ClinicalTrials.gov: metabolite | Last update posted in the last 7 days

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
1	NCT05532644	Correlation of P-glycoprotein Polymorphisms With Microbial Metabolites in Patients With Alzheimer's Disease on Medication Study Documents:	Title Acronym: Other Ids: MicroGeneAD	Not yet recruiting	Alzheimer Disease	Other: AD drugs AD drugs	Study Type: Observational Phase: Study Design: Observational Model: Case-Crossover Time Perspective: Prospective Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 135 Original Estimated Enrollment: *Same as current* Age: 50 Years to 85 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: September 2022 Primary Completion: December 2023 (Final data collection date for primary outcome measure) Study Completion: September 2024 First Posted: September 8, 2022 Results First Posted: Last Update Posted: September 8, 2022
2	NCT03065335	Neuropharmacologic Imaging and Biomarker Assessments of Response to Acute and Repeated-Dosed Ketamine Infusions in Major Depressive Disorder Study Documents:	Title Acronym: Other Ids: 170060 17-M-0060	Recruiting	• Healthy Volunteer • Major Depressive Disorder • Depression	• Drug: Ketamine N-methyl-D-aspartate (NMDA) glutamate receptor (NMDA-R) antagonist • Other: Placebo Placebo comparator • Device: Cobot TS MV robotic arm for TMS TMS-Cobot TS MV [Axilum Robotics] robotic arm for spatial positioning and orientation of the TMS coil • Device: NeurOptics PLRTM-30000 Pupillometer The Neu-rOptics PLRTM-3000 Pupillometer will use quantitative infrared technology to objectively and accurately measure pupil size and dynamics.	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: Randomized Intervention Model: Crossover Assignment Masking: Double (Participant, Investigator) Primary Purpose: Treatment Primary Outcome Measures: To demonstrate more robust neuropharmacodynamic effects measured by neuropharmacodynamic imaging (fMRI+EEG and MEG) of ketamine 0.5 mg/kg as compared to placebo administered over 40 minutes. [Time Frame: baseline; w/ drug] Secondary Outcome Measures: • To determine if increases in synaptic plasticity, using electrophysiological measures in response to TMS and in association with sleep (i.e. slow wave sleep EEG activity) are associated with better antidepressant response to 0.5 mg/kg [Time Frame: baseline and post-drug] • To demonstrate enhanced efficacy, as measured by the MADRS, of IV ketamine 0.5 mg/kg in participants with MDD using a psychophysiological technique (i.e. NPU-threat test). [Time Frame: baseline and post-drug] • To identify baseline peripheral measures associated with response to the administration of ketamine 0.5 mg/kg, as potential biomarkers of acute (24 hour) treatment response. [Time Frame: baseline and post-drug]	Actual Enrollment: Estimated Enrollment: 150 Original Estimated Enrollment: 100 Age: 18 Years to 65 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: May 25, 2017 Primary Completion: January 1, 2025 (Final data collection date for primary outcome measure) Study Completion: January 1, 2028 First Posted: February 27, 2017 Results First Posted: Last Update Posted: September 9, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
3	NCT03414242	Investigation of Neurocognitive Measures of Sport-Related Injury Study Documents:	Title Acronym: Other Ids: 17-006025	Enrolling by invitation	Concussion, Brain	Other: Cervical spine musculature Previously established cervical spine musculature training methodology will be utilized to develop a concussion prevention training program.	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Screening Primary Outcome Measures: *Same as current* Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 4000 Original Estimated Enrollment: *Same as current* Age: 12 Years to 30 Years (Child, Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: March 12, 2019 Primary Completion: December 2022 (Final data collection date for primary outcome measure) Study Completion: December 2022 First Posted: January 29, 2018 Results First Posted: Last Update Posted: September 12, 2022
4	NCT05414409	The Gut Microbiome in Type 1 Diabetes and Mechanism of Metformin Action Study Documents:	Title Acronym: Other Ids: 15498	Not yet recruiting	• Type 1 Diabetes • Obesity	Drug: Metformin Metformin is an oral medication that improves insulin sensitivity.	Study Type: Interventional Phase: Phase 3 Study Design: Allocation: Non-Randomized Intervention Model: Sequential Assignment Intervention Model Description: The investigators will examine the differences in the gut microbiome between lean and obese youth with type 1 diabetes and then enroll the obese youth with type 1 diabetes into the clinical trial to receive metformin as an intervention. Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 114 Original Estimated Enrollment: *Same as current* Age: 11 Years to 18 Years (Child, Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: October 2022 Primary Completion: August 2025 (Final data collection date for primary outcome measure) Study Completion: August 2026 First Posted: June 10, 2022 Results First Posted: Last Update Posted: September 9, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
