

# Pureis® Ultra-Pure CBD Clinical Studies



### Regulatory background

### WHY WE NEEDED TO CONDUCT CLINICAL TRIALS

- Within the last few years CBD has undergone regulatory change
- CBD was placed on the European Food Safety Authority (EFSA) catalogue of Novel Foods in January 2019; in doing this EFSA are assuring that CBD food supplements would fall under their regulatory watch
- To achieve a Novel Food Licence CBD companies are required to undergo extensive analytical and clinical safety studies; ensuring products are safe to use and compliant; For more information on Novel Foods regulation in both EU and the UK please see our **regulatory landscape slides**
- Committed to providing high quality, effective and safe products Chanelle McCoy Health to date have invested in excess of £1.5 million to conduct clinical studies
- The clinical studies undertaken by Chanelle McCoy Health in order to achieve this licence are equivalent to that of a Phase I toxicology study for a new drug application



### **Pureis®** Clinical Trials

### Short term clinical study using Pureis<sup>®</sup> CBD:

• The purpose of this study was to determine suitable doses for a subsequent longer study, as detailed below.

### Longer term clinical study using Pureis<sup>®</sup> CBD:

- This longer-term study provides information on the possible health hazards likely to arise from repeated exposure over a prolonged period of time.
- During this study there was no sign of adverse behaviour. Various parameters were assessed
  - clinical observations,
  - mobility,
  - reaction sensation,
  - body temperature,
  - ophthalmology (conditions relating to the eye),
  - haematology (blood analysis),
  - clinical chemistry (analysis of bodily fluids),
  - organ and tissue examination,
  - histology (microscopic structure of tissues),
  - sperm evaluation.



The control line represents the subjects that did not take CBD during the trial.

The body weight of the subjects that took **Pureis**<sup>®</sup> 10mg, 25mg and 50mg of CBD had the same body weight as those that did not take CBD.

This shows that **Pureis**<sup>®</sup> CBD was well tolerated and caused no toxic affect to any part of the body and is safe.

#### **Conclusion of Pureis® CBD studies**

- The results of our short term and long-term clinical studies demonstrated that our **Pureis**<sup>®</sup> CBD is safe and well tolerated for consumer use.
- In addition, we conducted a series of tests to demonstrate that **Pureis**<sup>®</sup> CBD does not have any mutagenic effects the results confirmed that **Pureis**<sup>®</sup> CBD has no evidence of mutagenicity.





### What the future holds for **Pureis®**

### **CBD Efficacy Studies**

- Committed to furthering our knowledge on our CBD; we are currently initiating Phase II clinical trials in the area of insomnia
- These studies are supported by a recent online Pureis<sup>®</sup> consumer survey assessing quality of sleep before and after taking Pureis<sup>®</sup>
- Of those surveyed 92% noted an improvement in their sleep
- Consumers quality of sleep was ranked 1-10 for quality prior to and after taking Pureis (1 being poor and 10 being excellent)
- The below graphs present an overview this assessment:

#### Graph 1. Assessment of quality of sleep before taking Pureis®

"On a scale of 1 to 10 how would you rate your sleep before taking Pureis® Ultra Pure CBD? (1 being poor and 10 being excellent)" 82 responses



#### Graph 2. Assessment of quality of sleep after taking Pureis®





## **Thank You**

# Chanelle McCoy Health

#NewScience

Chanelle House, Barrack Street, Loughrea, Co. Galway, H62 YX07, Ireland Lodge Down Stables, Lambourn Woodlands, Hungerford, Berks, RG17 7BJ, UK

### www.pureiscbd.com



Chanelle Lady McCoy Founder & CEO

chanelle@chanellemccoy.com

Caroline Glynn Co-Founder & CSO

caroline@chanellemccoy.com