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	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
1	NCT03573349	Ketamine Associated ACC GABA and Glutamate Change and Depression Remission: Study Documents:	Title Acronym: Other Ids: 17-011373	Enrolling by invitation	<ul style="list-style-type: none">Major Depressive DisorderTreatment Resistant DepressionBipolar Depression	Drug: Ketamine We will enroll 20 adults (aged 18-65 years) with treatment-resistant depression and will provide two i.v. ketamine infusions (0.5 mg/kg, infused over 40 minutes) and measure their depressive symptom responses. Biomarkers will be developed using blood samples from study subjects, taken prior to (predictive biomarkers), and following ketamine treatment (change biomarkers). This will be an open-label feasibility trial.	Study Type: Interventional Phase: Early Phase 1 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: Glutamate [Time Frame: 1 day] Evaluate change in central glutamate and peripheral glutamate with MRS after a single 40-minute infusion of i.v. racemic ketamine Secondary Outcome Measures: Mood [Time Frame: 1 day] Measure the change in depression symptoms using MADRS scale in participants with treatment-resistant major depression before receiving and 24 hours after the Ketamine infusion	Actual Enrollment: Estimated Enrollment: 20 Original Estimated Enrollment: 10 Age: 18 Years to 65 Years (Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: January 3, 2019 Primary Completion: December 2023 (Final data collection date for primary outcome measure) Study Completion: December 2023 First Posted: June 29, 2018 Results First Posted: Last Update Posted: September 14, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
2	NCT03492177	A Clinical Study of to Confirm the Doses of Selexipag in Children With Pulmonary Arterial Hypertension Study Documents:	Title Acronym: Other Ids: AC-065A203 2018-000145-39 (EudraCT Number) AC-065A203 (Other Identifier: Actelion)	Active, not recruiting	Pulmonary Arterial Hypertension	Drug: selexipag (Uptravi) Film-coated tablets for oral administration Other Names: <ul style="list-style-type: none">ACT-293987JNJ-67896049	<div>Study Type: Interventional</div> <div>Phase: Phase 2</div> <div>Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment</div> <div>Primary Outcome Measures: Area under the plasma concentration-time curve over a dose interval at steady state of selexipag and ACT-333679 combined (AUC,ss, combined) [Time Frame: PK sampling at Week 1 (or Week 12) at pre-dose, 1, 2, 4, 6, 8, and 12 post-morning dose as well as Weeks 2, 4 and 6 (prior to morning dose)] The AUC,ss,combined is the sum of the selexipag and ACT-333679 exposures weighted by their potency ratio, and determined during the 12 weeks up-titration period. The model will describe the body weight dependence of dose-exposure relationship for pediatric PAH patients. Blood samples for pharmacokinetic analyses will be collected in the 3 age cohorts.</div> <div>Secondary Outcome Measures:<ul style="list-style-type: none">Area under the plasma concentration-time curve over a dose interval at steady state (AUC,ss) of selexipag [Time Frame: PK sampling at Week 1 (or Week 12) at pre-dose, 1, 2, 4, 6, 8, and 12 post-morning dose as well as Weeks 2, 4 and 6 (prior to morning dose)] The AUC,ss for selexipag is calculated by non compartmental analysis to determine the total exposure to selexipag over a dosing intervalArea under the plasma concentration-time curve over a dose interval at steady state (AUC,ss) of ACT-333679 [Time Frame: PK sampling at Week 1 (or Week 12) at pre-dose, 1, 2, 4, 6, 8, and 12 post-morning dose as well as Weeks 2, 4 and 6 (prior to morning dose)] The AUC,ss for ACT-333679 is calculated by non compartmental analysis to determine the total exposure to ACT-333679 over a dosing intervalMaximum observed plasma concentration (Cmax,ss) of selexipag at steady state [Time Frame: PK sampling at Week 1 (or Week 12) at pre-dose, 1, 2, 4, 6, 8, and 12 post-morning dose as well as Weeks 2, 4 and 6 (prior to morning dose)] Cmax,ss of selexipag is directly obtained from the selexipag concentrations measured in the blood samples collected after at least 3 days on the same dose in order to reach steady stateMaximum observed plasma concentration (Cmax,ss) of ACT-333679 at steady state [Time Frame: PK sampling at Week 1 (or Week 12) at pre-dose, 1, 2, 4, 6, 8, and 12 post-morning dose as well as Weeks 2, 4 and 6 (prior to morning dose)] Cmax,ss of ACT-333679 is directly obtained from the ACT-333679 concentrations measured in the blood samples collected after at least 3 days on the same dose in order to reach steady stateTime to the maximum observed plasma concentration (tmax,ss) of selexipag at steady state [Time Frame: PK sampling at Week 1 (or Week 12) at pre-dose, 1, 2, 4, 6, 8, and 12 post-morning dose as well as Weeks 2, 4 and 6 (prior to morning dose)] tmax,ss of selexipag is directly obtained from the selexipag concentrations measured in the blood samples