



Research Advisory Panel of California

**49th and 50th
Annual Report to
the Governor and
Legislature of California**

RESEARCH ADVISORY PANEL OF CALIFORNIA

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This report represents a consensus among Panel members acting as individual experts.

It does not represent policies or positions of the appointing agencies nor have those agencies been consulted by the Panel during its function or during the preparation of this report.

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RESEARCH ADVISORY PANEL OF CALIFORNIA

California law, pursuant to Health & Safety Code Sections § 11480 & § 11481, requires proposed research studies using certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I (Cal Health & Saf Code § 11054) and Schedule II (Cal Health & Saf Code § 11055) Controlled Substances as their main study drug(s), to be reviewed and authorized by the Research Advisory Panel of California in the Attorney General's Office.

The Research Advisory Panel of California (RAPC) primarily seeks to ensure the safety and protection of participating human research subjects and adequate security of the controlled substances used in the study. The Panel Members evaluate the scientific validity of each proposed project, and may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of California subjects to the risk of research.

**2019 AND 2020
RESEARCH ADVISORY PANEL OF CALIFORNIA
PANEL MEMBERS**

The Research Advisory Panel of California (RAPC) consists of the Panel Chair, Executive Officer, and the Panel members.

Enid Camps, JD

Deputy Attorney General V, State of California AG's Office, San Francisco
Panel Chair, Appointed by the California State Attorney General

Chwen-Yuen Angie Chen, MD, FACP

Clinical Associate Professor, Stanford University School of Medicine
Appointed by Stanford University

Patrick R. Finley, PharmD, BCPP

Professor of Clinical Pharmacy, UCSF School of Pharmacy
Appointed by the California State Board of Pharmacy

James J. Gasper, PharmD, BCPP

Psychiatric and Substance Use Disorder Pharmacist, CA. Dept. of Health Care Services
Appointed by the California Department of Public Health

Andrew S. Kayser, MD, PhD

Associate Professor of Neurology, UCSF School of Medicine
Appointed by the University of California

Jennifer Mitchell, PhD

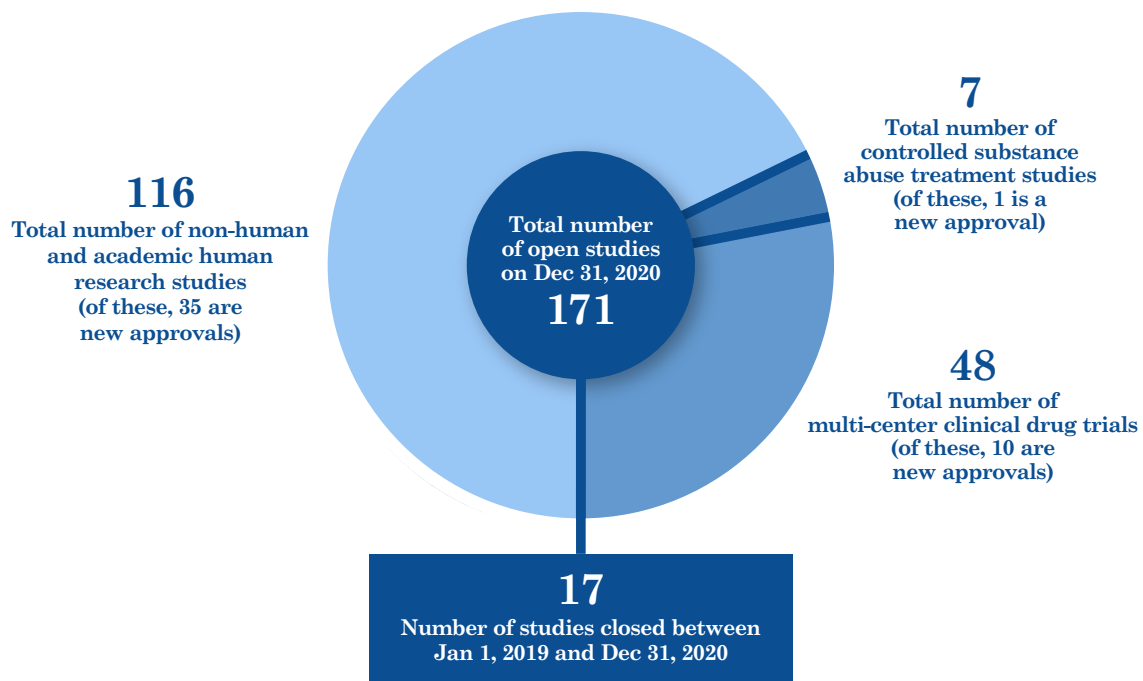
Professor of Neurology and Psychiatry & Behavioral Sciences, UCSF School of Medicine
Appointed by the California State Governor

SUMMARY OF 2019-2020 PANEL ACTIVITIES

During calendar year 2019 (Jan 1-Dec 31) and calendar year 2020 (Jan 1-Dec 31), the Panel reviewed 49 research study submissions. Forty-six were approved by the Panel. Among the approved studies, 35 studies were non-human (animal models or in-vitro studies) and academic human research (human subjects for academic research) studies, and 10 studies were multi-center clinical drug trial research (human subjects at multiple research sites inside and outside of California) studies. One research study on the treatment of controlled substance abuse was approved.

Seventeen research studies were completed in 2019 and 2020, and they were closed on the Panel's records.

At the end of 2020, the Panel was monitoring 171 research projects. Note Appendices A, B, and C for specific listings.



As part of the Panel's supervisory responsibility, ongoing projects are monitored by means of annual reports, significant adverse event (SAE) reports and site visits. No site visits were performed between January 1, 2019 and December 31, 2020. Approval may be withdrawn if the study deviates significantly from the approved protocol.

Table 1 is a list of the studies approved by the Panel in 2019 and 2020 and Table 2 is a list of the studies closed by the Panel in 2019 and 2020. Due to COVID-related delays, the Annual Reports for 2019 and 2020 are combined.

SELECTED RESEARCH FINDINGS

Below are brief summary reports of several Panel approved projects which are of interest and indicative of the types of controlled substance research projects currently ongoing in California:

David Dulcis, PhD and colleagues at the University of California San Diego, School of Medicine provided the Panel with the following summary of Non-Human Research entitled “Effects of Neonatal Nicotine Exposure on Dopamine Neurons Affecting Consumption of Substances of Abuse in the Adult.”

A. Summary of Research

In April 2018, I was awarded a Tobacco-Related Disease Research Program (TRDRP) grant for the High Impact Research Project Award mechanism. The proposed studies investigate the cellular and molecular identity of neurons undergoing neurotransmitter plasticity occurring in the developing reward centers of the brain and the mechanism affecting reward-seeking behaviors towards substances of abuse, including nicotine and marijuana.

We used Tetrahydrocannabinol (THC) in preclinical research conducted on laboratory mice to investigate the developmental effects of prenatal (3mg/kg) and perinatal (3mg/kg) THC administration over a 10-day period on development of cortical (mPFC) GABAergic interneurons and Dopamine neurons of the reward center (VTA). Our pilot experiments on THC exposure were performed delivering THC to pups through THC-loaded osmotic pump implanted in the pregnant or nursing mom then to adults via IP injections and Delta-9 THC was detected in the mouse blood. Due to the pandemic and university closure, we were unable to perform the experiments we had planned for the past year.

B. Research plans

In the upcoming calendar year, postdoctoral fellow Dr. Martina Ulivieri, will perform several cohort of THC exposure experiments. THC-treated pups will be raised normally until adulthood (P60) then exposed to a second THC challenge (10 mg/kg/day, 2 weeks) and sacrificed soon after (75). Brain tissue will be processed for immunohistochemical analysis of neurotransmitter markers in mPFC and VTA regions. No additional controlled substances are planned for procurement in the upcoming year.