5	NCT04966520	Accelerated Neuromodulation to Alleviate Cognitive Deficits Due to Cancer Therapy Study Documents:	Title Acronym: Other Ids: 202101546	Recruiting	Cancer	Other: Accelerated repetitive intermittent theta-burst transcranial stimulation (iTBS) Accelerated iTBS will be used to stimulate the regions of interest of mPFC and L-DLPFC nodes in cancer survivors or patients. Accelerated iTBS will be administered in a single half-day period to allow for a 50minutes interval between any two treatments to minimize interference effects between treatments. Thus, there will be ~10 minute sessions of stimulation x 2 applications per node x 2 nodes (L-DLPFC, mPFC) = 40 total minutes of daily stimulation - each session delivers 1800 pulses in a 5 Hz triplet burst frequency, 2 second trains with intertrain interval of 8 seconds; triplets occur with 50 Hz frequency, as per standard iTBS protocols for depression treatment. The treatment will be offered for five consecutive days.	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 15 Original Estimated Enrollment: *Same as current* Age: 18 Years to 99 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: • American Cancer Society-Holden Comprehensive Cancer Society • Fraternal Order of Eagles (Iowa)	Study Start: June 1, 2021 Primary Completion: September 30, 2023 (Final data collection date for primary outcome measure) Study Completion: September 30, 2023 First Posted: July 19, 2021 Results First Posted: Last Update Posted: September 6, 2022
6	NCT05515588	A Study in Healthy Men to Test How BI 690517 is Taken up and Handled by the Body Study Documents:	Title Acronym: Other Ids: 1378-0013 2022-001818-18 (EudraCT Number)	Not yet recruiting	Healthy	• Drug: BI 690517 (C-14) BI 690517 (C-14) • Drug: BI 690517 BI 690517	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: Non-Randomized Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 14 Original Estimated Enrollment: *Same as current* Age: 18 Years to 55 Years (Adult) Sex: Male	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: September 21, 2022 Primary Completion: November 8, 2022 (Final data collection date for primary outcome measure) Study Completion: November 8, 2022 First Posted: August 25, 2022 Results First Posted: Last Update Posted: September 8, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
7	NCT00078078	Clinical and Laboratory Study of Methylmalonic Acidemia Study Documents:	Title Acronym: Other Ids: 040127 04-HG-0127	Recruiting	• Organic Acidemia • Methylmalonic Acidemia • Inborn Errors of Metabolism	Not Provided	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Prospective Primary Outcome Measures: Not Provided Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 2275 Original Estimated Enrollment: Age: 1 Month and older (Child, Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: June 7, 2004 Primary Completion: Not Provided Study Completion: Not Provided First Posted: February 19, 2004 Results First Posted: Last Update Posted: September 8, 2022
8	NCT05386758	A Study to Evaluate Molnupiravir (MK-4482; MOV) in Participants With Severe Renal Impairment (MK-4482-003) Study Documents:	Title Acronym: Other Ids: 4482-003 MK-4482-003 (Other Identifier: Merck)	Recruiting	Renal Impairment	Drug: Molnupiravir Four 200 mg capsules administered orally as a single dose Other Name: MK-4482; MOV; EIDD-2801	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: Non-Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 18 Original Estimated Enrollment: *Same as current* Age: 18 Years to 75 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: June 29, 2022 Primary Completion: November 7, 2022 (Final data collection date for primary outcome measure) Study Completion: November 18, 2022 First Posted: May 23, 2022 Results First Posted: Last Update Posted: September 12, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
9	NCT03900286	Low Energy Diet and Familial Partial Lipodystrophy Study Documents:	Title Acronym: Other Ids: A095183	Recruiting	• Lipodystrophy • Diabetes • Diet Modification	Dietary Supplement: Total Dietary Replacement Total Dietary Replacement	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: • A change from baseline in HbA1c [Time Frame: 1 year] mmol/mol • A change from baseline in fasting glucose [Time Frame: 12 weeks, 1 year] mmol/l • A change from baseline in triglycerides [Time Frame: 12 weeks, 1 year] mmol/l • A change from baseline in liver fat [Time Frame: 12 weeks, 1 year] % liver fat on MRI • A change from baseline in pancreatic fat [Time Frame: 12 weeks, 1 year] % pancreatic fat on MRI • A change from baseline in insulin sensitivity [Time Frame: 12 weeks, 1 year] Insulin pmol/l values during oral glucose tolerance test • A change from baseline in quality of life scores [Time Frame: 12 weeks, 1 year] Change in scores of EQ-5D-3LQOL from baseline. • A change from baseline in anxiety scores [Time Frame: 12 weeks, 1 year] Change in scores of GAD7 from baseline. • A change from baseline in depression scores [Time Frame: 12 weeks, 1 year] Change in scores of PHQ9, from baseline. • A change from baseline in antidiabetic medication use [Time Frame: 12 weeks, 1 year] A change in the amount of antidiabetic drugs taken and/or a change in dose.	Actual Enrollment: Estimated Enrollment: 20 Original Estimated Enrollment: *Same as current* Age: 18 Years to 99 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: January 16, 2020 Primary Completion: April 2023 (Final data collection date for primary outcome measure) Study Completion: May 2023 First Posted: April 3, 2019 Results First Posted: Last Update Posted: September 8, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