collected after at least 3 days on the same dose in order to reach steady stateTime to the maximum observed plasma concentration (tmax,ss) of ACT-333679 at steady state [Time Frame: PK sampling at Week 1 (or Week 12) at pre-dose, 1, 2, 4, 6, 8, and 12 post-morning dose as well as Weeks 2, 4 and 6 (prior to morning dose)] tmax,ss of ACT-333679 is directly obtained from the ACT-333679 concentrations measured in the blood samples collected after at least 3 days on the same dose in order to reach steady state</div>	<div>Actual Enrollment: 63</div> <div>Estimated Enrollment:</div> <div>Original Estimated Enrollment: 55</div> <div>Age: 2 Years to 17 Years (Child)</div> <div>Sex: All</div>	<div>Study Sponsors: Same as current</div> <div>Collaborators: Not Provided</div>	<div>Study Start: July 23, 2018</div> <div>Primary Completion: April 18, 2022 (Final data collection date for primary outcome measure)</div> <div>Study Completion: December 9, 2026</div> <div>First Posted: April 10, 2018</div> <div>Results First Posted:</div> <div>Last Update Posted: September 14, 2022</div>

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3	NCT05480488	A Study to Examine the Effect of Daridorexant on the Way the Body Absorbs, Distributes, and Gets Rid of Midazolam and Warfarin in Healthy Male Subjects Study Documents:	Title Acronym: Other Ids: ID-078-126	Recruiting	Healthy	<ul style="list-style-type: none">Drug: Midazolam Subjects will receive a single oral dose of 2 mg midazolam (Treatment A, B, and C).Drug: Warfarin Subjects will receive a single oral dose of 25 mg warfarin (Treatment A and B).Drug: Daridorexant Subjects will receive an o.d. oral dose of 50 mg daridorexant from Day 1 to Day 7 of Treatment B and a single oral dose of 50 mg daridorexant on Day 1 of Treatment C.	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: N/A Intervention Model: Sequential Assignment Intervention Model Description: This is a prospective, open-label, fixed-sequence Phase 1 study. Masking: None (Open Label) Primary Purpose: Other Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 18 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years to 45 Years (Adult) Sex: Male	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: August 23, 2022 Primary Completion: September 15, 2022 (Final data collection date for primary outcome measure) Study Completion: September 15, 2022 First Posted: July 29, 2022 Results First Posted: Last Update Posted: September 13, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
4	NCT05414084	Aggregate Metabolic Phenotypes for (Poly)Phenols: Development of an Oral (Poly)Phenol Challenge Test (OPCT) Study Documents:	Title Acronym: Other Ids: 1352/2020/SPER/UNIPR	Recruiting	<ul style="list-style-type: none">Individual Variability in (Poly)Phenol MetabolismCardiometabolic Health	Dietary Supplement: Oral (poly)phenol challenge test (OPCT) Nutritional challenge with standardized (poly)phenol-rich tablets	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: <i>Same as current</i> Secondary Outcome Measures: <ul style="list-style-type: none">Assessing common cardiometabolic health biomarkers in blood samples [Time Frame: Baseline] Samples will be processed for the analysis of common biomarkers of cardiometabolic health: total cholesterol (mg/dL), HDL-cholesterol (mg/dL), triglycerides (mg/dL), glucose (mg/dL), insuline (uUI/mL). Analyses will follow standardised routine procedures.Assessing risk prediction scores [Time Frame: Baseline] Risk prediction scores (i.e., Framingham General Cardiovascular Risk Score, Framingham Heart Study Primary Risk Functions for heart disease, stroke, diabetes, fatty liver disease, and hypertension, Atherosclerotic Cardiovascular Disease (ASCVD) Risk, QRISK3®, QDScore®, Finnish Diabetes Risk Score (FINDRISC)) will be assessed to understand their relationship with the aggregate phenolic metabotypes observed. The higher the scores, the worse the risk of developing the disease.Evaluating trimethylamine N-oxide (TMAO) in urine and plasma samples [Time Frame: Baseline] TMAO will be quantified in baseline urine and fasting plasma samples by UHPLC-MS/MS.Evaluating eicosanoids in urine samples [Time Frame: Baseline] Eicosanoids, including prostaglandins, thromboxanes, leukotrienes, isoprostanes and neuroprostanes will be evaluated in baseline urine samples (0-h) by UHPLC-QqQ-MS/MS.Assessing DNA oxidation catabolites and branched fatty acyl esters of hydroxyl fatty acids (FAHFAs) in plasma samples [Time Frame: Baseline] DNA oxidation catabolites and FAHFAs will be measured in fasting plasma samples by UHPLC-QqQ-MS/MS.Determining genetic differences among subjects [Time Frame: Baseline] Genotyping will be conducted using genome wide, SNP array approach untargeted methodology, using commercially available SNP arrays and a tSNP approach. This approach will involve the genotyping of approximately 300 SNPs. Genomic DNA will be prepared from PBMCs isolated from blood samples.Assessing transcriptomic signatures in peripheral blood