UC Irvine Health

Neurology Clinical Trials Unit

Dementia

Contact: Breana Chew (949) 824-7524

- A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Study of Crenezumab in Patients with Prodromal to Mild Alzheimer's Disease
- A Phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of AVP-786 (deuterated [d6]-dextromethorphan hydrobromide [d6-DM]/quinidine sulfate [Q]) for the treatment of agitation in patients with dementia of the Alzheimer's type.

Epilepsy

- A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Multicenter Study To Evaluate The Efficacy and Safety of Lacosamide As Adjunctive Therapy for Uncontrolled Primary Generalized Tonic-Chronic Seizures in Subjects With Idiopathic Generalized Epilepsy: **Study Coordinator Breana Chew (949) 824-7524**
- An open-label, multicenter extension study to evaluate the long-term safety and efficacy of lacosamide as adjunctive therapy for uncontrolled primary generalized tonic-clonic seizures in subjects with idiopathic generalized epilepsy: **Study Coordinator Breana Chew (949) 824-7524**
- RNS® System Post-Approval Study in Epilepsy; **Study Coordinator Ivonne Turner (714) 456-8323**
- Efficacy and Safety of Eslicarbazepine Acetate as First Add-on to Levetiracetam or Lamotrigine Monotherapy or as Later Adjunctive Treatment for Subjects with Uncontrolled Partial-onset Seizures: A Multicenter, Open-label, Non-randomized Trial: **Study Coordinator Jeein Kim (714) 509-2487**
- A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study Exploring the Efficacy, Safety, and Tolerability of Natalizumab (BG00002) as Adjunctive Therapy in Adult Subjects With Drug-Resistant Focal Epilepsy: **Study Coordinator Jeein Kim (714) 509-2487**

Movement Disorders

Contact: Everlyne Gomez (949) 824-8116 or Breana Chew (949) 824-7524

- An Open-Label Study in Subjects with Parkinson's Disease to Evaluate the Safety and Tolerability of Titration and Continuous Subcutaneous Infusion of ABBV-951 for up to 4 Weeks in an Outpatient Setting (M15-739)
- Enroll-HD: A Prospective Registry Study in a Global Huntington's Disease Cohort A CHDI Foundation Project
- A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Examine the Efficacy, Safety and Tolerability of APL-130277 in Levodopa Responsive Patients with Parkinson's Disease Complicated by Motor Fluctuations ("OFF" Episodes)
- An Open-Label, Phase 3 Study Examining the Long-Term Safety, Tolerability and Efficacy of APL-130277 in Levodopa Responsive Patients with Parkinson's Disease Complicated by Motor Fluctuations ("OFF" Episodes)
- An Observational Study of Personal KinetiGraph™ (PKG™) Movement Recording System Use in Routine Clinical Care of Patients with Parkinson's Disease
- A Phase 3 Double-Blind, Placebo Controlled, Parallel Group Study of Isradipine as a Disease Modifying Agent in Subjects with Early Parkinson Disease
- Characterization of Movement Disorders and Its Biomarkers

- Efficacy, Safety, and Tolerability of Fosmetpantotenate (RE-024), a Phosphopantothenate Replacement Therapy, in Patients With Pantothenate Kinase-Associated Neurodegeneration (PKAN): A Randomized, Double-Blind, Placebo-Controlled Study With an Open-Label Extension
- A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Trial to Evaluate the Efficacy and Safety of a Single Treatment of DaxibotulinumtoxinA for Injection in Adults with Isolated Cervical Dystonia (ASPEN-1)

Coming Soon:

- Effect of LY3154207 on Cognition in Mild-to-Moderate Parkinson's *Disease Dementia (PDD)*
- A Phase 3, Open-Label, Multi-Center Trial to Evaluate the Long-Term Safety and Efficacy of Repeat Treatments of DaxibotulinumtoxinA for Injection in Adults with Isolated Cervical Dystonia (ASPEN-OLS)
- A Randomized, Placebo Surgery Controlled, Double-blinded, Multi-center, Phase 2 Clinical Trial, Evaluating the Efficacy and Safety of VY-AADC02 in Advanced Parkinson's Disease with Motor Fluctuations

Multiple Sclerosis

Contact: Everlyne Gomez (949) 824-8116 or Breana Chew (949) 824-7524

- A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study in Subjects With Relapsing Multiple Sclerosis to Evaluate the Efficacy and Safety of BIIB033 as an Add-On Therapy to Anti-Inflammatory Disease-Modifying Therapies
- An Open-Label, Single-Arm Study to Evaluate the Effectiveness and Safety of Ocrelizumab in Patients with Early Stage Relapsing Remitting Multiple Sclerosis

Neuromuscular

Amyotrophic Lateral Sclerosis (ALS)