10	NCT04791969	Intermittent Oral Naltrexone Enhanced With an Ecological Momentary Intervention for Methamphetamine-using MSM Study Documents:	Title Acronym: Other Ids: 20-32912 DA053171-01A1 (Other Grant/Funding Number: National Institute on Drug Abuse (NIDA))	Recruiting	Methamphetamine Use Disorder	• Drug: Naltrexone Hydrochloride Intermittent Oral Naltrexone, 50 mg Other Name: ReVia • Drug: Placebo Intermittent Oral Placebo • Behavioral: Ecological Momentary Intervention Receive ecological momentary intervention if ecological momentary assessment reports meth craving, stress, not taking study drug, or antecedents detected for "high risk" meth use. Other Name: EMI	Study Type: Interventional Phase: Phase 2 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Intervention Model Description: 2:1 Naltrexone with EMI vs. Placebo with EMI Masking: Triple (Participant, Care Provider, Investigator) Masking Description: Double-blind, placebo controlled 2b clinical trial Primary Purpose: Treatment Primary Outcome Measures: Mean Change in meth-positive sweat patches from baseline to week 12 between Intermittent Oral Naltrexone vs. placebo groups [Time Frame: Every two weeks from enrollment to the end of treatment at 12 weeks] As measured by the proportion of meth-positive sweat patch tests. Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 54 Original Estimated Enrollment: 150 Age: 18 Years to 70 Years (Adult, Older Adult) Sex: Male	Study Sponsors: University of California, San Francisco Collaborators: National Institute on Drug Abuse (NIDA)	Study Start: December 14, 2021 Primary Completion: April 1, 2024 (Final data collection date for primary outcome measure) Study Completion: July 1, 2024 First Posted: March 10, 2021 Results First Posted: Last Update Posted: September 9, 2022
11	NCT05531357	Physiologic Mechanisms Underlying Ovarian Follicular Waves During the Menstrual Cycle Study Documents:	Title Acronym: Other Ids: Bio 2080	Recruiting	Reproductive Issues	Diagnostic Test: Transvaginal ultrasound scans Transvaginal ultrasound scans to map ovarian follicle growth and ovulation, finger-prick blood sampling for dried blood spot (DBS) hormonal assays and urine sampling for hormone metabolites, every consecutive day for an interovulatory interval. Weekly venipuncture samples will be taken for standard ELISA hormonal assays. The hormones of interest are FSH, LH, estradiol, progesterone, AMH, inhibins A and B, GDF-9 and BMP-15. Other Names: • Finger-prick blood sampling for dried blood spots • Urine sampling • Venipunctures	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Prospective Primary Outcome Measures: *Same as current* Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 50 Original Estimated Enrollment: *Same as current* Age: 18 Years to 40 Years (Adult) Sex: Female	Study Sponsors: *Same as current* Collaborators: Ansh Labs	Study Start: September 2022 Primary Completion: December 2024 (Final data collection date for primary outcome measure) Study Completion: June 2025 First Posted: September 7, 2022 Results First Posted: Last Update Posted: September 7, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
12	NCT03927391	Effect of a Reduced Dose Enzalutamide in Frail (m)CRPC Patients on Cognitive Side Effects Study Documents:	Title Acronym: Other Ids: REDOSE	Recruiting	Prostatic Neoplasms, Castration-Resistant	Drug: Enzalutamide enzalutamide treatment	Study Type: Interventional Phase: Phase 4 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Intervention Model Description: Normal enzalutamide dose versus reduced dose in two patient groups Masking: Single (Outcomes Assessor) Masking Description: Outcome assessor does not know the treatment arm Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 50 Original Estimated Enrollment: *Same as current* Age: 18 Years and older (Adult, Older Adult) Sex: Male	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: May 30, 2019 Primary Completion: March 1, 2023 (Final data collection date for primary outcome measure) Study Completion: March 1, 2023 First Posted: April 25, 2019 Results First Posted: Last Update Posted: September 12, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
13	NCT04133376	Electronic Hookah and Endothelial Cell Function Study Documents:	Title Acronym: Other Ids: T30IP1013	Recruiting	• Smoking • Endothelial Dysfunction	• Other: Electronic Hookah Inhalation (+ nicotine) Participants will be instructed to inhale a typical 30-minute session of e-hookah containing nicotine • Other: Electronic Hookah Inhalation (- nicotine) Participants will be instructed to inhale a typical 30-minute session of e-hookah not containing nicotine • Other: Sham Inhalation Participants will be instructed to inhale a 30-minute sham session	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Crossover Assignment Masking: None (Open Label) Primary Purpose: Other Primary Outcome Measures: • Acute effects of e-hookah bowl inhalation on endothelial function. [Time Frame: 30 minutes] Flow-Mediated Dilation (FMD), % from pre- to post-cuff occlusion performed before and after each exposure experiment. • Acute effects of e-hookah bowl inhalation on biomarkers of oxidative stress and inflammation. [Time Frame: 30 minutes] plasma 8-iso-prostaglandin F2 before and after each exposure experiment. • Acute effects of e-hookah bowl inhalation on biomarkers of oxidative stress and inflammation. [Time Frame: 30 minutes] plasma fibrinogen before and after each exposure experiment. • Acute effects of e-hookah bowl inhalation on biomarkers of oxidative stress and inflammation. [Time Frame: 30 minutes] plasma oxidized LDL before and after each exposure experiment. • Acute effects of e-hookah bowl inhalation on endothelial cells [Time Frame: 30 minutes] nitric oxide bioavailability (DAF-2DA) before and after each exposure experiment. • Acute effects of e-hookah bowl inhalation on endothelial cells [Time Frame: 30 minutes] nuclear factor-B activation before and after each exposure experiment. • Acute effects of e-hookah bowl inhalation on endothelial cells [Time Frame: 30 minutes] nitrotyrosine before and after each exposure experiment. Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 18 Original Estimated Enrollment: *Same as current* Age: 21 Years to 39 Years (Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Tobacco Related Disease Research Program	Study Start: November 1, 2019 Primary Completion: April 27, 2023 (Final data collection date for primary outcome measure) Study Completion: April 27, 2023 First Posted: October 21, 2019 Results First Posted: Last Update Posted: September 6, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
14	NCT04852120	Compound Sodium Picosulfate Granules for Bowel Preparation in Chinese Population Study Documents:	Title Acronym: Other Ids: 000373	Recruiting	Bowel Cleansing	Other: No intervention Compound Sodium Picosulfate Granules administered by the patient prior to X-ray examination, endoscopy or surgery when judged clinically necessary in accordance to usual practice consistent with the local prescribing information.	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Prospective Primary Outcome Measures: • Incidence and seriousness of known and unexpected adverse events (AEs)/adverse drug reactions (ADRs) [Time Frame: Up to 37(+2) hours after drug administration] • Incidence, seriousness and relatedness of adverse events of special interest (AESIs) [Time Frame: Up to 37(+2) hours after drug administration] • Incidence of serious adverse events (SAEs)/serious adverse drug reactions (SADRs) [Time Frame: Up to 37(+2) hours after drug administration] • Patients with risk factors for known AEs/ADRs, unexpected AEs/ADRs, AESI, and SAEs/SADRs [Time Frame: Up to 37(+2) hours after drug administration] Number of patients with relevant risk factors for known AEs/ADRs, unexpected AEs/ADRs, AESI, and SAEs/SADRs will be presented. Secondary Outcome Measures: • Number of patients with compliance to drug administration and liquid intake [Time Frame: On Day 1, at time of drug administration] Number of patients with compliance to drug administration and liquid intake will be reported. Non-compliance of drug administration was defined per label as having taken a total amount of medication less than 1.5 sachets. Non-compliance of liquid intake defined per label as having taken less than 5 cups of clear liquid (250mL per cup after the first dose or less than 3 cups of clear liquid (250mL per cup) after the second dose. • Percentage of patients with compliance to drug administration and liquid intake [Time Frame: On Day 1, at time of drug administration] Percentage of patients with compliance to drug administration and liquid intake will be reported. Non-compliance of drug administration was defined per label as having taken a total amount of medication less than 1.5 sachets. Non-compliance of liquid intake defined per label as having taken less than 5 cups of clear liquid (250mL per cup after the first dose or less than 3 cups of clear liquid (250mL per cup) after the second dose. • Patient drug satisfaction [Time Frame: Up to 37(+2) hours after drug administration] A self-satisfaction evaluation will be collected on the electronic Patient Reported Outcomes (ePRO) database: ease of consuming, cleansing level of the colon as reaching the clear yellow liquid poop stage, overall experience as well as willingness and acceptance to use for future bowel preparation. • Number of patients with risk factors associated with drug use, package and distribution [Time Frame: Up to 37(+2) hours after drug administration] This information or any risk will be collected in ePRO database (adverse event part). This information will be sent to Pharmacovigilance department for assessment. • Percentage of patients with risk factors associated with drug use, package and distribution [Time Frame: Up to 37(+2) hours after drug administration] This information or any risk will be collected in ePRO database (adverse event part). This information will be	Actual Enrollment: Estimated Enrollment: 3000 Original Estimated Enrollment: *Same as current* Age: Child, Adult, Older Adult Sex: All	Study Sponsors: *Same as current* Collaborators: DeltaMed	Study Start: September 14, 2021 Primary Completion: December 2022 (Final data collection date for primary outcome measure) Study Completion: December 2022 First Posted: April 21, 2021 Results First Posted: Last Update Posted: September 9, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
