Neuronascent Receives FDA Orphan Drug Designation for

NNI-351 Treatment of Fragile X Syndrome

Rockville, MD, June 1, 2022 (GlobeNewswire) -- Neuronascent Inc, today announced that the U.S. Food and Drug Administration (FDA) granted “Orphan Drug Designation” for the company’s NNI-351 treatment of Fragile X Syndrome.

This Orphan Drug Designation follows closely on Neuronascent’s recent receipt of the “Rare Pediatric Drug Designation” by the FDA, suggesting the agency’s support for novel therapies to treat young patients with Fragile X Syndrome, a rare disorder that affects less than 200,000 patients in the United States.

Fragile X Syndrome is an inherited, X-linked disorder, predominantly found in males, and is a major cause of intellectual disabilities and autism. Presently, there are no effective therapies to treat the many hippocampal-related deficits of Fragile X Syndrome, such as social anxiety, learning disability and hyperactivity, as well as impaired neurogenesis.

Evaluation of NNI-351 in preclinical models of Fragile X Syndrome (supported in part by the FRAXA organization, https://www.fraxa.org) showed that Neuronascent’s novel therapy selectively promotes neurogenesis, seemingly accounting for the associated NNI-351-induced reversal of behavioral deficits back to normal levels in animal models. NNI-351 could therefore potentially slow and even reverse these behavioral deficits in young and young adults with Fragile X Syndrome.

Marketing application for NNI-351 is required prior to receiving FDA-initiated benefits from these dual designations. The Orphan Drug Designation benefits could include exemptions from user fees and the addition of seven-years of market exclusivity. The Rare Pediatric Drug Designation could provide a valuable Priority Review Voucher that could be used by Neuronascent or sold to a pharmaceutical company.

“Both the Orphan Drug Designation and the Rare Pediatric Drug Designation provide greater incentive for collaborations aimed at completing the Investigational New Drug Application and clinical stage evaluations of NNI-351 to effectively treat this developmental disorder,” said founder and CEO, Judith Kelleher-Andersson, PhD.

About NNI-351

NNI-351 is Neuronascent’s lead, patented, new chemical entity aimed at reversing developmental disorders by promoting new neurons postnatally, thus enhancing neurogenesis diminished during early development. NNI-351’s ability to reverse behaviors in a number of models of developmental disorders, including models of Fragile X Syndrome (FXS), suggests this novel therapy could be the first therapy to show true clinical benefit in young FXS patients.

About Neuronascent, Inc.

Neuronascent, Inc., a privately-held, clinical-stage pharmaceutical company, focused on developing its 1st-in-class novel neuron-generating therapies to cure CNS disorders with high-unmet need. Through its proprietary phenotypic screening platform, Neuronascent has

discovered a pipeline of small molecule regenerative candidates with patents issued, including NNI-362 for age-related disorders specifically Alzheimer's and Parkinson's disease.

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