Chanelle McCoy Health
#NewScience

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Ethics Approval granted for significant *Ultra Pure Synthetic CBD* Phase III Efficacy Clinical Trial

- **Irish company Chanelle McCoy Health granted Ethics Approval to commence Phase III Efficacy Clinical Trial for the treatment of Sleep Disturbance CMH-CBD-001 using their Ultra Pure Synthetic Cannabinoid (CBD) formulation with pharmaceutical grade FDA registered raw material.**
- **After already investing greatly in Phase I Safety and Toxicity Pre-Clinical Trials to support their product, this is the next step in achieving an Over-The-Counter (OTC) pharmacy only medicine license.**
- **The company can begin recruiting participants for this Efficacy Clinical Trial, registering as a Schedule 3 CBD product for the Australian market, allowing CBD to be sold in pharmacy without a prescription, to improve sleep.**
- **Upon successful completion of this clinical trial, the company will start launching the product on the Australian Market with ambitions to move into the European market and beyond. There are currently no CBD medicine products sold in pharmacy without a prescription on any global market.**

R&D Pharmaceutical company, **Chanelle McCoy Health**, founded by Lady Chanelle McCoy and Caroline Glynn, are pleased to announce they have received **Ethics Approval** from Bellberry Human Research Ethics Committee in Australia. Today's major milestone will enable the company to **begin recruiting** for this pivotal clinical trial.

The results of the clinical trial should give key data on the efficacy of **Ultra Pure Synthetic CBD** in relation to **sleep disturbance** and **improved sleep**.

This CBD formulation (CMH-CBD-001) which received Ethics Approval in Australia has the highest quality of pharmaceutical grade **raw material** being **FDA Registered** with a **Drug Master File.**

The company has already successfully completed **Phase I Safety and Toxicity Pre-Clinical Trials** which revealed their Ultra Pure Synthetic CBD was **well tolerated** and there was no sign of adverse behaviour in the dose ranges proposed in the efficacy trial.

Successful completion of the **Phase III Efficacy Clinical Trial**, coupled with their **substantial existing scientific data**, will support the company's registration as a **pharmacy only medicine product** with Australian health authorities, **Therapeutic Goods Administration** (TGA). This enables pharmacists to supply Chanelle McCoy Health's Ultra Pure CBD **(CMH-CBD-001)** product to Australian patients **without a prescription** for the treatment of **sleep disturbance** and **improve sleep**.

CMH-CBD-001 product contains **Ultra Pure Synthetic CBD**, which is **NOT** derived from the cannabis plant. This ensures **NO** pollutants, toxins, terpenes, heavy metals, pesticides, insecticides and no other harmful natural cannabinoid compounds including THC that can occur naturally in the cannabis plant.

Also, there is no concern about crop failure, no reliance on weather or soil conditions which affects yield of plant grown source, minimal water usage and is more **sustainable** and **environmentally friendly**. No **intra batch variability** meaning each batch is the exact same, this may differ in plant sources due to different harvest conditions. Synthetic CBD is **scalable** to produce large batch sizes which reduces cost and risk, no reliance on land to scale.

Chanelle McCoy Health was founded by pharmaceutical trailblazers Lady Chanelle McCoy and Caroline Glynn Sc., MSc., L.LM with 20 years in the pharma industry, registering over 2,500+ much needed medical licenses across 96 countries.

Qualified with a degree in Pharmacology, a Masters in Biomedical Science and a Masters in Law, Founder and CSO, Caroline Glynn B.Sc., MSc., L.LM commented on this pivotal moment for the company: *"The beginning of this trial is incredibly significant for Chanelle McCoy Health as a company but also in driving the data surrounding Ultra Pure Synthetic CBD. We are beginning the process of recruiting for our clinical trial.*

Registering our Product as an OTC medicine will allow us to finally address the demands of many people who suffer from insomnia or sleep disturbance. This is the first of many Phase III Efficacy Clinical Studies in our R&D Strategic Plan using our Ultra Pure Synthetic CBD."

Both Chanelle and Caroline knew they had the expertise to carry out clinical safety studies and navigate through tricky regulatory landscapes to develop the highest quality CBD. With no Ultra Pure CBD on the market, they embarked on their mission to bring a pure, safe, quality assured CBD product that was **backed by clinical studies**. Since setting up the company, the pair have **taken the UK market by storm** having **gained years of experience in marketing a Synthetic CBD** in various forms as a food supplement on the UK market.

Chanelle McCoy Health had already completed a **Phase I Safety and Toxicity Pre-Clinical Trials**, various parameters were assessed:

• Clinical observations	• Haematology (blood analysis)
• Mobility	• Clinical chemistry (analysis of bodily fluids)
• Reaction sensation	• Organ and tissue examination
• Body temperature	• Histology (microscopic structure of tissues)
• Ophthalmology (conditions relating to the eye)	• Sperm evaluation

Chanelle McCoy Health is a pharmaceutical company dedicated to developing new quality medicinal cannabinoid therapies for the treatment of human diseases and disorders.

For additional information and quotes, please contact Annie Shivers at annie@chanellemccoy.com