Eric Hardter, PhD, RAC (US, CAN, EU) and colleagues from The Emmes Company have provided the Panel with the following study summary of activities for human research entitled “A Randomized, Double-Blind, Support-of-Concept Phase 2 Study of Single-Dose Psilocybin for Major Depressive Disorder (MDD).”

A. Summary of Activities

Protocol PSIL201 is a Phase 2, randomized, double-blind, multi-site study evaluating the use of psilocybin (or placebo) along with conjunctive “set and setting” context and post-dose integration sessions in patients with major depressive disorder (MDD). The study intends to recruit 80 adult participants (ages 21-65) with documented major depressive disorder who do not show an unacceptably large degree of symptom improvement between Screening and Baseline for a 1:1 randomization to either psilocybin or placebo (niacin).

Participants will remain enrolled for approximately six weeks and will be followed for depressive symptoms, clinical global functioning, functional disability, anxiety symptoms and health-related quality of life. The primary objective of the PSIL201 study is to evaluate the potential efficacy of a single 25 mg oral dose of psilocybin for major depressive disorder compared to placebo in otherwise medically healthy participants, as assessed by the difference between groups in changes in depressive symptoms from Baseline to Day eight post-dose. Since study inception and prior to the end of the reporting period, 16 participants have been randomized across seven study sites. One California site, the University of California San Francisco, opened to recruitment but has not yet randomized any participants.

Global study recruitment was paused for two months in March and April 2020, due to the COVID-19 pandemic, and sites re-opened when able in accordance with applicable local/institutional requirements. There have been no new findings relative to the study objectives and endpoints since inception, and no publications regarding trial progress are available. No serious adverse events (SAEs) have been reported by participants randomized to either psilocybin or placebo.

B. Research Plan for 2021

Participant enrollment and follow-up is ongoing at all sites, and is expected to continue throughout 2021. Additionally, a second site, Pacific Neuroscience Institute in Santa Monica, is currently in activation status and will begin to enroll participants in 2021.

Kim Janda, PhD of The Scripps Research Institute in La Jolla, CA has provided the following summary and findings regarding the research entitled “Vaccine Research (Vaccines and Antidotes Against Drugs of Abuse).”

A. Specific Aims

The overarching goal of our research involving Schedule I and Schedule II controlled substances is geared towards the development and optimization of “vaccines” that could be used to diminish or block the negative consequences resulting from the potential abuse of and/or addiction to these “drugs.” During this and previous years we have focused on abused drugs like cocaine, methamphetamine, opioids and their synthetic counterparts (heroin, morphine, oxycodone, fentanyl, carfentanil, isotonitazene, etonitazene), and most recently on illegally made and sold “street drugs” like the synthetic cannabinoids.

B. Summary of Research Performed and Findings

In general, most of the controlled substances used in research during 2020 were used in various stages along the progression towards developing “vaccines” that might create an immune response in an animal model leading to circulating antibodies that could bind to and/or eliminate circulating drugs of abuse and prevent drug passage across the blood-brain barrier. The research “progression” often includes: organic chemical synthesis of a drug-like hapten; linking that hapten to some immunogenic carrier protein; injecting that conjugate into a rodent; harvesting blood after a response time to do ELISA titer tests for antibody binding to the drug; doing further SPR/Biacore binding studies on the best antibody candidates; and, ultimately, testing “vaccines” in animals again to check for protection from drug challenges or reduction in addictive behavior.

C. Highlights from the published research

1. Production of an anti-fentanyl vaccine developed using a unique double conjugation strategy to enhance the immune response exploiting the opsonization effect.
2. Development of new anti-heroin vaccines generated using sulfonates as carboxylate isosteres within the original hapten design.
3. The improvement of an anti-heroin vaccine’s efficacy through the use of regioselective hapten deuteration
4. A study to evaluate the effectiveness of a dual heroin/fentanyl vaccine through review of two measurable behavioral responses in rats.
5. Further evaluation of a dual heroin/fentanyl vaccine against exposure to heroin contaminated with fentanyl.
6. A review of the status of research aimed at addressing the development of vaccines against methamphetamine abuse.
7. A study of how an anti-fentanyl vaccine altered fentanyl self-administration and fentanyl vs. food choice in monkeys.
8. The development of new opioid (heroin and fentanyl) vaccine formulations and storage techniques toward a clinically viable treatment.
9. The initial development of hapten screening systems and admixture vaccines against synthetic cannabinoids with efficacy studies including behavioral analysis and a drug inhalation (vaping) scenario in mice.

D. Research Plans for the Upcoming Calendar Year

The research plans for the coming year will be a continuation of much of the work done in 2020. There may be a heavier emphasis on immunotherapy to counteract lethal doses of carfentanil as well as process development, manufacturing, and pre-clinical evaluation of a monoclonal antibody for fentanyl overdose.

Stephen Canning and Alkermes, Inc. have provided the Panel with the following summary of multicenter clinical drug trial research performed with ALKS 3831 and the findings made between January 2020 and December 2020 for research entitled “A Study to Evaluate the Effect of ALKS 3831 Compared to Olanzapine on Body Weight in Young Adults with Schizophrenia, Schizophreniform or Bipolar I Disorder Who are Early in Their Illness.”

A. Overview

ALKS 3831 is composed of two active substances: olanzapine and samidorphan. It is under investigation for the treatment of schizophrenia and bipolar I disorder. Olanzapine is FDA-approved for the treatment of schizophrenia and bipolar I disorder and is not a controlled substance by the Drug Enforcement Agency (DEA). Samidorphan is a new molecular entity, 17-(cyclopropylmethyl)-4, 14-dihydroxy-6-oxo-morphinan-3-carboxamide (CAS No. 852626-86-2). Samidorphan was classified as a Schedule II substance by DEA under the Controlled Substances Act (“CSA”) (CSCN 9668) because it is derived from opium alkaloids. Samidorphan is a μ -opioid receptor antagonist. The mechanism of action could be mediated through opioid receptor antagonism. To date, over 1800 subjects have been exposed to ALKS 3831. [Note from Panel: As of April 19, 2021, samidorphan has been removed from DEA scheduling (Federal Register/Vol.86, No.73/Monday, April 19, 2021) after scientific and medical evaluation of clinical trial data. This proposed rule is supported by eight factor analyses evaluating the abuse potential of samidorphan conducted by the DEA and Department of Health and Human Services (HHS)].

This Phase 3, multicenter, randomized, double-blind study is to evaluate the effect of ALKS 3831 compared to olanzapine on body weight in young adults with schizophrenia, schizophreniform disorder, or bipolar I disorder who are early in their illness. Subjects are screened at Visit 1, up to 30 days prior to randomization. At Visit 2, eligible subjects are randomized (1:1) to ALKS 3831 or olanzapine and receive study drug for up to 12 weeks.

This study was ongoing during the reporting period. Of the sites within the United States, four are located in California. The study enrolled 169 subjects during the reporting period, two of whom participated at sites located in California. Enrollment for this study is ongoing, and the last patient is estimated to complete fourth quarter, 2021. Due to the blinded nature of the study, no efficacy results are available as of the date of this report. No serious adverse reactions (SARs) were reported during the reporting period. Ongoing monitoring of safety and tolerability will continue through the end of the study.