mononuclear cells (PBMCs). [Time Frame: Baseline] Specific patterns of gene expression related to each metabotype will be investigated in PBMCs by using a microarray-based approach. Analysis will be carried out in a subset of 10 samples for each metabotype.Determining gut microbiota composition and functionality in fecal samples [Time Frame: Baseline] Microbial profiling will be assessed by shallow shotgun metagenomics. Full shotgun metagenomics analysis will be carried out to determine functional pathways.Assessing dietary habits [Time Frame: Baseline]	Actual Enrollment: Estimated Enrollment: 300 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years to 74 Years (Adult, Older Adult) Sex: All	Study Sponsors: <i>Same as current</i> Collaborators: <ul style="list-style-type: none">Azienda Ospedaliero-Universitaria di ParmaUniversity of BirminghamCentro de Edafología y Biología Aplicada del Segura (CEBAS-CSIC)	Study Start: May 31, 2022 Primary Completion: April 2023 (Final data collection date for primary outcome measure) Study Completion: April 2023 First Posted: June 10, 2022 Results First Posted: Last Update Posted: September 16, 2022

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5	NCT05537090	A Study to Assess Effect of BV100 on the Pharmacokinetics of Midazolam in Healthy Participants Study Documents:	Title Acronym: Other Ids: BV100-005	Recruiting	Healthy Volunteers	<ul style="list-style-type: none">Drug: BV100 Rifabutin for InfusionDrug: Midazolam Syrup for oral administration	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: N/A Intervention Model: Sequential Assignment Intervention Model Description: This is an open-label, 3 period fixed-sequence, Phase 1 clinical study to evalu-ate the effect of multiple doses of BV100 on the Pharmacokinetics on midazo-lam and its metabolite 1-hydroxymidazolam in healthy volunteers. Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 16 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years to 55 Years (Adult) Sex: All	Study Sponsors: Same as current Collaborators: CRU Hungary Kft	Study Start: September 1, 2022 Primary Completion: October 30, 2022 (Final data collection date for primary outcome measure) Study Completion: December 30, 2022 First Posted: September 13, 2022 Results First Posted: Last Update Posted: September 15, 2022
6	NCT05489744	Human Mass Balance and Biotransformation Study of [14C]Afuresertib Study Documents:	Title Acronym: Other Ids: LAE002CN1001	Recruiting	Healthy Volunteer	Drug: [14C]Afuresertib Suspension containing approximately 125 mg of Afuresertib (containing 150 µCi of [14C]Afuresertib) is administered orally on an empty stomach, with approximately 240 mL of water for suspending and drug taking. Other Name: [14C]LAE002	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Other Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 10 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years to 45 Years (Adult) Sex: Male	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: July 28, 2022 Primary Completion: March 2023 (Final data collection date for primary outcome measure) Study Completion: May 2023 First Posted: August 5, 2022 Results First Posted: Last Update Posted: September 13, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
7	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: <i>Same as current</i> Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 4000 Original Estimated Enrollment: <i>Same as current</i> Age: 12 Years to 30 Years (Child, Adult) Sex: All	Study Sponsors: <i>Same as current</i> 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 10, 2022
8	NCT02932410	A Study to Assess Whether Macitentan Delays Disease Progression in Children With Pulmonary Arterial Hypertension (PAH) Study Documents:	Title Acronym: Other Ids: AC-055-312	Recruiting	Pulmonary Arterial Hypertension	<ul style="list-style-type: none">Drug: Macitentan Dispersible tablet; Oral use Other Name: ACT-064992Other: Standard-of-care Standard-of-care as per site's clinical practice which may comprise treatment with PAH non-specific treatment and/or up to two PAH-specific medications excluding macitentan and IV/SC prostanoids.	Study Type: Interventional Phase: Phase 3 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: Time to the first CEC-confirmed disease progression event [Time Frame: Between randomization and EOS/study closure; up to 6 years] Time to the first of the following CEC-confirmed disease progression events: • Death (all causes) • Atrial septostomy or Potts' anastomosis, or registration on lung transplant list • Hospitalization due to worsening PAH • Clinical worsening of PAH Secondary Outcome Measures: <ul style="list-style-type: none">Time to first CEC-confirmed hospitalization for PAH occurring between randomization and EOS [Time Frame: Between randomization and EOS/study closure; up to 6 years]Time to CEC-confirmed death due to PAH occurring between randomization and EOS [Time Frame: Between randomization and EOS/study closure; up to 6 years]Time to death (all causes) occurring between randomization and Study Closure [Time Frame: Between randomization and EOS/study closure; up to 6 years]	Actual Enrollment: Estimated Enrollment: 300 Original Estimated Enrollment: <i>Same as current</i> Age: 1 Month to 17 Years (Child) Sex: All	Study Sponsors: <i>Same as current</i> Collaborators: Not Provided	Study Start: October 24, 2017 Primary Completion: February 29, 2024 (Final data collection date for primary outcome measure) Study Completion: February 29, 2024 First Posted: October 13, 2016 Results First Posted: Last Update Posted: September 14, 2022

