

**PaxMedica selected by American Academy of Child and Adolescent Psychiatry (AACAP) to Present Data from its Recent Phase 2 Trial of PAX-101 (IV suramin) in Children with Autism Spectrum Disorder (ASD) in the Research Pipeline Program**

- *David Hough, MD, CMO of PaxMedica will present trial results at the upcoming AACAP Annual Meeting during the “Research Pipeline: New Findings on Diagnostics and Therapeutics” program on October 27, 2021 at 3:15 PM EST*
- *The company recently reviewed these results during a pre-IND meeting with FDA in July 2021*

**TARRYTOWN, NY, August 19, 2021** – PaxMedica, Inc. (“PaxMedica” or the “Company”), a biopharmaceutical company focused on developing medicines that help overcome the challenges of living with complex neurological conditions, today announced that it has been selected to present the results from its Phase 2 dose-ranging clinical trial evaluating PAX-101 (IV suramin), an investigational drug with a proposed novel mechanism of action that the Company is developing as a potential treatment for the core and related symptoms of Autism Spectrum Disorder (ASD). This trial, using low doses of suramin once monthly, expanded on earlier published reports of the potential for intravenous suramin as a treatment for the core and related symptoms of ASD and lends support to purine mediated mechanisms playing an important role in the treatment of ASD.

“We are honored to have AACAP select us to present our findings from this important Phase 2 study in Autism Spectrum Disorder,” said David Hough, MD, Chief Medical Officer of PaxMedica. “These data are very encouraging and merit further clinical studies of PAX-101 as a potential treatment to reduce core and related symptoms of ASD. PaxMedica recently completed a pre-IND meeting with FDA to review the results of this trial as a first step toward conducting US clinical trials with PAX-101 in the near future.”

The Phase 2 study was a dose-ranging, randomized, double-blind, placebo-controlled, multidose trial evaluating the safety and efficacy of PAX-101 in patients diagnosed with moderate to severe autism spectrum disorder. In the 14-week trial, patients were randomized 1:1:1 to receive 10mg/kg of PAX-101, 20mg/kg of PAX-101 or placebo infusions every 4 weeks. Infusions were administered at baseline, week 4 and week 8 with the end of study visit at week 14.

The primary endpoint of the study was the change between baseline and Week 14 in the Aberrant Behavior Checklist (ABC) composite score of core symptoms (ABC Core) including ABC-II (lethargy/social withdrawal), ABC-III (stereotypy) and ABC-V (inappropriate speech). Secondary outcome measures included: ABC individual sub-scores, Clinical Global Impression of Improvement scale, adapted for autism (CGI-I), Autism Diagnostic Observation Scale, version 2 (ADOS-2) changes, Autism Treatment Evaluation Checklist (ATEC), and safety and tolerability.

PaxMedica’s mission is to change the therapeutic paradigm for ASD and other neurologic disorders. In addition to PAX-101, PaxMedica is developing PAX-102, a proprietary intranasal formulation of suramin for ASD as well as other neurologic disorders.

### **About PAX-101 (IV suramin)**

PAX-101 is an antipurinergic agent delivered as an IV infusion. The mechanism of the drug's action, when delivered in a once-monthly low dose to treat the core and related symptoms of ASD, has been proposed to act primarily through purinergic receptor blockade, reversing the effects of mitochondrial dysfunction, which has been postulated as a cause of ASD symptoms. Other research indicates that ASD may arise from neuro-inflammatory mechanisms. This relationship is not well understood and PAX-101 may also act through mechanisms that reduce neuroinflammation in this population.

### **About Autism Spectrum Disorder (ASD)**

ASD is a complex neurodevelopmental disorder characterized by difficulties with social communication and interaction, restricted interests, and repetitive behaviors. These symptoms are present from early childhood and affect daily functioning of individuals with ASD in school, work, and other areas of life. The term "spectrum" refers to the wide range of symptoms, skills, and levels of disability in functioning that can occur in people with ASD. ASD occurs in every racial and ethnic group, and across all socioeconomic levels. Approximately 1 in 54 children in the U.S. is diagnosed with an autism spectrum disorder with boys being four times more likely to be diagnosed than girls. There are presently no FDA approved therapies for the core symptoms of autism spectrum disorder.

### **About PaxMedica, Inc.**

PaxMedica is a clinical-stage pharmaceutical company leading the development of PAX-101 to advance its use in autism spectrum disorder, myalgic encephalomyelitis/chronic fatigue syndrome, Long Covid Syndrome, and fragile X-associated tremor/ataxia syndrome. Though ASD is commonplace in many communities, no FDA approved treatments for its core symptoms exist. PaxMedica's most clinically advanced therapeutic, PAX-101, is currently being evaluated in clinical trials to support children with ASD and treat their core and associated symptoms. For more information, visit <https://www.paxmedica.com/>.

### **Forward-Looking Statements**

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to

future events and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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