TABLE 1

RESEARCH STUDIES APPROVED IN 2019 AND 2020

Alkermes, Inc. | Waltham, MA

A Phase 3b Extension Study of Adjunctive ALKS 5461 in the Treatment of Refractory Major Depressive Disorder
(ALK5461-218)

Stephan Anagnostaras, PhD | UC San Diego | La Jolla, CA

MDMA and Memory, Addiction, Social Behavior, Anxiety, and Depression: A Dose-Effect Analysis

Andy Barron | CRO: Worldwide Clinical Trials Ltd. | Morrisville, NC

The Safety and Efficacy of Psilocybin as an Augmentation Therapy in Participants with Treatment Resistant Depression
(COMP 003)

Ryan Baxter, PhD | UC Merced | Merced, CA

Cannabinoid Isolation, Purification, and Structure Diversification

Devin K. Binder, MD, PhD | UC Riverside | Riverside, CA

Translational EEG Biomarkers in a Mouse Model of Fragile X Syndrome

Brian Brandley | Biopharmaceutical Research Company (BRC) | Castroville, CA

Characterization of Model Systems for Longevity Studies, Genetics and Neuroscience; Simple model systems for examination of cannabinoid effects on genetics, development and nervous systems using roundworms (*C. elegans*) and/or killifish (*Nothobranchius*)

Ellen Breen, PhD | UC San Diego | San Diego, CA

In Defense Against Vaping Nicotine and Cannabis - Alarmins

Joshua Britton, PhD | Debut Biotechnology, Inc. | Carlsbad, CA

Production of Cannabinoids and their Precursors and via Purified Enzymes in a Continuous System

Joseph Califano, MD | UC San Diego | La Jolla, CA

THC-Cannabinoid Receptor Pathway and CBD Activation of GPCRs on Cannabinoid Signaling Pathways in Head and Neck Squamous Cell Carcinoma (HNSCC)

Ziva Cooper, PhD | UCLA Semel Institute | Los Angeles, CA

Sex-Dependent Effects of Cannabis: Assessing Analgesic, Abuse-Related and Pharmacokinetic Differences Between Men and Women

Ziva Cooper, PhD | UCLA Semel Institute | Los Angeles, CA

Subjective and Analgesic Effects of Terpenes, Beta-Caryophyllene and Myrcene, Vaporized Alone and in Combination with THC

Corbus Pharmaceuticals, Inc. | Norwood, MA

A Multicenter, Randomized, Double-Blind, Placebo Controlled Phase 2 Trial to Evaluate Efficacy and Safety of Lenabasum in Cystic Fibrosis (JBT101-CF-002)

Karl Deisseroth, MD, PhD | Stanford University | Palo Alto, CA

Effects of LSD on Brain-Wide Neural Activity and Behavior

CRO: The Emmes Corporation | Rockville, MD

A randomized, Double-Blind, Support-of-Concept Phase 2 Study of Single-Dose Psilocybin for Major Depressive Disorder (MDD) (PSIL201))

David Entwistle, PhD | Codexis, Inc. | Redwood City, CA

Project 1. Study of Cannabigerolic acid (CBGA) and Cannabodiolic acid (CBDA) Concentrations in Yeast Cultures Containing Engineered Recombinant Synthase Enzymes

David Entwistle, PhD | Codexis, Inc. | Redwood City, CA

Project 2. Study of the Effect of recombinant syntheses an Cannabigerolic acid (CBGA), Determination of CBGA and Cannabodiolic acid (CBDA) Concentrations

Randall Espinosa, MD | UCLA Semel Institute | Los Angeles, CA

Psilocybin Pilot for Treatment-Resistant Depression (TRD)

W. Brooks Gentry, MD | InterveXion Therapeutics | Little Rock, AK

Study of Antibody for Methamphetamine Outpatient Therapy

Catherine Hagan, DVM, PhD | Valley Biosystems | West Sacramento, CA

Cannabis for Veterinary Use and Model Development

Boris Dov Heifets, MD, PhD | Stanford University | Stanford, CA

Effects of Classical Hallucinogens on Learning and Memory

Adam Halberstadt | UC San Diego | La Jolla, CA

The Next Generation of Hallucinogens: A New Class of Synthetic Psychoactive Drugs

Keith Heinzerling, MD | Pacific Neuroscience Institute | Santa Monica, CA

Pilot trial of Visual Healing®, a nature-themed virtual immersive experience, to optimize set and setting in psilocybin-assisted therapy for alcohol use disorder

William Jagust, MD | University of California, Berkeley | Berkeley, CA

Dopaminergic mechanisms underlying decision making:

Academic human subjects research with Schedule II drug (Methylphenidate)

Kim Janda, PhD | Scripps Research | La Jolla, CA

Vaccine Research (Vaccines and Antidotes Against Drugs of Abuse)

Walter Kaye, MD | UCSD | San Diego, CA

Evaluation of Psilocybin in Reducing Core Symptoms in Anorexia Nervosa: Safety and Efficacy

Heather Knych, DVM, PhD | UC Davis School of Veterinary Medicine | Davis, CA

Pharmacokinetics and Selected Pharmacodynamic Effects of Cannabidiol in Horses

David Kokel, PhD | UC San Francisco | San Francisco, CA

Assessment of Zebrafish Phenotypic Assays to Model the Toxicology and Behavioral Pharmacology of Synthetic Cannabinoids and Other Psychoactive Compounds

Charles Lee, PhD | USDA-ARS
Low THC Industrial Hemp Cultivars

Robert Lindblad, MD | NIDA / NIH | Rockville, MD
Panel Approved Research Study

Robert Malenka, MD, PhD | Stanford University School of Medicine | Stanford, CA
The Role of Oxytocin in the Pathogenesis of Autism

Multidisciplinary Association for Psychedelic Studies (MAPS) | Santa Cruz, CA
Panel Approved Research Study (1)

Multidisciplinary Association for Psychedelic Studies (MAPS) | Santa Cruz, CA
Panel Approved Research Study (2)

Multidisciplinary Association for Psychedelic Studies (MAPS) | Santa Cruz, CA
Panel Approved Research Study (3)

Benjamin Reese, PhD | Neuroscience Research institute | UC Santa Barbara
Cannabinoid Neuroprotection of Retinal Ganglion Cells in Glaucoma

Pierre Riviere, PhD | Peptide Logic | San Diego, CA
Opioid Antidotes (PL005)

Christopher Savile, PhD | Epimeron USA, Inc. | Mt. View, CA
Development of a Cannabidiol (CBD) Producing Yeast Strain and Fermentation-Based Production Process

Nathaniel M. Schuster, MD | UC San Diego Center for Pain Medicine | La Jolla, CA
Efficacy of Inhaled Cannabis Versus Placebo for the Acute Treatment of Migraine: a Randomized, Double-Blind, Placebo-Controlled, Crossover Trial

Stephen A. Spector, MD | UC San Diego | La Jolla, CA
Function of the brain's endocannabinoid system and its role in Neuro-AIDS and Neuro-inflammation

Trisha Suppes, MD, PhD | VA Palo Alto Health Care System | Palo Alto, CA

The Safety and Efficacy of Psilocybin in Participants with Severe Treatment-Resistant Depression (P-TRD)

Mark Sussman, PhD | San Diego State University | San Diego, CA

Prenatal nicotine tetrahydrocannabinol exposure promotes myocardial damage: A brain-heart parallel

Nancy Tich, MS, PhD | Zynerba Pharmaceuticals | Devon, PA

An Open-Label Extension Study to Assess the Long-Term Safety and Tolerability of ZYN002 Administered as a Transdermal Gel to Children and Adolescents with Fragile X Syndrome - CONNECT-FX Open Label Extension (OLE). Clinical study Of cannabidiol in children and adolescents with Fragile X (CONNECT-FX OLE) (Zyn2-CL-017)

Jacob Vogan, PhD | CB Therapeutics | Carlsbad, CA

Laboratory Scale Biosynthesis of DMT and Related Substituted Tryptamine Compounds in Baker's Yeast

Jacob Vogan, PhD | CB Therapeutics | Carlsbad, CA

Laboratory Scale Biosynthesis of Psilocybin in Baker's Yeast

CRO: Worldwide Clinical Trials | Durham, NC

The Safety and Efficacy of Psilocybin in Participants with Treatment Resistant Depression (PTRD) (COMP 001)

Joseph Wu, MD, PhD | Stanford University | Stanford, CA

Human iPSCs for Elucidating Cardiovascular Risks of Cannabis

Jianmin Xu, PhD | Latitude Pharmaceuticals, Inc. | San Diego, CA

Development of Oral and Injectable Formulation Technologies for Cannabidiol (CBD) and Tetrahydrocannabinol (THC)