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9	NCT03218761	POTS NET mRNA Functional Correlation With NET Activity Study Documents:	Title Acronym: Other Ids: IRB#170714	Enrolling by invitation	Postural Tachycardia Syndrome	<ul style="list-style-type: none">Diagnostic Test: NET mRNA level quantification of mRNA to the Norepinephrine Transporter (NET)Diagnostic Test: Plasma catechols plasma for assay of norepinephrine (NE), DHPG (intraneuronal metabolite of NE), and other catecholsDiagnostic Test: Urine Catechols urine for assay of norepinephrine (NE), DHPG (intraneuronal metabolite of NE), and other catechols	Study Type: Observational [Patient Registry] Phase: Study Design: Observational Model: Cohort Time Perspective: Prospective Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 200 Original Estimated Enrollment: <i>Same as current</i> Age: 13 Years to 80 Years (Child, Adult, Older Adult) Sex: All	Study Sponsors: <i>Same as current</i> Collaborators: <ul style="list-style-type: none">National Institute of Neurological Disorders and Stroke (NINDS)University of CalgaryDysautonomia International	Study Start: July 14, 2017 Primary Completion: December 31, 2025 (Final data collection date for primary outcome measure) Study Completion: December 31, 2025 First Posted: July 17, 2017 Results First Posted: Last Update Posted: September 14, 2022
10	NCT05041348	Metabonomic of Patients With Hepatitis B Cirrhosis Complicated With Sarcopenia. Study Documents:	Title Acronym: Other Ids: QYFYWZLL26461	Completed	Sarcopenia	Diagnostic Test: CT at the level of the third lumbar vertebra (L3) Muscle mass loss was defined as an skeletal muscle mass index (SMI) less than 46.96 cm²/m² for males and less than 32.46 cm²/m² for females	Study Type: Observational Phase: Study Design: Observational Model: Case-Control Time Perspective: Cross-Sectional Primary Outcome Measures: <ul style="list-style-type: none">amino acids [Time Frame: 2021.09.01-2022.08.01] Amino acids, especially BCCAs, is involved in muscle protein synthesis. So it is important for maintaining and increasing muscle mass . The concentration(μmol/L) of amino acids in the blood will be different in the three groups, especially amino acids associated with muscle metabolism.myostatin [Time Frame: 2021.09.01-2022.08.01] increased myostatin levels contribute to muscle loss. So the concentration(pg/mL) of myostatin predicts to be higher in the sarcopenia patients. Secondary Outcome Measures: Not Provided	Actual Enrollment: 60 Estimated Enrollment: Original Estimated Enrollment: 90 Age: 18 Years to 60 Years (Adult) Sex: All	Study Sponsors: <i>Same as current</i> Collaborators: Not Provided	Study Start: August 17, 2021 Primary Completion: July 15, 2022 (Final data collection date for primary outcome measure) Study Completion: August 17, 2022 First Posted: September 13, 2021 Results First Posted: Last Update Posted: September 15, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
11	NCT05543369	Study to Compare the Level of Elafibranor in Blood After Repeat Administration in Japanese and Non-Asian Healthy Participants Study Documents:	Title Acronym: Other Ids: CLIN-60190-450	Not yet recruiting	Healthy Volunteers	Drug: Elafibranor Oral Tablet Other Name: GFT505	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: Non-Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Other Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 48 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years to 55 Years (Adult) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: September 15, 2022 Primary Completion: December 23, 2022 (Final data collection date for primary outcome measure) Study Completion: December 23, 2022 First Posted: September 16, 2022 Results First Posted: Last Update Posted: September 16, 2022
12	NCT05199610	An Open-Label, Single-Dose, Parallel-Group Study of the Pharmacokinetics and Safety of EQ143 Study Documents:	Title Acronym: Other Ids: EQ143-102	Recruiting	Severe Hepatic Impairment	Drug: aumolertinib A single dose of 55-mg EQ143 tablet will be administered in the morning on Day 1, and participants will remain for 5 days (4 nights) in the study center for collection of blood samples and safety monitoring. Participants will attend outpatient follow-up visits on Days 5, 6, 8, and 9 for additional blood sampling and safety assessments. Other Name: HS-10296	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 12 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years to 75 Years (Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: March 22, 2022 Primary Completion: December 2022 (Final data collection date for primary outcome measure) Study Completion: December 2022 First Posted: January 20, 2022 Results First Posted: Last Update Posted: September 13, 2022

