



Axial Biotherapeutics Announces First Patient Dosed in Phase 1b/2a Clinical Trial of AB-2004 for Treatment of Gastrointestinal Dysfunction and Associated Behavioral Symptoms of Autism Spectrum Disorder

WALTHAM, Mass., July 16, 2019 – Axial Biotherapeutics, a biotechnology company dedicated to building a unique class of gut-targeted programs for neurodegenerative diseases and neurodevelopmental disorders, today announced the dosing of the first patient in its Phase 1b/2a clinical trial of AB-2004. In animal models, AB-2004 has demonstrated the ability to repair leaky gut and improve repetitive behavior, anxiety and Autism Spectrum Disorder (ASD)-related sensorimotor gating deficits by removing key microbial metabolites.

“The dosing of the first patient in the Phase 1b/2a clinical trial of AB-2004 is an important milestone for Axial as we advance this program further into the clinic. ASD is an indication that currently has no approved therapies for the treatment of the core symptoms. We believe that AB-2004 has the potential to be a first-in-class drug targeting gastrointestinal (GI) symptoms and core behavioral symptoms,” said David H. Donabedian, Ph.D., co-founder and CEO of Axial Biotherapeutics. “The Axial hypothesis proposes that altered microbial metabolites may drive GI and behavioral symptoms in ASD subjects. We look forward to collecting Phase 1b/2a results to further study the potential of AB-2004 and its impact on improving GI and behavioral symptoms associated with ASD.”

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 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 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 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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