- Fluid Biomarkers with Deep Phenotyping in Patients with ALS: **Study Coordinator Ivonne Turner (714)456-8323 or Veena Mathew (714) 456-2864**
- A Phase 3, Randomized, Double-Blind, Placebo-Controlled Multicenter Study to Evaluate Efficacy and Safety of Repeated Administrations of Nurown® (Autologous Mesenchymal Stem Cells Secreting Neurotrophic Factors) in Participants with Amyotrophic Lateral Sclerosis (ALS): **Study Coordinator Jeanette Overton (714-456-8520) or Veena Mathew (714) 456-2864**
- A Phase 2, Multi-Center, Double-Blind, Randomized, Dose-Ranging, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Toolerability of CK-2127107 In Patients with Amyotrophic Lateral Sclerosis (ALS): **Study Coordinator Ivonne Turner (714) 456-8323 or Veena Mathew (714) 456-2864**
- A Multicenter, Double Blind, Placebo Controlled Study to Assess the Efficacy and Safety of H.P. Acthar Gel in the Treatment of Subjects with Amyotrophic Lateral Sclerosis: **Study Coordinator Ivonne Turner (714) 456-8323 or Veena Mathew (714) 456-2864**
- Evaluation of the safety, tolerability, efficacy and activity of AMX0035, a fixed combination of Phenylbutyrate (PB) and Tauroursodeoxycholic Acid (TUDCA), for treatment of amyotrophic lateral sclerosis (ALS): **Study Coordinator Ivonne Turner (714) 456-8323 or Veena Mathew (714) 456-2864**
- Effect of Mexiletine on Cortical Hyperexcitability in Sporadic Amyotrophic Lateral Sclerosis (SALS): **Study Coordinator Ivonne Turner (714) 456-8323 or Veena Mathew (714) 456-2864**

Coming Soon:

- Effects of oral levosimendan (ODM-109) on respiratory function in patients with ALS
- A Phase 3, Randomised, Placebo-Controlled Trial of Arimoclomol in Amyotrophic Lateral Sclerosis

Myopathies

- Prospective, Double-blind, Randomized, Placebo-Controlled Phase III Study Evaluating Efficacy and Safety of Octagam 10% in Patients With Dermatomyositis ("ProDERM study"): **Study Coordinator Jeanette Overton (714-456-8520)**
- A Phase 3, Randomized, Double-Blind Clinical Trial to Evaluate the Efficacy and Safety of Abatacept SC with Standard Treatment Compared to Standard Treatment Alone in Improving Disease Activity in Adults with Active Idiopathic Inflammatory Myopathy (IIM): **Study Coordinator Jeanette Overton (714-456-8520)**
- Belimumab for Maintenance Therapy in Idiopathic Inflammatory Myositis: **Study Coordinator Jeanette Overton (714-456-8520)**

Coming Soon:

- Phase II Study of Arimoclomol in IBM

Charcot-Marie-Tooth

- A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study of ACE-083 in Patients with Charcot-Marie-Tooth Disease Types 1 and X: **Study Coordinator Jeanette Overton (714-456-8520)**

Myasthenia Gravis

- A Randomized, Placebo-Controlled, Parallel Group Study to Evaluate the Effect of Amifampridine Phosphate in Patients with MuSK Antibody Positive Myasthenia Gravis, and a Sample of AChR Antibody Positive Myasthenia Gravis Patients: **Study Coordinator Veena Mathew (714)456-2864**
- A Phase 2, Multicenter, Randomized, Double Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Preliminary Efficacy of RA101495 in Subjects with Generalized Myasthenia Gravis: **Study Coordinator Veena Mathew (714)456-2864**

Coming Soon:

- Long Term Safety Study of Amifampridine Phosphate in Patients with MuSK Antibody Positive and AChR Antibody Positive Myasthenia Gravis Patients: **Study Coordinator Veena Mathew (714)456-2864**

Pompe

- An Open-label, Ascending-Dose, First-in-Human Study to Assess the Safety, Tolerability, and Pharmacokinetics of Intravenous Infusions of ATB200 Alone and ATB200 Co-administered with Oral AT2221 in Adult Subjects with Pompe Disease who were Previously Treated with Alglucosidase alfa: **Study Coordinator Marie Wencel (714-456-2525)**
- A Retrospective Characterization of Response to Enzyme Replacement Therapy in Late onset Pompe Disease: **Study Coordinator Marie Wencel (714-456-2525)**
- A phase 3 randomized, multicenter, multinational, double-blinded study comparing the efficacy and safety of repeated biweekly infusions of neoGAA (GZ402666) and alglucosidase alfa in treatment-naïve patients with late-onset Pompe disease
- Investigating Pompe Prevalence in NEuromuscular Medicine Academic Practices (IPANEMA Study)

- A Three-month, Open-Label, Randomized, Parallel Active Control, Single and Repeat Dose, Dose-escalation Study of the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Efficacy of VAL-1221 Delivered Intravenously (IV) in Ambulatory and Ventilator-free Patients with Late-Onset GSD-II: **Study Coordinator Marie Wencel (714-456-2525)**