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13	NCT04448392	Valacyclovir in Neonatal Herpes Simplex Virus Disease Study Documents:	Title Acronym: Other Ids: 300005567	Recruiting	Neonatal Herpes Simplex Infection	Drug: Valacyclovir Upon completion of standard of care acyclovir for treatment of neonatal HSV disease, valacyclovir oral suspension (per ASHP recipe), 20 mg/kg every 8 hours, to be given for 2 (up to 7) days	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Other Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 10 Original Estimated Enrollment: <i>Same as current</i> Age: 2 Weeks to 12 Weeks (Child) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: July 1, 2021 Primary Completion: October 2025 (Final data collection date for primary outcome measure) Study Completion: November 2025 First Posted: June 25, 2020 Results First Posted: Last Update Posted: September 13, 2022

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14	NCT03370991	Blueberries for Improving Vascular Endothelial Function in Postmenopausal Women With Elevated Blood Pressure Study Documents:	Title Acronym: Other Ids: 1255927	Completed	<ul style="list-style-type: none">MenopauseElevated Blood PressureHypertensionEndothelial Dysfunction	<ul style="list-style-type: none">Dietary Supplement: Blueberry Powder 22 g/day freeze-dried blueberry powder for 12 weeksDietary Supplement: Placebo Powder 22 g/day placebo powder for 12 weeks	<p>Study Type: Interventional</p> <hr/> <p>Phase: Not Applicable</p> <hr/> <p>Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Triple (Participant, Investigator, Outcomes Assessor) Primary Purpose: Treatment</p> <hr/> <p>Primary Outcome Measures:</p> <ul style="list-style-type: none">Endothelium-dependent dilation [Time Frame: Baseline] Assessed as brachial artery flow-mediated dilationEndothelium-dependent dilation [Time Frame: 12 weeks] Assessed as brachial artery flow-mediated dilationEndothelium-independent dilation [Time Frame: Baseline] Assessed as brachial artery diameter responses to sublingual nitroglycerinEndothelium-independent dilation [Time Frame: 12 weeks] Assessed as brachial artery diameter responses to sublingual nitroglycerin <hr/> <p>Secondary Outcome Measures:</p> <ul style="list-style-type: none">Vascular oxidative stress [Time Frame: Baseline and 12 weeks] Change in brachial artery flow-mediated dilation following acute infusion of ascorbic acid (a dose known to scavenge superoxide) as an index of vascular oxidative stressEndothelial cell nitric oxide production, oxidative stress, and inflammation [Time Frame: Baseline and 12 weeks] Protein expression markers will be measured by quantitative immunofluorescence in biopsied venous endothelial cellsSystemic markers of cardiometabolic health [Time Frame: Baseline and 12 weeks] Circulating markers of lipid and glucose metabolism, nitric oxide, and inflammationPlasma blueberry polyphenol metabolites [Time Frame: Baseline and 12 weeks] Targeted analysis of plasma metabolites by GC-MS and LC-MSPeripheral blood mononuclear cell inflammation and oxidative stress [Time Frame: Baseline and 12 weeks] Exploratory measures analyzed by flow cytometryEpisodic memory [Time Frame: Baseline and 12 weeks] Exploratory measures assessed using the NIH Cognitive Toolbox iPad appExecutive function and attention [Time Frame: Baseline and 12 weeks] Exploratory measures assessed using the NIH Cognitive Toolbox iPad appWorking memory [Time Frame: Baseline and 12 weeks] Exploratory measures assessed using the NIH Cognitive Toolbox iPad appLanguage [Time Frame: Baseline and 12 weeks] Exploratory measures assessed using the NIH Cognitive Toolbox iPad appProcessing speed [Time Frame: Baseline and 12 weeks]	<p>Actual Enrollment: 43</p> <hr/> <p>Estimated Enrollment:</p> <hr/> <p>Original Estimated Enrollment: 58</p> <hr/> <p>Age: 45 Years to 65 Years (Adult, Older Adult)</p> <hr/> <p>Sex: Female</p>	<p>Study Sponsors: Same as current</p> <hr/> <p>Collaborators: U.S. Highbush Blueberry Council</p>	<p>Study Start: December 2, 2017</p> <hr/> <p>Primary Completion: September 30, 2021 (Final data collection date for primary outcome measure)</p> <hr/> <p>Study Completion: September 30, 2021</p> <hr/> <p>First Posted: December 13, 2017</p> <hr/> <p>Results First Posted:</p> <hr/> <p>Last Update Posted: September 14, 2022</p>