TABLE 2

RESEARCH STUDIES CLOSED IN 2019 AND 2020

Alkermes, Inc. | Waltham, MA

A Phase 3 E & S Study of ALKS5461 for the Adjunctive Treatment of Major Depressive Disorder (the FORWARD-5 Study) (ALKS5461-208)

Alkermes, Inc. | Waltham, MA

A Phase 3, Multicenter Study to Assess the Long Term Safety and Tolerability of ALKS 3831 in Subjects with Schizophrenia (ALK3831-A306)

Alkermes, Inc. | Waltham, MA

A Phase 3b Extension Study of Adjunctive ALKS 5461 in the Treatment of Refractory Major Depressive Disorder (ALK5461-218)

Alkermes, Inc. | Waltham, MA

A Phase 3b Efficacy and Safety Study of Adjunctive ALKS5461 in Treatment Refractory Major Depressive Disorder (ALK5461-217)

Alkermes, Inc. | Waltham, MA

A Phase 3 Study to Evaluate Weight Gain of ALKS 3831 Compared to Olanzapine in Adults with Schizophrenia
(ALK3831-A303)

Alkermes, Inc. | Waltham, MA

A Phase 1 Study to Evaluate the Effect of Multiple Doses of ALKS 3831 on QTc interval in Subjects with Schizophrenia (ALK3831-A1 09)

Alkermes, Inc. | Waltham, MA

A Randomized, Double-Blind, Parallel-Group Study in Healthy Subjects to Characterize Insulin Sensitivity and Lipid Metabolism in Response to Treatment with ALKS 3831 and Olanzapine
(ALK3831-A108)

Sirine C. Fakra, PhD | Lawrence Berkeley National Laboratory | Emeryville, CA
Evaluation of Industrial Hemp for Phytoremediation and Se Biofortification Applications

Flamel Ireland | CRO: INC Research | Austin, TX

A Double-Blind, Randomized, Placebo Controlled, Two Arm Multi-Center Study to Assess the Efficacy and Safety of a Once Nightly Formulation of Sodium Oxybate for Extended-Release Oral Suspension (FT218) for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Subjects with Narcolepsy (CLFT218-1501)

Daniel Levin, PhD | S&B Pharma, Inc. | Azusa, CA
Panel Approved Research Study

Multidisciplinary Association for Psychedelic Studies (MAPS) | Santa Cruz, CA
Panel Approved Research Study (6)

NIDA/NSC/NIH | Bethesda, MD

Comparing Treatments for HIV-Infected Opioid Users in an Integrated Care Effectiveness Study (CHOICES) Scale-Up (NIDA CTN 0067)

NIDA/CTN | Rockville, MD

Accelerated Development of Additive Pharmacotherapy Treatment (ADAPT-2) for Methamphetamine Use Disorder (NIDA CTN 0068)

Recro Pharma | Malvern, PA

A Phase 2, Randomized, Double-Blind, Placebo- and Active-Controlled, Evaluation of the Efficacy and Safety of DEX-IN Following Painful Outpatient Procedures (REC-17-023)

Shire | CRO: PPD | Canandaigua, NY

A Phase 3, Open-label, Multicenter, 12-Month Safety and Tolerability Study of SHP465 in Children Aged 4 to 12 Years Diagnosed with Attention Deficit/Hyperactivity Disorder ADHD (SHP465-308)

Joshua Woolley, MD, PhD | UC San Francisco VA Medical Ct. | San Francisco, CA
Psilocybin-Assisted Group Therapy for Demoralization in long-Term Aids Survivors

Zynerba Pharmaceuticals, Pty. Ltd. | Southbank, VIC | Australia

A Randomized, Double-Blind, Placebo Controlled Multiple-Center, Efficacy and Safety
Study of ZYN002 Administered as a Transdermal Gel to Children and Adolescents with
Fragile X Syndrome
(ZYN2-CL-016)

APPENDIX A

OPEN (through December 31, 2020) SCHEDULE I AND SCHEDULE II NON-HUMAN AND ACADEMIC HUMAN RESEARCH STUDIES

Stephan Anagnostaras, PhD | UC San Diego | La Jolla, CA

MDMA and Memory, Addiction, Social Behavior, Anxiety, and Depression: A Dose-Effect Analysis

Marc Azar, PhD | Behavioral Pharma, Inc. | La Jolla, CA

Effects of Client's Test Compound on Cue Induced Reinstatement of Heroin-Seeking Behavior

Marc Azar, PhD | Behavioral Pharma, Inc. | La Jolla, CA

Effects of Test Compound on Rats Trained to Intravenously Self-Administer Heroin

Richard Baldwin, PhD | nanoComposix | San Diego, CA

Biosensor for the Detection of Synthetic Cannabinoids

Nelson Barton, PhD | Genomatica, Inc. | San Diego, CA

Microbial Processes for the Manufacture of Specialty Chemicals

Asser Bassyouni, | M.S. Pfizer, Inc. | San Diego, CA

Understanding the Translation of the Response of the CB1 Agonist

Ryan Baxter, PhD | UC Merced | Merced, CA

Cannabinoid Isolation, Purification, and Structure Diversification

Neal L. Benowitz, MD | UC San Francisco | San Francisco, CA

Vaping THC from Electronic Cigarettes: a Novel Evaluation of Intake and Pharmacokinetics

Neal L. Benowitz, MD | UC San Francisco | San Francisco, CA

Evaluating the Characteristics of Daily Cannabis Users

Neal L. Benowitz, MD | UC San Francisco | San Francisco, CA

Intake and Pharmacokinetics of THC Vaped from Electronic Cigarettes

Devin K. Binder, MD, PhD | UC Riverside | Riverside, CA

Translational EEG Biomarkers in a Mouse Model of Fragile X Syndrome

Brian Brandley | Biopharmaceutical Research Company (BRC) | Castroville, CA

Characterization of Model Systems for Longevity Studies, Genetics and Neuroscience;
Simple model systems for examination of cannabinoid effects on genetics, development
and nervous systems using roundworms (*C. elegans*) and/or killifish (*Nothobranchius*)

Ellen Breen, PhD | UC San Diego | San Diego, CA

In Defense Against Vaping Nicotine and Cannabis - Alarmins

Nancy E. Buckley, PhD | CA State Polytech University | Pomona, CA

Investigating the effect of THC on the susceptibility to systemic *C. Albicans* infection in
mice treated with an anti-cancer drug

Joshua Britton, PhD | Debut Biotechnology, Inc. | Carlsbad, CA

Production of Cannabinoids and their Precursors and via Purified Enzymes in a
Continuous System

Nicholas Butowski, MD | UC San Francisco | San Francisco, CA

CBD Developmental Research Project

Jeremy Caldwell, PhD | Novartis Foundation | San Diego, CA

High-Throughput Screening of Known Drugs for Novel Biological Activity in Cell-based
Assays

Joseph Califano, MD | UC San Diego | La Jolla, CA

THC-Cannabinoid Receptor Pathway and CBD Activation of GPCRs on Cannabinoid
Signaling Pathways in Head and Neck Squamous Cell Carcinoma (HNSCC)

John R. Cashman, PhD | Human BioMolecular Research Institute | San Diego, CA
Molecular Evolution of Human Cocaine Catalysis

Kent Chu | YJ Bio-Products | Cordova, CA
Immunochromatographic Test Device for THC and LSD

Laura Colin | Biostride, Inc. | Redwood City, CA
Panel Approved Research Study

Ziva Cooper, PhD | UCLA Semel Institute | Los Angeles, CA
Sex-Dependent Effects of Cannabis: Assessing Analgesic, Abuse-Related and Pharmacokinetic Differences Between Men and Women

Ziva Cooper, PhD | UCLA Semel Institute | Los Angeles, CA
Subjective and Analgesic Effects of Terpenes, Beta-Caryophyllene and Myrcene, Vaporized Alone and in Combination with THC

