Synaptogenix Moves Forward with Clinical Development Plans for Bryostatin-1 as a Treatment for Multiple Sclerosis

Filing of protocol and Investigational New Drug Application expected in the first half of 2022; Clinical trial to follow

PR Newswire

NEW YORK , Feb. 23, 2022 /PRNewswire/ -- Synaptogenix, Inc. (Nasdaq: SNPX), a clinical-stage biopharmaceutical company developing regenerative therapeutics for neurodegenerative disorders, today announced plans to develop Bryostatin-1 for the treatment of multiple sclerosis ("MS"), a third indication for the drug candidate. The Company will collaborate with the Cleveland Clinic through a new consulting agreement.

"Synaptogenix is excited to work with this internationally recognized team of experts. A clinical trial focused on both safety and efficacy is the priority of the collaboration. Advancing our clinical development plans through partnership has been a strategic focus over the past year and will continue to be a key focus going forward. We are very pleased that we've been able to partner with world leading institutions on endeavors such as this collaboration with Cleveland Clinic for MS and our previously announced Fragile X partnership with Nemours A. I. Dupont ," stated Dr. Alan Tuchman , CEO of Synaptogenix, Inc.

"Multiple sclerosis joins Alzheimer's disease ("AD") and Fragile X syndrome as our third indication with potential clinical benefit from Bryostatin-1. Elimination of synapses in MS patients, like those lost in AD, has not been addressed by currently available drug strategies. Through its synaptogenic, restorative mechanisms of action, we believe that Bryostatin-1 is uniquely positioned to target synaptic loss and cognitive dysfunction in MS, and potentially other aspects of the disease such as inflammation and demyelination. We will work with the Cleveland Clinic to finalize a protocol as soon as possible with the goal of moving towards a clinical trial soon thereafter," stated Dr. Daniel Alkon , the Company's President and Chief Scientific Officer.

About Synaptogenix, Inc.

Synaptogenix is a clinical-stage biopharmaceutical company that has historically worked to develop novel therapies for neurodegenerative diseases. Synaptogenix has conducted clinical and preclinical studies of its lead therapeutic candidate, Bryostatin-1, in Alzheimer's disease. Preclinical studies have also demonstrated Bryostatin's regenerative mechanisms of action for the rare disease, Fragile X syndrome, and for other neurodegenerative disorders such as multiple sclerosis, stroke, and traumatic brain injury. The U.S. Food and Drug Administration has granted Orphan Drug Designation to Synaptogenix for Bryostatin-1 as a treatment for Fragile X syndrome. Bryostatin-1 has already undergone testing in more than 1,500 people in cancer studies, thus creating a large safety data base that will further inform clinical trial designs.

Additional information about Synaptogenix, Inc. may be found on its website: www.synaptogen.com .

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. These forward-looking statements include statements regarding the anticipated initiation of a clinical trial to treat multiple sclerosis with Bryostatin and continued development of use of Bryostatin-1 for Fragile X, Autistic Spectrum Disorder Deficits and other cognitive diseases, and the collaboration with the Cleveland Clinic. Such forward-looking statements are subject to risks and uncertainties and other influences, many of which the Company has no control over. There can be no assurance that the clinical program for Bryostatin-1 will be successful in demonstrating safety and/or efficacy, that we will not encounter problems or delays in clinical development, or that Bryostatin-1 will ever receive regulatory approval or be successfully commercialized. Actual results and the timing of certain events and circumstances may differ materially from those described by the forward-looking statements as a result of these risks and uncertainties. Additional factors that may influence or cause actual results to differ materially

from expected or desired results may include, without limitation, the Company's inability to obtain adequate financing, the significant length of time associated with drug development and related insufficient cash flows and resulting illiquidity, the Company's patent portfolio, the Company's inability to expand its business, significant government regulation of pharmaceuticals and the healthcare industry, lack of product diversification, availability of the Company's raw materials, existing or increased competition, stock volatility and illiquidity, and the Company's failure to implement its business plans or strategies. These and other factors are identified and described in more detail in the Company's filings with the Securities and Exchange Commission. The Company does not undertake to update these forward-looking statements.

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