQ/PQ Validation in process

Plant Growth Data

- Indoor harvest
- Selected cultivars
- Seed-to-sale tracking on each plant
- Finished product is cultivar agnostic
- Complete independent QA/QC for over 200 KPI Safe and efficient production assured*

* licensed Michigan Med. Marijuana processor & grower

Pharmacovigilence

41,000 customers in 10 months

~500,000 dosages

No adverse events

Side effects:

1. Overwhelming sense of well-being

2. Transient drowsiness in ~ 4% patients following first dosage – we suggest patients take first dose before bedtime to mitigate this issue.

Product Labeling