Nissar A. Darmani, PhD | Western University of Health Sciences | Pomona, CA
Project 1: Mechanisms of vomiting induced by chemotherapeutics, related emetics, & GI disorders. Project 2: Development changes in monoamine function following prenatal & early postnatal exposure to serotonergic altering drugs in mice

Michael DeGregorio, PharmD | Immuno Tess, Inc. | Roseville, CA
Effects of Cannabinoids on Immune Response in Combination with Immunomodulators: Potential Utility in Cancer Immunotherapy

Karl Deisseroth, MD, PhD | Stanford University | Palo Alto, CA
Effects of LSD on Brain-Wide Neural Activity and Behavior

Karl Deisseroth, MD, PhD | Stanford University | Palo Alto, CA
Neural Circuit Dynamics of LSD-Induced Psychosis

Davide Dulcis, PhD | UC San Diego | La Jolla, CA
Effects of Neonatal Nicotine Exposure on Dopamine Neurons Affecting Consumption of Substances of Abuse in the Adult

David Entwistle, PhD | Codexis, Inc. | Redwood City, CA

Project 1. Study of Cannabigerolic acid (CBGA) and Cannabodiolic acid (CBDA) Concentrations in Yeast Cultures Containing Engineered Recombinant Synthase Enzymes

David Entwistle, PhD | Codexis, Inc. | Redwood City, CA

Project 2. Study of the Effect of recombinant syntheses an Cannabigerolic acid (CBGA), Determination of CBGA and Cannabodiolic acid (CBDA) Concentrations

Randall Espinosa, MD | UCLA Semel Institute | Los Angeles, CA

Psilocybin Pilot for Treatment-Resistant Depression (TRD)

Aaron Ettenberg, PhD | UC Santa Barbara | Santa Barbara, CA

Dopamine involvement in Opiate and Stimulant Reinforcement

Sirine C. Fakra, PhD | Lawrence Berkeley National Laboratory | Emeryville, CA

Evaluation of Industrial Hemp.for Phytoremediation and Se Biofortification Applications

Christie Fowler, PhD | UC Irvine | Irvine, CA

Mechanisms of Drug Reinforcement

Neil K. Garg, PhD | UCLA | Los Angeles, CA

Optical and Electrochemical Detection of Tetrahydrocannabinol (THC) Towards a Functional Quantitative Breathalyzer

Genomics Institute of Novartis | San Diego, CA

Use of Selected DEA Schedule 1 Controlled Substances as a Building Blocks in the Synthesis of Novel Chemical Entities in Support of Biological Studies (referred to as Biological Studies)

Olivier George, PhD | The Scripps Research Institute | La Jolla, CA

Preclinical Testing of CBD for the Treatment of Nicotine Dependence

Olivier George, PhD | The Scripps Research Institute | La Jolla, CA

Animal Models of Addiction: Preliminary Studies of Vaporized THC Self Administration in a Rat Model

Olivier George, PhD | The Scripps Research Institute | La Jolla, CA

Animal Models of Addiction: Preliminary Studies for Heroin Dependence and Treatments

Mark A. Geyer, PhD | UC San Diego | La Jolla, CA

Effects of Cannabidiol on Mania-relevant Locomotor and Investigatory Behavior

Alidad Ghiassi, MD | Keck School of Medicine | USC

A Randomized Trial Comparing Ibuprofen Plus Acetaminophen Versus Oxycodone After Outpatient Soft Tissue Hand Surgery

Anushka Goonawardena, PhD | SRI International | Menlo Park, CA

Cannabinoid Regulation on Resting State Quantitative EEG, Sleep and Cognition

Catherine Hagan, DVM, PhD | Valley Biosystems | West Sacramento, CA

Cannabis for Veterinary Use and Model Development

Adam Halberstadt, PhD | UC San Diego | La Jolla, CA

The Next Generation of Hallucinogens: A New Class of Synthetic Psychoactive Drugs

Boris Dov Heifets, MD, PhD | Stanford University | Stanford, CA

Effects of Classical Hallucinogens on Learning and Memory

Keith Heinzerling, MD | Pacific Neuroscience Institute | Santa Monica, CA

Pilot trial of Visual Healing®, a nature-themed virtual immersive experience, to optimize set and setting in psilocybin-assisted therapy for alcohol use disorder

Judith Hellman, MD | UC San Francisco | San Francisco, CA

Cannabinoid-Dependent Modulation of Acute Inflammation and Immune Responses in Infection and Injury

Brook Henry, PhD | UC San Diego | San Diego, CA

Effect of Cannabis Administration and Endocannabinoids on HIV Neuropathic Pain Study - Phase 2

Kanthi Hettiarachchi, PhD | SRI International | Menlo Park, CA
Analysis of Controlled Substances

William Jagust, MD | University of California, Berkeley | Berkeley, CA
Dopaminergic mechanisms underlying decision making:
Academic human subjects research with Schedule II drug (Methylphenidate)

Kim D. Janda, PhD | The Scripps Research Institute | La Jolla, CA
Vaccines for the Treatment of Opiate Addiction

Kim D. Janda, PhD | The Scripps Research Institute | La Jolla, CA
Immunopharmacology Therapy for Methamphetamine Addiction

Kim D. Janda, PhD | The Scripps Research Institute | La Jolla, CA
Vaccine Research (Vaccines and Antidotes Against Drugs of Abuse)

Walter Kaye, MD | UC San Diego | San Diego, CA
Evaluation of Psilocybin in Reducing Core Symptoms in Anorexia Nervosa: Safety and Efficacy

Jay Keasling, PhD | Joint Bioenergy Institute | Emeryville, CA
Engineering the Industrial Microbe *Saccharomyces Cerevisiae* for Biosynthesis of Cannabinoids

Heather Knych, DVM, PhD | UC Davis School of Veterinary Medicine | Davis, CA
Pharmacokinetics and Selected Pharmacodynamic Effects of Cannabidiol in Horses

David Kokel, PhD | UC San Francisco | San Francisco, CA
Assessment of Zebrafish Phenotypic Assays to Model the Toxicology and Behavioral Pharmacology of Synthetic Cannabinoids and Other Psychoactive Compounds

Charles Lee, PhD | USDA-ARS | Albany, CA
Low THC Industrial Hemp Cultivars

Sulggi A. Lee, MD, PhD | UC San Francisco | San Francisco, CA
Effect of Methamphetamine on Residual Latent HIV Disease (EMRLHD) Study

Daniel Levin, PhD | S&B Pharma, Inc. | Azusa, CA
Panel Approved Research Study (1)

Daniel Levin, PhD | S&B Pharma, Inc. | Azusa, CA
Panel Approved Research Study (2)

Marie Lin, PhD | Lin-Zhi International | Sunnyvale, CA
Lin-Zhi Immunoassay Development Study

Mallory Loffin, PhD | San Diego Veterans Affairs Medical Center | San Diego, CA
Cannabidiol as an Adjunctive to Prolonged Exposure for PTSD

Stephen Mahler, PhD | UC Irvine | Irvine, CA
Neural Circuits Underlying Motivation and Addiction

Robert Malenka, MD, PhD | Stanford University School of Medicine | Stanford, CA
The Role of Oxytocin in the Pathogenesis of Autism

Thomas Marcotte, PhD | UC San Diego Health Care System | San Diego, CA
A Randomized, Controlled Trial of Cannabis in Healthy Volunteers Evaluating Simulated Driving, Field Performance Tests and Cannabinoid Levels

Sean D. McAllister, PhD | CPMC Research Institute | San Francisco, CA
Panel Approved Research Study

Faith Kennedy McDaniel, PhD | Koniku Inc. | Berkeley, CA
Development of a Device that Detects Controlled Substances

Rachel Eshima McKay, MD | UC San Francisco | San Francisco, CA
Evaluation of Pupillary Unrest in Prediction of Opioid Induced Respiratory Depression

