



Axial Biotherapeutics Announces Completion of Enrollment in Phase 1b/2a Clinical Trial Evaluating AB-2004 in Patients with Autism Spectrum Disorder

Waltham, Mass., November 18, 2019 -- Axial Biotherapeutics, a biotechnology company dedicated to building a unique class of gut-targeted therapeutic programs for neurodegenerative diseases and neurodevelopmental disorders, today announced the completion of enrollment in its Phase 1b/2a clinical trial evaluating AB-2004. AB-2004 is a first-in-class therapeutic that removes certain metabolites from the gastrointestinal (GI) tract, in patients with Autism Spectrum Disorder (ASD).

“The completion of enrollment in our AB-2004 Phase 1b/2a clinical trial marks an important milestone for Axial as we now have all subjects enrolled in this first clinical trial within our target population of ASD,” said David Donabedian, Ph.D., Co-founder and Chief Executive Officer of Axial Biotherapeutics. “We look forward to a further advancing this program to help a significantly underserved ASD patient population. We plan to report topline data from this trial next year.”

The Phase 1b/2a clinical trial is designed to examine the safety and tolerability of AB-2004 in up to 25 male adolescent subjects with ASD. Exploratory endpoints include changes in bacterial metabolite levels, GI function, gut microbiome and behavior.

About AB-2004

AB-2004 is a first-in-class, orally administered therapeutic, targeting Autism Spectrum Disorder (ASD). In a preclinical mouse model of ASD, AB-2004 reduced urinary levels of 4-EPS and other key metabolites, repaired leaky gut and improved repetitive behavior, anxiety and ASD-related sensorimotor gating deficits. The company anticipates topline data from the Phase 1b/2a study in 2020.

About Autism Spectrum Disorder

According to the Center for Disease Control (CDC), about 1 in 59 children has been identified with Autism Spectrum Disorder (ASD). Core symptoms of ASD include impairments in social interaction, communication and the presence of stereotyped repetitive behaviors. Comorbidities are extensive and diverse, and include gastrointestinal (GI) dysfunction, metabolic abnormalities, allergies, autoimmune disorders, neuroinflammation, anxiety and epilepsy. GI dysfunction is estimated to occur in 40-70% of individuals with ASD. The medical severity of core and non-core ASD symptoms and the lack of safe and effective long-term treatments argue strongly for pursuing fundamentally new measures to address this significant unmet medical need.

About Axial Biotherapeutics

Axial Biotherapeutics is a clinical stage biopharmaceutical company pioneering novel science focused on the interaction between the brain and the gut to mitigate the causes and symptoms of central nervous system (CNS) and other gut-derived diseases. The Company has built a pipeline of novel small-molecules and live biotherapeutics with lead programs to address the significant unmet patient needs associated with Parkinson’s Disease and Autism Spectrum Disorder.

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