15	NCT04613596	Phase 2 Trial of MRTX849 Monotherapy and in Combination With Pembrolizumab for NSCLC With KRAS G12C Mutation KRYSTAL-7 Study Documents:	Title Acronym: Other Ids: 849-007	Recruiting	• Advanced Non-Small Cell Lung Cancer • Metastatic Non-Small Cell Lung Cancer	• Drug: MRTX849 Monotherapy MRTX849 Inhibitor will be administered orally twice daily in a continuous regimen (Cohort 1b). Other Name: Adagrasib • Drug: MRTX849 in Combination with Pembrolizumab MRTX849 Inhibitor will be administered orally twice daily in a continuous regimen. Pembrolizumab is administered as an intravenous infusion once every 3 weeks (Cohort 2). Other Name: Adagrasib • Drug: MRTX849 in Combination with Pembrolizumab MRTX849 Inhibitor will be administered orally twice daily in a continuous regimen. Pembrolizumab is administered as an intravenous infusion once every 3 weeks (Cohort 1a). Other Name: Adagrasib	Study Type: Interventional Phase: Phase 2 Study Design: Allocation: Randomized Intervention Model: Sequential Assignment Intervention Model Description: MRTX849 Monotherapy and in Combination with Pembrolizumab Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: Evaluate the clinical activity of MRTX849 in combination with pembrolizumab [Time Frame: 11 months] Objective Response Rate (ORR) RECIST 1.1 Secondary Outcome Measures: • To characterize the safety and tolerability of the combination regimen in the selected population. [Time Frame: 11 months] • Safety characterized by type, incidence, severity, timing, seriousness and relationship to study treatment of adverse events and laboratory abnormalities. • Duration of Response (DOR) [Time Frame: 11 months] MRTX849 in combination with pembrolizumab	Actual Enrollment: Estimated Enrollment: 250 Original Estimated Enrollment: 120 Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: December 2, 2020 Primary Completion: October 30, 2023 (Final data collection date for primary outcome measure) Study Completion: November 30, 2024 First Posted: November 3, 2020 Results First Posted: Last Update Posted: September 8, 2022
16	NCT05463120	Minipuberty of Infancy and the Timing of Pubertal Development in Adolescence: a Follow-up of the Infant Feeding and Early Development (IFED) Cohort Study Documents:	Title Acronym: Other Ids: 10000945 000945-E	Enrolling by invitation	Puberty	Not Provided	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Prospective Primary Outcome Measures: *Same as current* Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 566 Original Estimated Enrollment: *Same as current* Age: 8 Years and older (Child, Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: September 15, 2022 Primary Completion: March 1, 2024 (Final data collection date for primary outcome measure) Study Completion: March 1, 2024 First Posted: July 18, 2022 Results First Posted: Last Update Posted: September 12, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
17	NCT02535702	Development Of Neuroimaging Methods To Assess The Neurobiology Of Addiction Study Documents:	Title Acronym: Other Ids: 150186 15-AA-0186	Recruiting	Normal Physiology	• Other: In vivo MRS 1H MR spectroscopy to assess brain metabolites. • Other: fMRI Three fMRI sessions to assess test-retest reliability of functional connectivity (FC) measures at rest and during task performance. • Other: EEG/EOG Electroencephalography or electrooculography (EEG/EOG) sessions to record electrical activity of the brain or measure corneo-retinal standing potentials. • Other: Stimulation tasks To be used in the context of fMRI to study blood-oxygenation-level dependent responses in the brain to sensory stimulation. • Other: NSPRD To be used in conjunction with pupillometry in the context of fMRI to study blood-oxygenation-level-dependent responses to selective neurostimulation of pain fibers.	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Basic Science Primary Outcome Measures: • To develop novel neuroimaging techniques with greater sensitivity for future studies on the neurobiology of reward and SUD. [Time Frame: 6 years] • To obtain pilot data to be used for estimating sample sizes in future studies aimed at specifically applying the new tools for studying SUD. [Time Frame: 6 years] Secondary Outcome Measures: Autonomic response data. [Time Frame: Ongoing]	Actual Enrollment: Estimated Enrollment: 360 Original Estimated Enrollment: *Same as current* Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: June 28, 2016 Primary Completion: December 31, 2025 (Final data collection date for primary outcome measure) Study Completion: December 31, 2026 First Posted: August 31, 2015 Results First Posted: Last Update Posted: September 8, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
18	NCT04431453	Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of Remdesivir (GS-5734™) in Participants From Birth to Study Documents:	Title Acronym: Other Ids: GS-US-540-5823 2020-001803-17 (EudraCT Number)	Recruiting	COVID-19	Drug: Remdesivir Administered as an intravenous infusion Other Names: • GS-5734™ • Veklury®	Study Type: Interventional Phase: Phase 2 Phase 3 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: • Proportion of Participants Experiencing any Treatment-Emergent Adverse Events [Time Frame: First dose date up to Day 30 Follow-up Assessment] • Proportion of Participants Experiencing any Treatment-Emergent Graded Laboratory Abnormalities [Time Frame: First dose date up to Day 30 Follow-up Assessment] • Plasma Concentrations of Remdesivir (RDV) and Metabolites [Time Frame: Day 2: end of infusion and 4 hours post end of infusion, Day 3: pre-infusion and 2 hours post end of infusion, and Day 5: middle of infusion and 6 hours post end of infusion; infusion duration: 30 minutes to 2 hours] Plasma concentrations will be drawn as follows: (1) for cohorts 1-4 on Day 2, and Day 