Sara Mednick, PhD | UC Riverside | Riverside, CA

The Effects of Zolpidem and Dextroamphetamine on Cognitive Performance

Lupe Mejorado, PhD | Alere San Diego, Inc. | San Diego, CA

In Vitro Assay for the Synthetic Cannabinoids Belonging to JWH and Pinaca Family

Byung-Sook Moon | ARK | Freemont, CA

Research and Development of in-Vitro Diagnostic (IVD) Immunoassays for Drug of Abuse Testing

Stephen Morairty, PhD | SRI International | Menlo Park, CA

Panel Approved Research Study

Heinz Moser, PhD | Novartis Institute | Emeryville, CA

Synthesis and Optimization of Novel Therapeutics

Alysson Muotri, PhD | UC San Diego | La Jolla, CA

The Impact of CBD/THC on Human Neurodevelopment

Fatta B. Nahab, MD | UC San Diego | La Jolla, CA

A Double-Blind, Cross-Over, Placebo Controlled Efficacy and Tolerability Study of Oral Cannabidiol (CBD) and Tetrahydrocannabinol (THC) for Essential Tremor (ET)

David E. Olson, PhD | UC Davis | Davis, CA

Chemical Modulation of Neural Plasticity, Learning and Memory

Lori Olson, M.S. | SRI International | Menlo Park, CA

Identification and isolation of specific pesticides from cannabinoid oils

Jeanne Paz, PhD | The J. David Gladstone Institutes | San Francisco, CA

Role of CBD in Inflammation in Genetic and Acquired Epileps

Mark Peterman, PhD | OndaVia | Hayward, CA
Development of a Rapid and Field-Ready Heroin analysis Tool

Joy Phillips, PhD | San Diego State University | San Diego, CA
Effect of Cannabis Inhalation on Respiratory Inflammation and Immune Function

Daniele Piomelli, PhD | UC Irvine | Irvine, CA
1. Effect of Adolescent Cannabis Exposure in Adults Mice and Rats
2. In Vitro and In Vivo Pharmacological Characterization of Acid Phytocannabinoids

Birgit Puschner, DVM, PhD | UC Davis School of Veterinary Medicine | Davis, CA
Analysis of Cannabinoids in Hemp Oil Veterinary Treats/Supplements

Benjamin Reese, PhD | Neuroscience Research institute | UC Santa Barbara
Cannabinoid Neuroprotection of Retinal Ganglion Cells in Glaucoma

Richard Reznicek, MD | Harbor-UCLA | Los Angeles, CA
Panel Approved Research Study

Pierre Riviere, PhD | Peptide Logic | San Diego, CA
Opioid Antidotes (PL005)

Pietro Paolo Sanna, MD | The Scripps Research Institute | La Jolla, CA
Neural Substrates of Opiate-HIV Interactions

Nathaniel M. Schuster, MD | UC San Diego Center for Pain Medicine | La Jolla, CA
Efficacy of Inhaled Cannabis Versus Placebo for the Acute Treatment of Migraine: a Randomized, Double-Blind, Placebo-Controlled, Crossover Trial

Christopher Savile, PhD | Epimeron USA, Inc. | Mt. View, CA
Development of a Cannabidiol (CBD) Producing Yeast Strain and Fermentation-Based Production Process

David Schubert, PhD | Salk Institute | La Jolla, CA

The Identification of Neuroprotective Compounds in Cannabis

Mehrdad Shamloo, PhD | Stanford University | Palo Alto, CA

Efficacy of Cannabinoid in Treatment of Opioid Addiction and CNS Diseases

Philip Schwartz, PhD | Children's Hospital of Orange County | Orange, CA

Effect of Receptor Activation on Human Neuron Stem Cell Function

Ivan Soltesz, PhD | Stanford University | Stanford, CA

Investigating the Effect of Naturally Occurring Cannabinoids on Synaptic Physiology, Cognition and Epilepsy

Matthew L. Springer, PhD | UC San Francisco | San Francisco, CA

Assessment of Harmful Cardiovascular Effects of Marijuana Secondhand Smoke and Vaporizers

Mark Sussman, PhD | San Diego State University | San Diego, CA

Prenatal nicotine tetrahydrocannabinol exposure promotes myocardial damage: A brain-heart parallel

Trisha Suppes, MD, PhD | VA Palo Alto Health Care System | Palo Alto, CA

The Safety and Efficacy of Psilocybin in Participants with Severe Treatment-Resistant Depression (P-TRD)

Michael Taffe, PhD | The Scripps Research Institute | La Jolla, CA

Behavioral and Physiological Toxicities of Cannabinoids

Michael Taffe, PhD | The Scripps Research Institute | La Jolla, CA

Behavioral and Physiological Toxicities of Cannabinoids: Effects of Cannabidiol

Michael Taffe, PhD | The Scripps Research Institute | La Jolla, CA

Behavioral Toxicities of Amphetamine and Cathinone Stimulant Drugs (1)

Michael Taffe, PhD | The Scripps Research Institute | La Jolla, CA
Behavioral Toxicities of Amphetamine and Cathinone Stimulant Drugs (2)

Francesca Telese, PhD | UC San Diego | La Jolla, CA
Epigenetic Regulation of Gene Expression in the Brain

Jeff Ubersax | Demetrix, Inc. | Emeryville, CA
Panel Approved Research Study

Jacob Vogan, PhD | CB Therapeutics | Carlsbad, CA
Laboratory Scale Biosynthesis of DMT and Related Substituted Tryptamine Compounds in Baker's Yeast

Jacob Vogan, PhD | CB Therapeutics | Carlsbad, CA
Laboratory Scale Biosynthesis of Psilocybin in Baker's Yeast

Rama Voladri, PhD | Codexis, Inc. | Redwood City, CA
Transaminase Evolution Proposal for Genentech. Engineering ATA-P2-A07 for a synthesis of G03044577

Friedbert Weiss, PhD | The Scripps Research Institute | La Jolla, CA
Ethanol Seeking and Relapse: Therapeutic Potential of Transdermal Cannabidiol

Friedbert Weiss, PhD | The Scripps Research Institute | La Jolla, CA
Implementation of Novel Methodology to Study the Anti-Relapse Potential of Cannabidiol

Joshua Woolley, MD, PhD | UC San Francisco VA Medical Center | San Francisco, CA
Psilocybin-Assisted Group Therapy for Demoralization in Long-Term Aids Survivors

Matthew Worley, PhD | UC San Diego | La Jolla, CA
Behavioral Economic Mechanisms of ' Prescription Opioid Addiction in Chronic Pain

Joseph Wu, MD, PhD | Stanford University | Stanford, CA
Human iPSCs for Elucidating Cardiovascular Risks of Cannabis

Jianmin Xu, PhD | Latitude Pharmaceuticals, Inc. | San Diego, CA

Development of Oral and Injectable Formulation Technologies for Cannabidiol (CBD) and Tetrahydrocannabinol (THC)

Roya Yumul | Cedars-Sinai Medical Ct. | Los Angeles, CA

Intra-operative ketamine and methadone for laminectomy: effect on recovery, post operative pain, and opioid requirements

Brandon Zipp, PhD | Vitality Biopharma, Inc. | Los Angeles, CA

Cannabinoid-Glycoside Pharmaceutical Prodrug Development and Evaluation

APPENDIX B

OPEN (through December 31, 2020) SCHEDULE I AND SCHEDULE II CLINICAL DRUG TRIAL STUDIES

Alkermes, Inc. | Waltham, MA

A Study to Evaluate the Effect of ALKS 3831 Compared to Olanzapine on Body Weight in Young Adults with Schizophrenia, Schizophreniform or Bipolar I Disorder Who are Early in Their Illness
(ALK3831-A307)

Alkermes, Inc. | Waltham, MA

A Phase 3 Study to Assess the Long Term Safety, Tolerability, and Durability of Treatment Effect of ALKS 3831 in Subjects with Schizophrenia, Schizophreniform Disorder, or Bipolar I Disorder
(ALK3831-A308)