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15	NCT05365451	Pharmacokinetic Drug-Drug Interaction Study to Identify Biomarkers of Kidney Transporters Study Documents:	Title Acronym: Other Ids: 19163 R01HD081299 (U.S. NIH Grant/Contract)	Recruiting	<ul style="list-style-type: none">InteractionEndogenous Biomarkers	<ul style="list-style-type: none">Drug: MetFORMIN Oral Solution liquid Other Name: RiometDrug: Cimetidine 400 MG tablet Other Name: TagametDrug: Furosemide Oral Liquid Product oral solution Other Name: LasixDrug: Probenecid 500 MG tablet Other Name: Probalan	Study Type: Interventional Phase: Early Phase 1 Study Design: Allocation: Non-Randomized Intervention Model: Crossover Assignment Masking: None (Open Label) Primary Purpose: Basic Science Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 32 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years to 65 Years (Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: <ul style="list-style-type: none">Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)National Institutes of Health (NIH)	Study Start: April 11, 2022 Primary Completion: June 30, 2023 (Final data collection date for primary outcome measure) Study Completion: June 30, 2024 First Posted: May 9, 2022 Results First Posted: Last Update Posted: September 14, 2022
16	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: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 18 Original Estimated Enrollment: <i>Same as current</i> 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 16, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
17	NCT04540744	A Study of Macitentan/Tadalafil Combination Administered a Fixed-dose Combination Formulation Compared to the Reference Free Combination of Macitentan and Tadalafil Study Documents:	Title Acronym: Other Ids: CR108794 2020-000566-42 (EudraCT Number) 67896062PAH1001 (Other Identifier: Janssen Research & Development, LLC)	Completed	Healthy	<ul style="list-style-type: none">Drug: FDC of macitentan/tadalafil (10 mg/20 mg) FDC of macitentan/tadalafil (10 mg/20 mg) tablet will be administered orally as per assigned treatment sequence. Other Names:<ul style="list-style-type: none">OpsumitAdcircaDrug: Macitentan 10 mg Macitentan 10 mg tablet will be administered orally as a free combination as per assigned treatment sequence. Other Name: OpsumitDrug: Tadalafil 20 mg Tadalafil 20 mg tablet will be administered orally as a free combination as per assigned treatment sequence. Other Name: Adcirca	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: Randomized Intervention Model: Crossover Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: 18 Estimated Enrollment: Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years to 55 Years (Adult) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: April 30, 2021 Primary Completion: August 8, 2021 (Final data collection date for primary outcome measure) Study Completion: August 30, 2021 First Posted: September 7, 2020 Results First Posted: Last Update Posted: September 14, 2022
18	NCT05490888	Single Dose Escalation of PHIN-214 in Child-Pugh A and B Liver Cirrhotics Study Documents:	Title Acronym: Other Ids: PHIN-001	Recruiting	<ul style="list-style-type: none">Cirrhosis, LiverLiver FibrosisAscites Hepatic	Drug: PHIN-214 Subcutaneous injection Single subcutaneous injection with PHIN-214 terlipressin derivative, single ascending dose Other Name: Terlipressin derivative	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: N/A Intervention Model: Sequential Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 13 Original Estimated Enrollment: <i>Same as current</i> Age: 18 Years to 70 Years (Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: January 3, 2022 Primary Completion: December 31, 2022 (Final data collection date for primary outcome measure) Study Completion: February 28, 2023 First Posted: August 8, 2022 Results First Posted: Last Update Posted: September 13, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
19	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: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 50 Original Estimated Enrollment: <i>Same as current</i> 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 10, 2022
20	NCT00687765	Study of the Poly (ADP-ribose) Polymerase-1 (PARP-1) Inhibitor BSI-201 in Patients With Newly Diagnosed Malignant Glioma Study Documents:	Title Acronym: Other Ids: TCD11616 20070104 (Other Identifier: BiPar)	Completed	Glioblastoma	Drug: bsi-201 plus temozolomide BSI-201 given iv. 2x weekly, temozolomide given orally	Study Type: Interventional Phase: Phase 1 Phase 2 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: Not Provided	Actual Enrollment: 126 Estimated Enrollment: Original Estimated Enrollment: 100 Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: BiPar Sciences Collaborators: Not Provided	Study Start: July 2008 Primary Completion: June 2015 (Final data collection date for primary outcome measure) Study Completion: June 2015 First Posted: June 2, 2008 Results First Posted: Last Update Posted: September 14, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