3, Day 5 is optional; (2) for cohorts 5-7 on Day 2 or Day 3. Secondary Outcome Measures: • Change From Baseline in Oxygenation Use [Time Frame: Baseline, up to Day 30 Follow-up Assessment] • Change From Baseline in the Use of Mechanical Ventilation or Extracorporeal Membrane Oxygenation (ECMO) [Time Frame: Baseline, up to Day 30 Follow-up Assessment] • Clinical Improvement on a 7-point Ordinal Scale [Time Frame: First dose date up to 10 days] The ordinal scale is an assessment of the clinical status at a given day. Each day, the worst score from the previous day will be recorded. The scale is as follows: 1.) Death 2.) Hospitalized, on invasive mechanical ventilation or Extracorporeal Membrane Oxygenation (ECMO) 3.) Hospitalized, on non-invasive ventilation or high flow oxygen devices 4.) Hospitalized, requiring low flow supplemental oxygen 5.) Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (coronavirus (COVID-19) related or otherwise) 6.) Hospitalized, not requiring supplemental oxygen - no longer required ongoing medical care (other than per protocol Remdesivir administration) 7.) Not hospitalized. • Time (days) to Discharge From Hospital [Time Frame: First dose date up to Day 30 Follow-up Assessment] • Days to First Confirmed Negative Polymerase Chain Reaction (PCR) Result [Time Frame: First dose date up to 10 days] Confirmed negative PCR is defined by 2 consecutive negative PCR results. • Change From Baseline in Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) Viral Load [Time Frame: Baseline, up to 10 days or up to the first confirmed negative PCR results (whichever comes first)] • Bilirubin Concentrations in < 14-day-old Participants [Time Frame: First dose date up to 10 days] • Clinical Improvement Based on Scoring Using the Pediatric Early Warning Score (PEWS) Improvement Scale [Time Frame: First dose date up to 10 days]	Actual Enrollment: Estimated Enrollment: 62 Original Estimated Enrollment: 52 Age: up to 18 Years (Child, Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: July 21, 2020 Primary Completion: February 2023 (Final data collection date for primary outcome measure) Study Completion: February 2023 First Posted: June 16, 2020 Results First Posted: Last Update Posted: September 7, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
19	NCT03633227	Study of Obeticholic Acid (OCA) Evaluating Pharmacokinetics and Safety in Participants With Primary Biliary Cholangitis (PBC) and Hepatic Impairment Study Documents:	Title Acronym: Other Ids: 747-401	Terminated	Liver Cirrhosis, Biliary	• Drug: Obeticholic Acid (OCA) OCA will be administered per dose and schedule specified in the arm description. Other Names: ○ 6alpha-ethylchenodeoxycholic acid (6-ECDCA) ○ INT-747 • Drug: Placebo OCA matching placebo will be administered per the schedule specified in the arm description.	Study Type: Interventional Phase: Phase 4 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) Primary Purpose: Treatment Primary Outcome Measures: • Evaluate maximum concentration (Cmax) of OCA, its conjugates and total OCA (sum of OCA and its conjugates) [Time Frame: Weeks 12, 18, 24, 30 and 48: 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 7, 8, 9, and 24 hours at] • Evaluate area under the concentration curve versus time curve from 0 to 24 hours (AUC 0-24) of OCA, its conjugates and total OCA [Time Frame: 24 hours at Day 1, and Weeks 12, 18, 24, 30, 36, and 48] Area under the concentration versus time curve from time 0 to 24 hours with measurable analyte concentration • Evaluate safety and tolerability as assessed by the incidence of treatment emergent adverse events and serious treatment emergent adverse events comparing OCA to placebo [Time Frame: Baseline, Weeks 3, 6, 12, 18, 24, 30, 36, 42, 48, and every 3 months thereafter through approximately 3 years] Secondary Outcome Measures: • Evaluate the effect of OCA treatment compared to placebo on the model of end-stage liver disease (MELD) and its components [Time Frame: Baseline, Weeks 3, 6, 12, 18, 24, 30, 36, 42, 48, and every 3 months thereafter through approximately 3 years] MELD Scores range from 6 [low risk] to 40 [high risk]. The three components of MELD (total bilirubin [mg/dL], serum creatinine[mg/dL], and INR) are input into the following equation to generate a MELD Score: MELD = 3.78×ln[total bilirubin (mg/dL)] + 11.2×ln[INR] + 9.57×ln[serum creatinine (mg/dL)] + 6.43 • Evaluate the effect of OCA treatment compared to placebo on Child-Pugh score and its components [Time Frame: At Day 1, and Weeks 6, 12, 18, 24, 30, 36, and 48] The 5 components of the Child Pugh Score are scored on a scale of 1-3 by increasing severity and then summed together to calculate the total score (range: 5 [compensated cirrhosis] - 15 [decompensated cirrhosis]). The components of the Child Pugh Score are total bilirubin [mg/dL], serum albumin [g/dL], INR, Ascites [none-severe], hepatic encephalopathy [none-grade 4] • Evaluate the effect of OCA treatment compared to placebo on total bilirubin (mg/dL) and direct bilirubin (mg/dL) [Time Frame: Baseline, Weeks 3, 6, 12, 18, 24, 30, 36, 42, 48, and every 3 months thereafter through approximately 3 years] • Evaluate the effect of OCA treatment compared to placebo on alkaline phosphatase (U/L), alanine aminotransferase (U/L), aspartate transaminase (U/L), and gamma glutamyl transaminase (U/L) [Time Frame: Baseline, Weeks 3, 6, 12, 18, 24, 30, 36, 42, 48, and every 3 months thereafter through approximately 3 years] • Evaluate the effect of OCA treatment compared to placebo on platelets (109/L) [Time Frame: Baseline, Weeks 3, 6, 12, 18, 24, 30, 36, 42, 48, and every 3	Actual Enrollment: 22 Estimated Enrollment: Original Estimated Enrollment: 50 Age: 18 Years to 85 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: June 22, 2018 Primary Completion: July 9, 2021 (Final data collection date for primary outcome measure) Study Completion: July 9, 2021 First Posted: September 6, 2022 Results First Posted: September 6, 2022 Last Update Posted: September 6, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
