Biotech Check Up: US FDA approves first clinical trial of naturally derived psychedelic drugs

The FDA has approved a clinical test which could have mind-blowing results.

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STOCKHEAD
9:15AM JULY 21, 2022

In a groundbreaking development, the US FDA has just approved a clinical trial studying the effects of naturally derived psychedelic drugs.

And that could ultimately be the start of a market-altering experience for a

The phase one clinical trial, conducted at the University of California, is the first to directly administer psilocin and psilocybin derived from real mushrooms, as opposed to lab-created synthetic substances.

Specifically, the trial will investigate three proprietary botanical drug candidates owned by Filament Health, a biotech company listed on the Neo Exchange in the US.

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The drug candidates are naturally extracted and stabilised forms of the psychedelic compounds found in certain mushrooms.

The trial objective is to compare the physiological and psychological effects of orally administered psilocybin, orally administered psilocin, and sublingually administered psilocin among healthy adults over a series of

Dr. Joshua Woolley, the study's principal investigator, said the trial will provide crucial information about the effects and mechanisms of these compounds that could allow for greatly enhanced psychedelic-assisted therapy.

First steps in a long trip

This is an important step forward because all previous trials had relied on lab-made versions to ensure consistency and purity of the compounds

Although experts say that pure synthetic psilocybin is chemically no different than pure naturally-derived psilocybin, using naturally derived drugs may have potential benefits.

For example, pure natural psilocybin contains additional sub metabolites extracted from the "magic mushroom", which many believe may offer a potential 'entourage effect'.

In medicinal cannabis, the entourage effect is a mechanism by which cannabis compounds other than tetrahydrocannabinol (THC) act synergistically with it to modify the overall psychoactive effects of the plant.

Using a naturally extracted psilocybin also has psychological effects, according to experts, as people tend to prefer anything natural.

ASX companies in the psychedelic space (regarding business, not the decor) include: **Emyria (ASX:EMD), Incannex Healthcare (ASX:IHL), Creso Pharma (ASX:CPH),** and **Little Green Pharma (ASX: LGP).**

Other ASX biotech news from the past week

TISSUE REPAIR (ASX:TRP)

Tissue Repair rose after submitting a Type C Meeting request with the FDA which, if endorsed, will provide clarity for the company to progress into a Phase III clinical program for its lead drug candidate TR-987, to aid healing of wounds.

At the meeting, Tissue Repairs will seek to clarify a broad set of matters required to facilitate progression into the trial program.

Should the FDA endorse the plans, program and recommendations contained in this meeting request, the company should have sufficient clarity on the substantive items required to obtain Phase III clinical trial approval early in 2023.

ADHERIUM (ASX:ADR)

The respiratory eHealth company announced it has signed a distribution agreement for US patient monitoring with Perigon Health to sell the Hailie platform.

Perigon's world-class proprietary platform, Medesto, is an enterprise drug and therapy monitoring platform that consolidates remote monitoring services into one portal.

RHINOMED (ASX:RNO)

Rhinomed has finalised an exclusive supply agreement with SureScreen Australia to supply Rhinoswabs and Rhinoswab Juniors for inclusion in SureScreen's range point of care test kits.

This covers markets in Australia, New Zealand, Singapore and the South Pacific.

The first product to market will be the ARTG registered SureScreen SARS-CoV-2 Antigen Rapid test Cassette Gold for children, which features Rhinomed's novel Rhinoswab Junior.

This will be the first SARS-CoV-2 rapid antigen test kit designed specifically for children aged 4-12 on the Australian market.

RADIOPHARM THERANOSTICS (ASX:RAD)

Radiopharm has extended its agreement with global oncology provider GenesisCare, which will support a second Radiopharm clinical trial in Australia.

The trial will use Radiopharm's PSA targeting antibody to start a therapeutic Phase 1 in prostate cancer, with an expected commencement in the coming months.

Discovered by Professor David Ulmert, previously at Memorial Sloan Kettering and now UCLA, the proprietary monoclonal antibody is capable of targeting free human prostate kallikrein (PSA) in prostate cancer cells.

New data from non-small cell lung cancer patients in Imugene's Phase I IMPRINTER trial has been selected for a poster presentation at the IASLC 2022 World Conference on Lung Cancer (WCLC) taking place from 6-9 August in Vienna.

WCLC is the world's largest international gathering of clinicians, researchers and scientists in the field of lung cancer and thoracic oncology.

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