21	NCT05307692	A Study of Seltorexant in Participants With Probable Alzheimer's Disease Study Documents:	Title Acronym: Other Ids: CR109177 42847922ALZ2001 (Other Identifier: Janssen Research and Development, LLC)	Recruiting	Alzheimer Disease	<ul style="list-style-type: none">Drug: Seltorexant Seltorexant 20 mg will be administered orally as a tablet. Other Name: JNJ-42847922Drug: Placebo Matching placebo will be administered orally as a tablet.	Study Type: Interventional Phase: Phase 2 Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Double (Participant, Investigator) Primary Purpose: Treatment Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 86 Original Estimated Enrollment: <i>Same as current</i> Age: 55 Years to 85 Years (Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: May 19, 2022 Primary Completion: April 19, 2023 (Final data collection date for primary outcome measure) Study Completion: April 19, 2023 First Posted: April 1, 2022 Results First Posted: Last Update Posted: September 15, 2022
22	NCT05541887	Use Muscadine Wine and Nutraceuticals to Improve Brain Health, Cognition, and Mental Health Study Documents:	Title Acronym: Other Ids: IRB202201851	Not yet recruiting	<ul style="list-style-type: none">Cognitive PerformanceMemoryMoodAnxiety	<ul style="list-style-type: none">Other: Muscadine Wine 12% ABV red muscadine wineOther: Muscadine Juice Muscadine juiceOther: Vodka Control for muscadine wine with matching alcohol content and color Other Name: Alcohol ControlOther: Sprite Control for muscadine juice with matching sugar content and color Other Name: Juice Control	Study Type: Interventional Phase: Not Applicable Study Design: Allocation: Randomized Intervention Model: Crossover Assignment Masking: Single (Participant) Primary Purpose: Supportive Care Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: Estimated Enrollment: 28 Original Estimated Enrollment: <i>Same as current</i> Age: 50 Years to 65 Years (Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: December 2022 Primary Completion: December 2023 (Final data collection date for primary outcome measure) Study Completion: March 2024 First Posted: September 15, 2022 Results First Posted: Last Update Posted: September 15, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
23	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: 10000945000945-E	Enrolling by invitation	Puberty	Not Provided	Study Type: Observational Phase: Study Design: Observational Model: Cohort Time Perspective: Prospective Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: Not Provided	Actual Enrollment: Estimated Enrollment: 566 Original Estimated Enrollment: <i>Same as current</i> Age: 8 Years and older (Child, Adult, Older Adult) Sex: All	Study Sponsors: <i>Same as current</i> Collaborators: Not Provided	Study Start: September 21, 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 16, 2022
24	NCT03773666	A Feasibility Study of Durvalumab +/- Oleclumab as Neoadjuvant Therapy for Muscle-invasive Bladder Cancer (BLASST-2) Study Documents:	Title Acronym: Other Ids: 18-507	Completed	Muscle Invasive Bladder Cancer	<ul style="list-style-type: none">Drug: Durvalumab Durvalumab is a monoclonal antibody (an antibody is a protein produced by the body's immune system) that works by blocking the Programmed Cell Death Ligand 1 (PD-L1), a protein on cancer cells that stops the body's immune system from killing cancer cells. Other Name: MEDI4736Drug: Oleclumab Oleclumab is a monoclonal antibody that works by reducing the amount of adenosine, a small molecule called a metabolite that binds to adenosine receptors on immune cells to regulate the immune system and suppress the immune response. Reducing the amount of immunosuppressive adenosine can increase the body's immune response to kill cancer cells. Other Name: MEDI9447	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: <i>Same as current</i> Secondary Outcome Measures: <i>Same as current</i>	Actual Enrollment: 12 Estimated Enrollment: Original Estimated Enrollment: 24 Age: 18 Years and older (Adult, Older Adult) Sex: All	Study Sponsors: <i>Same as current</i> Collaborators: AstraZeneca	Study Start: February 20, 2019 Primary Completion: February 4, 2021 (Final data collection date for primary outcome measure) Study Completion: August 2, 2021 First Posted: December 12, 2018 Results First Posted: Last Update Posted: September 13, 2022

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
25	NCT03934307	A Study to Evaluate ALN-AGT01 in Patients With Hypertension Study Documents:	Title Acronym: Other Ids: ALN-AGT01-001 2019-000129-39 (EudraCT Number)	Active, not recruiting	Hypertension	<ul style="list-style-type: none">Drug: ALN-AGT01 ALN-AGT01 will be administered by subcutaneous (SC) injection. Other Name: ZilebesiranDrug: ALN-AGT01-Matching Placebo Normal saline (0.9% NaCl) matching volume of ALN-AGT01 doses will be administered SC.Drug: Irbesartan Irbesartan will be administered orally.Drug: Irbesartan-Matching Placebo Irbesartan-matching placebo will be administered orally.	