Arbor Pharmaceuticals | CRO: Rho Inc. | Chapel Hill, NC

A Multicenter, Fixed-Dose, Double-Blind, Randomized Study to Evaluate the Efficacy and Safety of AR19 (Amphetamine Sulfate) in Adult Subjects (Ages 18-55) with Attention Deficit Hyperactivity Disorder (ADHD (AR19.004)

Avenue Therapeutics, Inc. | New York, NY

A Phase 3, Multicenter, Randomized, Double Blind, Three-Arm Study to Evaluate the Efficacy and Safety of Tramadol Infusion (AVE-901) Versus Placebo and Morphine in the Management of Postoperative Pain Following Abdominoplasty
(AVE-901-103)

Andy Barron | CRO: Worldwide Clinical Trials Ltd. | Morrisville, NC

The Safety and Efficacy of Psilocybin as an Augmentation Therapy in Participants with Treatment Resistant Depression”
(COMP 003)

Botanix | CRO: Premier Research | Research Triangle Park, NC

A Randomized, Double-Blind, Vehicle-Controlled Study of the Safety, Tolerability, and Efficacy of BTX 1204 in Patients with Moderate Atopic Dermatitis (BTX.2018.003)

Botanix | CRO: Premier Research | Research Triangle Park, NC

A Randomized, Double-Blind, Vehicle Controlled Study to Evaluate the Safety and Efficacy of BTX 1503 in Patients with Moderate to Severe Acne Vulgaris (BTX.2018.001)

Corbus Pharmaceuticals, Inc. | Norwood, MA

A Multicenter, Randomized, Double-Blind, Placebo Controlled Phase 2 Trial to Evaluate Efficacy and Safety of Lenabasum in Cystic Fibrosis (JBT101-CF-002)

Corbus Pharmaceuticals, Inc. | Norwood, MA

A Multicenter, Randomized, Double-Bind, Placebo-Controlled Phase 3 Trial of Evaluate Efficacy and Safety of Lenabasum in Dermatomyositis (JBT101-DM-002)

Corbus Pharmaceuticals, Inc. | Norwood, MA

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial to Evaluate Efficacy and Safety of Lenabasum in Diffuse Cutaneous Systemic Sclerosis (JBT1 01-SSc-002)

CNS Therapeutics | CRO: Social & Scientific Systems | Silver Spring, MD

Panel Approved Research Study (1)

CNS Therapeutics | CRO: Social & Scientific Systems | Silver Spring, MD

Panel Approved Research Study (2)

CRO: The Emmes Corporation | Rockville, MD

A randomized, Double-Blind, Support-of-Concept Phase 2 Study of Single-Dose Psilocybin for Major Depressive Disorder (MDD) (PSIL201))

W. Brooks Gentry, MD | InterveXion Therapeutics | Little Rock, AK

Study of Antibody for Methamphetamine Outpatient Therapy

Grunenthal/Janssen | CRO : inventive | Cary, NC

Panel Approved Research Study

GW | Cambridge, UK

Panel Approved Research Study (1)

GW | Cambridge, UK

Panel Approved Research Study (2)

GW | Cambridge, UK

Panel Approved Research Study (3)

INSYS Therapeutics | Chandler, AZ

A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Efficacy, Safety, and Tolerability of Cannabidiol Oral Solution as Adjunctive Therapy with Vigabatrin as Initial Therapy in Patients with Infantile Spasms (INS01 1-16-082)

INSYS Therapeutics | Chandler, AZ

A Randomized, Double-Blind, Placebo Controlled, Phase 2 Study to Assess the Efficacy, Safety, and Tolerability of Cannabidiol Oral Solution for the Treatment of Patients with Prader-Willi Syndrome (INS011-16-085)

INSYS Therapeutics | Chandler, AZ

A Phase 2, Open-Label, Dose-Finding Study to Assess the Efficacy, Safety, Tolerability, and Pharmacokinetics of Pharmaceutical Grade Synthetic Cannabidiol Oral Solution in Pediatric Patients with Treatment-Resistant Childhood Absence Seizures (INS01 1-17-103)

INSYS Therapeutics | Chandler, AZ

A Multicenter, Open-Label, Flexible Dose Study to Assess the Long-Term Safety of Pharmaceutical Grade Synthetic Cannabidiol Oral Solution as in Pediatric Patients with Treatment-Resistant Childhood Absence Seizures (INS01 1-17-113)

INSYS Therapeutics | Chandler, AZ

A Multicenter, Open-Label Study to Assess the Long-Term Safety of Pharmaceutical Grade Synthetic Cannabidiol Oral Solution in Patients with Prader-Willi Syndrome (INS01 1-17-115)

INSYS Therapeutics | Chandler, AZ

A multicenter, open-label, flexible dose study to assess the long-term safety of pharmaceutical Cannabidiol Oral Solution as an adjunctive treatment for pediatric and adult subjects with a treatment-resistant seizure disorder who complete INS011-14-024, INS01 1-14-025, or INS01 1-14-029 (INS01 1-14-030)

Jazz Pharmaceuticals | CRO: Quintiles | Overland Parks, KS

A Double-Blind, Placebo-Controlled, Randomized-Withdrawal, Multicenter Study of the Efficacy and Safety of JZP-258 in Subjects with Narcolepsy with Cataplexy (15-006)

Multidisciplinary Association for Psychedelic Studies (MAPS) | Santa Cruz, CA
Panel Approved Research Study (1)

Multidisciplinary Association for Psychedelic Studies (MAPS) | Santa Cruz, CA
Panel Approved Research Study (2)

Multidisciplinary Association for Psychedelic Studies (MAPS) | Santa Cruz, CA
Panel Approved Research Study (3)

Multidisciplinary Association for Psychedelic Studies (MAPS) | Santa Cruz, CA
Panel Approved Research Study (4)

Multidisciplinary Association for Psychedelic Studies (MAPS) | Santa Cruz, CA
Panel Approved Research Study (5)

NIH/NIAID | Rockville, MD

A Phase 2, Double-blind, Randomized, Placebo-controlled Multicenter Study to Evaluate Efficacy, Safety, and Tolerability of JBT-101 in Systemic Lupus Erythematosus (ALE09)

Noven Pharmaceuticals | New York, NY

A Randomized, Multiple-Dose, Open-Label, 4-Week Study to Characterize the Pharmacokinetics, Cumulative Irritation, Safety, and Tolerability of dl-Amphetamine Transdermal System (d-ATS) in Adults Diagnosed with ADHD (N25-015)

Pfizer | CRO: ICON | NewYork, NY

Panel Approved Research Study (1)

Pfizer | CRO: ICON | NewYork, NY

Panel Approved Research Study (2)

Purdue | CRO:PRA | Raleigh, NC

A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel Group, Laboratory Classroom Study to Evaluate the Safety and Efficacy of PRC-063 Compared to Placebo in Children (6-12 years of age) with ADHD
(063-015)

Receptor Life Sciences | CRO: WCCT Global | Cypress, CA

A Randomized, Open-Label, Two-Way Crossover Study of Oral and Inhaled Cannabis Formulations in Health Adult Participants (1) (RC-2018/01)

Receptor Life Sciences | CRO: WCCT Global | Cypress, CA

A Randomized, Open-Label, Two-Way Crossover Study of Oral and Inhaled Cannabis Formulations in Health Adult –Participants
(2) (RC-2018/01)

Relmada Therapeutics, Inc. | CRO: Syneos Health | Cary, NC

Phase 2a, Multicenter, Randomized, Double Blind, Placebo Controlled, 3 Arm Study to Assess the Safety, Tolerability, PK Profile, and Symptom Response of a 7-Day Dosing with REL 1017 25 mg QD and 50 mg QD as Adjunctive Therapy in the Treatment of Patients Diagnosed with Major Depressive Disorder
(REL-1017-202)

Shire | CRO: PPD | San Diego, CA

Panel Approved Research Study (1)

