FDA Grants Orphan Drug Designation for Tetra Discovery Partners' BPN14770 for the Treatment of Fragile X Syndrome

Grand Rapids, MI (April 3, 2018): Tetra Discovery Partners today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for BPN14770 for the treatment of Fragile X Syndrome. BPN14770 is a selective small molecule inhibitor of the phosphodiesterase type-4D (PDE4D) subtype. Research conducted collaboratively with the FRAXA Research Foundation has shown BPN14770 to improve the quality of connections between neurons and to improve multiple behavioral outcomes in the Fragile X mouse model.

"We are very pleased that FDA has recognized the potential benefit of BPN14770 in the treatment of Fragile X Syndrome, a genetic disorder for which there is neither a cure nor any approved therapy," said Mark E. Gurney, Ph.D., Chairman and Chief Executive Officer of Tetra Discovery Partners. "BPN14770, which has potential to improve cognitive and memory function in a variety of devastating brain disorders, addresses one of the biochemical dysfunctions involved in Fragile X Syndrome and possibly other autism spectrum disorders."

Tetra Discovery Partners is preparing to initiate a Phase 2 clinical study of BPN14770 in Fragile X Syndrome with support from the FRAXA Research Foundation during Q2 2018.

About Orphan Drug Designation

The FDA grants Orphan Drug Designation to novel drugs or biologics that treat rare diseases or conditions affecting fewer than 200,000 patients in the United States. The designation allows the sponsor of the drug to be eligible for a seven-year period of U.S. marketing exclusivity on approval of the drug, as well as tax credits for clinical research costs, the ability to apply for annual grant funding, clinical trial design assistance, and the waiver of Prescription Drug User Fee Act (PDUFA) filing fees.

About Fragile X Syndrome

Fragile X Syndrome is a genetic condition that results from the silencing of the X-linked, Fragile X Mental Retardation-1 (*FMR1*) gene. Fragile X Syndrome patients display a range of behavior and other symptoms, including seizures, sleep disorders, anxiety, irritability, hyperactivity, autism, mild-to-severe cognitive impairment and intellectual disability. While Fragile X Syndrome occurs in both genders, the condition is more common and generally more severe in males. There is no cure for Fragile X Syndrome or any products approved for its treatment. Medications may be used to treat symptoms associated with Fragile X Syndrome including seizures, mood problems or other neuropsychiatric symptoms. Fragile X Syndrome occurs in approximately 1 in 4,000 males and 1 in 8,000 females.

About BPN14770

BPN14770 is a novel therapeutic agent that selectively inhibits phosphodiesterase-4D (PDE4D) to enhance early and late stages of memory formation. This unique mechanism of action has the potential to improve cognitive and memory function in devastating disorders including Fragile X Syndrome, Alzheimer's disease and other dementias, learning/-developmental disabilities and schizophrenia. In preclinical studies of Fragile X Syndrome, BPN14770 improves behavioral outcomes in the Fragile X mouse model and improves the quality of connections between neurons. BPN14770 has completed three human Phase 1 clinical trials enrolling 147 subjects and has shown excellent safety, oral bioavailability, and preliminary cognitive benefit in elderly subjects. Preparations are under way to initiate Phase 2 trials of BPN14770 in adults with Fragile X Syndrome and in patients with Alzheimer's disease.

About the FRAXA Research Foundation

FRAXA's mission is to find effective treatments and ultimately a cure for Ffragile X Ssyndrome - the most common inherited cause of autism worldwide. FRAXA funds research and clinical trials at universities all over the world. For more information please visit our website at http://www.fraxa.org.

About Tetra Discovery Partners

Tetra Discovery Partners is a clinical stage biotechnology company developing a portfolio of therapeutic products that will bring clarity of thought to people suffering from neuro-developmental conditions such as Fragile X Ssyndrome, Alzheimer's disease, traumatic brain injury, and other brain disorders. Tetra uses structure-guided drug design to discover mechanistically novel, allosteric inhibitors of phosphodiesterase 4 (PDE4), an enzyme family that plays key roles in memory formation, learning, neuroinflammation, and traumatic brain injury. Tetra was a recipient of an NIH Blueprint Neurotherapeutics Program cooperative research agreement, and also receives major funding from the National Institute on Aging, the Alzheimer's Drug Discovery Foundation, the National Institute of Neurological Disorders and Stroke, and the National Institute of Mental Health through the Small Business Innovation Research (SBIR) program. Preclinical studies of Fragile X Syndrome were conducted through the FRAXA Research Foundation. Tetra Discovery Partners is headquartered in Grand Rapids, Michigan. For more information, please visit the company's website at http://www.tetradiscovery.com.

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