20	NCT03027388	Protein Phosphatase 2A Inhibitor, in Recurrent Glioblastoma Study Documents:	Title Acronym: Other Ids: 170037 17-C-0037	Recruiting	• Astrocytoma, Grades II, III and IV • Glioblastoma Multiforme • Giant Cell Glioblastoma • Glioma • Oligodendrogliomas	Drug: LB-100 LB-100 will be infused over 2 hours via IV infusion 2 to 4 hours before surgery. The dose established from a Phase I study will be 2.33 mg/m2.	Study Type: Interventional Phase: Phase 2 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Basic Science Primary Outcome Measures: To determine the pharmacodynamic (PD) effect of LB100 by assaying phospho-protein expression in treated glioblastoma tumor tissue compared to untreated tumor samples for comparison. [Time Frame: 8 hours following surgery] Secondary Outcome Measures: • To determine the concentration LB100 and its major metabolite, 7-oxabicyclo heptanes-2,3- dicarboxylic acid (LB100M) inglioblastoma tumor tissue when a known non-toxic dose of LB100 isdelivered intravenously over 2 hours. [Time Frame: 8 hours following surgery] • To determine the plasma concentration and calculated pharmacokinetic (PK) parameters of LB100 and LB100M (endothall) [Time Frame: 8 hours following surgery] • To determine changes in phosphoprotein expression in circulating PBMC. [Time Frame: 8 hours following surgery] • Intra-patient PD effect in PBMC and tumor tissue will be evaluated in all subjects for presence of correlation to identify potential predictive markers. [Time Frame: 8 hours following surgery]	Actual Enrollment: Estimated Enrollment: 25 Original Estimated Enrollment: 20 Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: January 9, 2019 Primary Completion: August 31, 2023 (Final data collection date for primary outcome measure) Study Completion: August 31, 2023 First Posted: January 23, 2017 Results First Posted: Last Update Posted: September 12, 2022
21	NCT03934177	Impact of Blueberry Consumption on Gastrointestinal Health Study Documents:	Title Acronym: Other Ids: 18557	Enrolling by invitation	• Obesity • Circadian Dysregulation	• Dietary Supplement: Blueberry powder Dried, powdered blueberries will be consumed at 24 g/day in two divided doses at least 4 hours apart. • Dietary Supplement: Placebo powder A placebo consisting maltodextrin will be consumed at 24 g/day in two divided doses at least 4 hours apart.	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Crossover Assignment Intervention Model Description: This 14-week crossover study includes 4 weeks for each of the two supplementation periods (blueberries and placebo), with a 4-week wash out between. Masking: Triple (Participant, Investigator, Outcomes Assessor) Masking Description: Participants, investigators, and statistician will blinded to treatment. Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 28 Original Estimated Enrollment: *Same as current* Age: 19 Years to 70 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: • Rush University Medical Center • University of Nebraska	Study Start: March 26, 2019 Primary Completion: May 31, 2023 (Final data collection date for primary outcome measure) Study Completion: May 31, 2023 First Posted: May 1, 2019 Results First Posted: Last Update Posted: September 12, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
22	NCT05455502	A Study to Evaluate the Relative Bioavailability and Food Effect of a New Tablet Formulation of VX-548 Study Documents:	Title Acronym: Other Ids: VX21-548-011	Active, not recruiting	Pain	Drug: VX-548 Tablet for oral administration.	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: Randomized Intervention Model: Crossover Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: 24 Estimated Enrollment: Original Estimated Enrollment: *Same as current* Age: 18 Years to 55 Years (Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: July 13, 2022 Primary Completion: September 2022 (Final data collection date for primary outcome measure) Study Completion: September 2022 First Posted: July 13, 2022 Results First Posted: Last Update Posted: September 8, 2022
23	NCT05319587	Study of Liposomal Annamycin in Combination With Cytarabine for the Treatment of Subjects With Acute Myeloid Leukemia (AML) Study Documents:	Title Acronym: Other Ids: MB-106	Not yet recruiting	Leukemia, Myeloid, Acute	• Drug: Liposomal Annamycin 2-hour intravenous infusion liposomal annamycin daily for 3 consecutive days followed by 18 days off study drug (i.e., one treatment cycle = 21 days). • Drug: Cytarabine Administered during cycle 1 at a dose of 2.0 g/m2/day by 4 hours IV infusion for 5 consecutive days and this dose will remain constant for all cohorts, including the expansion phase.	Study Type: Interventional Phase: Phase 1 Phase 2 Study Design: Allocation: N/A Intervention Model: Sequential Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 63 Original Estimated Enrollment: *Same as current* Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: September 16, 2022 Primary Completion: February 28, 2024 (Final data collection date for primary outcome measure) Study Completion: April 30, 2025 First Posted: April 8, 2022 Results First Posted: Last Update Posted: September 12, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