Shire | CRO: PPD | San Diego, CA

Panel Approved Research Study (2)

Stephen A. Spector, MD | UC San Diego | La Jolla, CA

Function of the brain's endocannabinoid system and its role in Neuro-AIDS and Neuro-inflammation

Nancy Tich, MS, PhD | Zynerba Pharmaceuticals | Devon, PA

An Open-Label Extension Study to Assess the Long-Term Safety and Tolerability of ZYN002 Administered as a Transdermal Gel to Children and Adolescents with Fragile X Syndrome - CONNECT-FX Open Label Extension (OLE) Clinical study Of caNNabidiol in childrEn and adolesCentTs with Fragile X (CONNECT-FX OLE)
(Zyn2-CL-017)

West-Ward Pharmaceuticals | CRO: Premier Research | Columbus, OH

A Multicenter, Open-Label, Safety and Pharmacokinetic Study of Oral Morphine Sulfate Administration in Pediatric Subjects 2 Years Old Through 17 Years Old with Postoperative Pain
(MORP-OS+T-(2-17)-SPK-2)

Worldwide Clinical Trials | Durham, NC

The Safety and Efficacy of Psilocybin in Participants with Treatment Resistant Depression (PTRD) (COMP 001)

Zynerba Pharmaceuticals, Pty. Ltd. | Southbank, VIC | Australia

A Randomized, Double-Blind, Placebo Controlled Multiple-Center, Efficacy and Safety Study of ZYN002 Administered as a Transdermal Gel to Children and Adolescents with Fragile X Syndrome
(ZYN2-CL-0 16)

APPENDIX C

OPEN (through December 31, 2020) RESEARCH STUDIES ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

Keith Heinzerling, MD | UC Los Angeles | Los Angeles, CA
Randomized Trial of Ibudilast for Methamphetamine Dependence

Keith Heinzerling, MD | UC Los Angeles | Los Angeles, CA
Phase 1 Safety-Interaction Study of Pomaglumetad Methionil for Methamphetamine Use Disorder

Robert Lindblad, MD | The Emmes Company, LLC | Rockville, MD
Panel Approved Research Study

NIDA/NSC/NIH | Bethesda, MD
Phase 2, Multi-Center Trial of Lorcaserin for the Treatment of Cocaine Use Disorder (NIDA CS #1033)

NIDA | The EMMES Corp. | Rockville, MD
Extended-Release Naltrexone vs Buprenorphine for Opioid Treatment (X:BOT) (0051)

Steven Shoptaw, PhD | UC Los Angeles | Los Angeles, CA
Varenicline for Methamphetamine Dependence

Steven Shoptaw, PhD | UC Los Angeles | Los Angeles, CA
Phase I Safety Interaction Trial of Ibudilast with Methamphetamine

APPENDIX D

STATUTORY AUTHORITY CONCERNING THE RESEARCH ADVISORY PANEL FROM THE CALIFORNIA HEALTH AND SAFETY CODE

§ 11213. Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to § 11480 and § 11481.

Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to § 11480 or § 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

§ 11480. The Legislature finds that there is a need to encourage further research into the nature and effects of marijuana and hallucinogenic drugs and to coordinate research efforts on such subjects.

There is a Research Advisory Panel which consists of a representative of the State Department of Health Services, a representative of the California State Board of Pharmacy, a representative of the Attorney General, a representative of the University of California who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a private university in this State who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a statewide professional medical society in this state who shall be engaged in the private practice of medicine and shall be experienced in treating controlled substance dependency, a representative appointed by and serving at the pleasure of the Governor who shall have experience in drug abuse, cancer, or controlled substance research and who is either a registered nurse, licensed pursuant to Chapter 6 (commencing with § 2700) of Division 2 of the Business and Professions Code, or other health professional. The Governor shall annually designate the private university and the professional medical society represented on the Panel. Members of the Panel shall be appointed by the heads of the entities to be represented, and they shall serve at the pleasure of the appointing power.

The Panel shall annually select a chairman from among its members.

The Panel may hold hearings on, and in other ways study, research projects concerning marijuana or hallucinogenic drugs in this state. Members of the Panel shall serve without compensation, but shall be reimbursed for any actual and necessary expenses incurred in connection with the performance of their duties.

The Panel may approve research projects, which have been registered by the Attorney General, into the nature and effects of marijuana or hallucinogenic drugs, and shall inform the Attorney General of the head of the approved research projects which are entitled to receive quantities of marijuana pursuant to § 11478.

The Panel may withdraw approval of a research project at any time, and when approval is withdrawn shall notify the head of the research project to return any quantities of marijuana to the Attorney General.

The Panel shall report annually to the Legislature and the Governor those research projects approved by the Panel, the nature of each research project, and, where available, the conclusions of the research project.

§ 11481. The Research Advisory Panel may hold hearings on, and in other ways study, research projects concerning the treatment of abuse of controlled substances.

The Panel may approve research projects, which have been registered by the Attorney General, concerning the treatment of abuse of controlled substances and shall inform the chief of such approval. The Panel may withdraw approval of a research project at any time and when approval is withdrawn shall so notify the chief.

The Panel shall, annually and in the manner determined by the Panel, report to the Legislature and the Governor those research projects approved by the Panel, the nature of each research project, and where available, the conclusions of the research project.

§ 11603. The Attorney General, with the approval of the Research Advisory Panel, may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceedings to identify the individuals who are the subjects of research for which the authorization was obtained.

§ 11604. The Attorney General, with the approval of the Research Advisory Panel, may authorize the possession and distribution of controlled substances by persons engaged in research. Persons who opt in this authorization are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.

§ 24172. Experimental subject's bill of rights; contents

As used in the chapter, “experimental subject's bill of rights,” means a list of the rights of a subject in a medical experiment, written in a language in which the subject is fluent. Except as otherwise provided in § 24175, this list shall include, but not be limited to the subject's right to:

- (a) Be informed of the nature and purpose of the experiment.
- (b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
- (c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
- (d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
- (e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
- (f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
- (g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
- (h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
- (i) Be given a copy of the signed and dated written consent form as provided for by § 24173 or § 24178.
- (j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

§ 24173. Informed consent

As used in this chapter, “informed consent” means the authorization given pursuant to § 24175 to have a medical experiment performed after each of the following conditions have been satisfied:

- (a) The subject or subject’s conservator or guardian, or other representative, as specified in § 24175, is provided with a copy of the experimental subject’s bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by § 24172, and the copy is signed and dated by the subject or the subject’s conservator or guardian, or other representative, as specified in § 24175.
- (b) A written consent form is signed and dated by the subject or the subject’s conservator or guardian, or other representative, as specified in § 24175.
- (c) The subject or subject’s conservator or guardian, or other representative, as specified in § 24175, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject’s conservator or guardian, or other representative, as specified in § 24175, is fluent, of the following facts of the proposed medical experiment, which might influence the decision to undergo the experiment, including, but not limited to:
 - (1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of the procedures, drugs, or devices. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of the experiment shall be informed of that fact; however, they need not be informed as to whether they will actually be administered or dispensed a placebo.
 - (2) A description of any attendant discomfort and risks to the subject reasonably to be expected.
 - (3) An explanation of any benefits to the subject reasonably to be expected, if applicable.
 - (4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
 - (5) An estimate of the expected recovery time of the subject after the experiment.
 - (6) An offer to answer any inquiries concerning the experiment or the procedures involved.

- (7) An instruction to the subject that he or she is free to withdraw his or her prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.
 - (8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.
 - (9) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.
 - (10) The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.
 - (11) The material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment. For purposes of this section, “material” means ten thousand dollars (\$10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned.
- (d) The written consent form is signed and dated by any person other than the subject or the conservator or guardian, or other representative of the subject, as specified in § 24175, who can attest that the requirements for informed consent to the medical experiment have been satisfied.
 - (e) Consent is voluntary and freely given by the human subject or the conservator or guardian, or other representative, as specified by § 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.

