Synaptogenix Completes Patient Enrollment in NIH Sponsored Phase 2b Alzheimer's Disease Trial

PR Newswire

- Top line results expected during the fourth quarter of 2022

- Data Safety Monitoring Board has confirmed no adverse safety issues

NEW YORK , April 19, 2022 /PRNewswire/ -- Synaptogenix, Inc. (Nasdaq: SNPX) ("the Company"), a clinical-stage biopharmaceutical company developing regenerative therapeutics for neurodegenerative disorders, today announced that it has completed enrolling its target of 100 patients for its ongoing National Institutes of Health ("NIH") sponsored Phase 2b clinical trial of Bryostatin-1 for patients suffering from advanced and moderately severe Alzheimer's disease ("AD"). The Company expects to announce topline data from the study during the fourth quarter of 2022.

Synaptogenix also reports that the independent Data Safety Monitoring Board ("DSMB") overseeing the trial has confirmed the absence of any drug-related adverse safety issues.

Bryostatin-1 caused highly significant cognitive enhancement (4.0 SIB psychometric score above baseline) for the pre-specified patients who received Bryostatin-1 in the absence of Namenda in our two previous, consolidated 3-month pilot trials, recently published in a peer-reviewed article (JAD, 2022) – while the Placebo-treated patients showed no significant benefit. Bryostatin-1 treatment has now been extended to include double the number of doses (N = 14) in the current 6-month, placebo-controlled trial, in which randomized enrollment has been carefully controlled for balanced baselines in the treatment and placebo cohorts. Patients will have been observed for as long as three months after all dosing cessation, given the persistence of benefit for at least 30 days after dosing that was previously observed.

"We are encouraged that the top line data due in the 4 th quarter, 2022, will reflect the same or greater benefit already observed for patients in identical, previously treated pre-specified cohorts in our previous Phase 2a pilot trials. The absence of any drug-related adverse events, as have been observed with the few other therapeutic strategies reaching limited Food and Drug Administration ("FDA") approval for AD, should facilitate our subsequent steps toward clinical utility. Benefits of at least 4.0 SIB scores, above baseline, are likely to be clinically meaningful, and therefore have the potential to treat the underlying disease as well as to provide symptomatic relief," stated Daniel Alkon , MD, the Company's President and Chief Scientific Officer.

Alan Tuchman M.D ., the Company's Chief Executive Officer, stated, "Evidence is growing and continues to support Bryostatin-1 as a potential treatment for Alzheimer's disease. We are excited today to announce the completion of our Phase 2b enrollment and we are eagerly awaiting the read out of our top line data later this year."

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

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. These forward-looking statements include statements regarding the Phase 2 clinical trial of Bryostatin-1 and further studies, and continued development of use of Bryostatin-1 for AD and other cognitive diseases. 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.

Investors and Media Contact:

800-811-5591
ir@synaptogen.com

Robert Weinstein
Chief Financial Officer
Synaptogenix, Inc.
rweinstein@synaptogen.com

View original content: https://www.prnewswire.com/news-releases/synaptogenix-completes-patient-enrollment-in-nih-sponsored-phase-2b-alzheimers-disease-trial-301528016.html

SOURCE Synaptogenix, Inc.