24	NCT03932331	Study of Acalabrutinib in Chinese Adult Subjects With Relapsed or Refractory Mantle Cell Lymphoma, Chronic Lymphocytic Leukemia or Other B-cell Malignancies Study Documents:	Title Acronym: Other Ids: D8220C00007 2018L02939 (Registry Identifier: CFDA/ NMPA)	Active, not recruiting	• Phase I: Relapsed or Refractory B-cell Malignancies • Phase II Cohort A: Relapsed or Refractory Mantle Cell Lymphoma • Phase II Cohort B: Relapsed or Refractory Chronic Lymphocytic Leukemia	Drug: Acalabrutinib Acalabrutinib 100 mg orally twice daily	Study Type: Interventional Phase: Phase 1 Phase 2 Study Design: Allocation: Non-Randomized Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: • Phase 1: Number of participants with Adverse Events (AEs) [Time Frame: approximately 2 years.] • Phase 2: Overall Response Rate (ORR) [Time Frame: up to 2 years.] • Phase 1: Pharmacokinetics Characterization after single dose, AUC (Area under the plasma concentration-time curve (from zero to infinity)) [Time Frame: approximately 1 month.] • Phase 1: Pharmacokinetics Characterization after single dose, AUC0-12 (Area under the plasma concentration-time curve (from zero to 12 hours)) [Time Frame: approximately 1 month.] • Phase 1: Pharmacokinetics Characterization after single dose, AUC0-t (Area under the plasma concentration-time curve (from zero to the time of the last measurable concentration)) [Time Frame: approximately 1 month.] • Phase 1: Pharmacokinetics Characterization after single dose, Cmax (Maximum observed plasma concentration) [Time Frame: approximately 1 month.] • Phase 1: Pharmacokinetics Characterization after single dose, tmax (Time to maximum concentration) [Time Frame: approximately 1 month.] • Phase 1: Pharmacokinetics Characterization after single dose, CL/F (Oral clearance) [Time Frame: approximately 1 month.] • Phase 1: Pharmacokinetics Characterization after single dose, Vz/F (Volume of distribution) [Time Frame: approximately 1 month.] • Phase 1: Pharmacokinetics Characterization after single dose, z (Terminal rate constant) [Time Frame: approximately 1 month.] • Phase 1: Pharmacokinetics Characterization after single dose, t1/2 (Terminal half life) [Time Frame: approximately 1 month.] • Phase 1: Pharmacokinetics Characterization after single dose, MR_Cmax (metabolite-to-parent ratio, Maximum observed plasma concentration) [Time Frame: approximately 1 month.] • Phase 1: Pharmacokinetics Characterization after single dose, MR_AUC (metabolite-to-parent ratio, Area under the plasma concentration-time curve (from zero to infinity)) [Time Frame: approximately 1 month.] • Phase 1: Pharmacokinetics Characterization after multiple doses, AUC,ss (Area under the plasma concentration-time curve across the dosing interval at steady state) [Time Frame: approximately 1 month.] • Phase 1: Pharmacokinetics Characterization after multiple doses, Cmax,ss (Maximum observed plasma concentration at steady state) [Time Frame: approximately 1 month.] • Phase 1: Pharmacokinetics Characterization after multiple doses, Cmin,ss (Minimum observed plasma drug concentration at steady state) [Time Frame: approximately 1 month.] • Phase 1: Pharmacokinetics Characterization after	Actual Enrollment: 105 Estimated Enrollment: Original Estimated Enrollment: 45 Age: 18 Years to 130 Years (Adult, Older Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: Not Provided	Study Start: April 29, 2020 Primary Completion: June 28, 2022 (Final data collection date for primary outcome measure) Study Completion: December 29, 2023 First Posted: April 30, 2019 Results First Posted: Last Update Posted: September 8, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
25	NCT05532358	A Drug-Drug Interaction Study to Assess the CYP1A2 and CYP3A4 Interaction Potential of TEV-56286 (anle138b) Study Documents:	Title Acronym: Other Ids: anle138b-P1-03 2022-002467-30 (EudraCT Number)	Not yet recruiting	Healthy: Drug-drug Interaction	• Drug: Anle138b (TEV-56286) Anle138b (TEV-56286) as perpetrator Other Names: ○ Caffeine ○ Midazolam ○ Fluvoxamine • Drug: Fluvoxamine 100 mg QD for 5 days Anle138b (TEV-56286) as victim Other Name: TEV-56286 150 mg QD for 14 days + 5 days of co-administation with fluvoxamine	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: Non-Randomized Intervention Model: Single Group Assignment Intervention Model Description: Drug drug interaction study Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: *Same as current* Secondary Outcome Measures: *Same as current*	Actual Enrollment: Estimated Enrollment: 56 Original Estimated Enrollment: *Same as current* Age: 18 Years to 55 Years (Adult) Sex: All	Study Sponsors: *Same as current* Collaborators: • Aptuit (Verona) Srl, an Evotec Company • Quotient Sciences • Teva Pharmaceutical Industries, Ltd.	Study Start: September 12, 2022 Primary Completion: December 2022 (Final data collection date for primary outcome measure) Study Completion: December 2022 First Posted: September 8, 2022 Results First Posted: Last Update Posted: September 8, 2022