<div>Study Type: Interventional</div> <div>Phase: Phase 1</div> <div>Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) Primary Purpose: Treatment</div> <div>Primary Outcome Measures: Number of Participants with Adverse Events (AEs) [Time Frame: Parts A and B: each up to approximately 12 months; Parts C and D: each up to approximately 18 months]</div> <div>Secondary Outcome Measures:<ul style="list-style-type: none">Change from Baseline in Blood Angiotensinogen (AGT) Level [Time Frame: Parts A and B: each up to approximately 12 months; Parts C and D: each up to approximately 18 months]Maximum Observed Plasma Concentration (Cmax) of ALN-AGT01 and of Potential Metabolites [Time Frame: Parts A and B: Up to day 15; Parts C and D: Up to day 99]Time to Maximum Observed Plasma Concentration (tmax) of ALN-AGT01 and of Potential Metabolites [Time Frame: Parts A and B: Up to day 15; Parts C and D: Up to day 99]Elimination Half-life (t1/2beta) of ALN-AGT01 and of Potential Metabolites [Time Frame: Parts A and B: Up to day 15; Parts C and D: Up to day 99]Area Under the Concentration-time Curve (AUC) of ALN-AGT01 and of Potential Metabolites [Time Frame: Parts A and B: Up to day15; Parts C and D: Up to day 99]Apparent Clearance (CL/F) of ALN-AGT01 and of Potential Metabolites [Time Frame: Parts A and B: Up to day 15; Parts C and D: Up to day 99]Apparent Volume of Distribution (V/F) of ALN-AGT01 and of Potential Metabolites [Time Frame: Parts A and B: Up to day 15; Parts C and D: Up to day 99]Fraction Excreted in Urine (fe) of ALN-AGT01 and of Potential Metabolites [Time Frame: Parts A and B: Days 1 and 2; Parts C and D: Up to day 86]Renal Clearance (CLR) of ALN-AGT01 and of Potential Metabolites [Time Frame: Parts A and B: Days 1 and 2; Parts C and D: Up to day 86]</div>	<div>Actual Enrollment: 124</div> <div>Estimated Enrollment:</div> <div>Original Estimated Enrollment: 168</div> <div>Age: 18 Years to 65 Years (Adult, Older Adult)</div> <div>Sex: All</div>	<div>Study Sponsors: Same as current</div> <div>Collaborators: Not Provided</div>	<div>Study Start: May 1, 2019</div> <div>Primary Completion: April 20, 2022 (Final data collection date for primary outcome measure)</div> <div>Study Completion: May 2023</div> <div>First Posted: May 1, 2019</div> <div>Results First Posted:</div> <div>Last Update Posted: September 14, 2022</div>

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/Collaborators	Dates
26	NCT05372640	Testing the Safety and Efficacy of the Combination of Two Anti-cancer Drugs, ZEN003694 and Abemaciclib, for Adult and Pediatric Patients (12-17 Years) With Metastatic or Unresectable NUT Carcinoma and Other Solid Tumors Study Documents:	Title Acronym: Other Ids: NCI-2022-04100 NCI-2022-04100 (Registry Identifier: CTRP (Clinical Trial Reporting Program)) 10509 (Other Identifier: Dana-Farber - Harvard Cancer Center LAO) 10509 (Other Identifier: CTEP) UM1CA186709 (U.S. NIH Grant/Contract)	Suspended	<ul style="list-style-type: none">Metastatic Malignant Solid NeoplasmMetastatic NUT CarcinomaUnresectable Malignant Solid NeoplasmUnresectable NUT Carcinoma	<ul style="list-style-type: none">Drug: Abemaciclib Given PO Other Names:<ul style="list-style-type: none">LY-2835219LY2835219VerzenioDrug: BET Bromodomain Inhibitor ZEN-3694 Given PO Other Names:<ul style="list-style-type: none">BETi ZEN-3694ZEN 3694ZEN-3694ZEN003694Procedure: Biopsy Undergo biopsy Other Names:<ul style="list-style-type: none">BIOPSY_TYPEBxProcedure: Diagnostic Imaging Undergo imaging evaluation Other Name: Medical Imaging	Study Type: Interventional Phase: Phase 1 Study Design: Allocation: N/A Intervention Model: Single Group Assignment Masking: None (Open Label) Primary Purpose: Treatment Primary Outcome Measures: <i>Same as current</i> Secondary Outcome Measures: <ul style="list-style-type: none">Pharmacokinetics [Time Frame: Up to 5 years]Thymidine kinase (TK) [Time Frame: Up to 5 years] Will compare exposures of abemaciclib and abemaciclib metabolites to TK activity at cycle 1 day 15 (C1D15) and beyond and also change in TK activity versus clinical outcomes. <ul style="list-style-type: none">Analysis of ATAC-sequence data [Time Frame: Up to 5 years]	Actual Enrollment: Estimated Enrollment: 30 Original Estimated Enrollment: 18 Age: 12 Years and older (Child, Adult, Older Adult) Sex: All	Study Sponsors: Same as current Collaborators: Not Provided	Study Start: August 12, 2022 Primary Completion: June 1, 2025 (Final data collection date for primary outcome measure) Study Completion: June 1, 2025 First Posted: May 13, 2022 Results First Posted: Last Update Posted: September 13, 2022
27	NCT03027388	Protein Phosphatase 2A Inhibitor, in Recurrent Glioblastoma Study Documents:	Title Acronym: Other Ids: 170037 17-C-0037	Recruiting	<ul style="list-style-type: none">Astrocytoma, Grades II, III and IVGlioblastoma MultiformeGiant Cell GlioblastomaGliomaOligodendrogliomas	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 phosphoprotein expression in treated glioblastoma tumor tissue compared to untreated tumor samples for comparison. [Time Frame: 8 hours following surgery] Secondary Outcome Measures: <ul style="list-style-type: none">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 10, 2022