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Novel Drug Treatment Shows Improved Cognition in a Phase 3 Clinical Trial in Persons with Mild-to-Moderate Alzheimer's Disease in China

Green Valley Pharmaceutical Company has submitted New Drug Applications and Market Authorization to China Food and Drug Administration (CFDA) for Sodium Oligomannurarate (GV-971)

BARCELONA, Oct 25, 2018 / PRNewswire / --
Green Valley Pharmaceutical Co., Ltd. (Headquarter: Shanghai) announced promising findings from a Phase 3 clinical trial of GV-971, a multi targeting carbohydrate-based drug, with 818 patients across 34 sites in China for treatment of patients with mild-to-moderate Alzheimer's disease at the 11th Clinical Trials on Alzheimer's Disease Conference (CTAD) in Barcelona, Spain.

In this double-blind, placebo-controlled, multi-center trial, 818 patients were randomized to receive either GV-971 450mg twice per day by oral administration or placebo for a treatment period of 36 weeks. The trial participants were between 50-85 years old, met clinical criteria for mild-to-moderate Alzheimer's disease, had MMSE scores of 11-26, and MRI evidence included medial temporal lobe atrophy visual rating scale (MTA) grade ≥2, Fazekas scale for white matter lesions grade <3, no more than 2 lacunar infarction lesions and no lacunar infarction lesions in the key brain regions. The primary efficacy end point was the change from baseline to week 36 on the ADAS-Cog 12, the secondary efficacy end points included the change from baseline to week 36 on CIBIC plus, ADCS-ADL and NPI. The safety evaluation includes AE, laboratory assessment, vital signs, ECGs, physical examinations.

GV-971 showed statistically significant improvement on the primary endpoint ADAS-Cog12 (p<0.0001). The mean difference between GV-971 vs. placebo in ADAS-Cog12 Score at 36 weeks was 2.54. This statistically significance difference between GV-971 vs. placebo was observed as early as week 4 and continued at each follow-up assessment visit. The drug placebo difference was also statistically significant in all three subgroups of patients with MMSE scores ranging from 11-14, 15-19 and 20-26. There was a non-significant trend for greater improvement on the CIBIC-plus (P=0.059). No statistically significant differences were observed in ADCS-ADL or NPI. The twice per day oral drug treatment was found to be safe and well tolerated. There were no statistically significant group differences in the percent of participants with adverse or severe adverse effects.

The 36-week trial was led by Shifu Xiao, MD, from Shanghai Jiao Tong University in Shanghai, Zhenxin Zhang, MD, from Peking Union Medical College Hospital in Beijing, and Dr. Meiyu Geng, conducted by investigators at 34 clinical trial sites in China, and supported by the clinical research organization (CRO) IQVIA (formerly Quintiles) and the imaging CRO Bioclinica.

"GV-971 is a novel, marine-derived oligosaccharide, which has multi targeting mechanisms including inhibition of amyloid-β fibril formation, neuroinflammation, and recondition of dysbiosis of gut microbiota", stated Dr. Meiyu Geng , PhD, professor at Shanghai Institute of Materia Medica, Chinese Academy of Sciences, the key inventor of GV-971. "We are encouraged by our findings from this Phase 3 clinical trial, we are excited to bringing new potential therapies to millions of patients around the world."

"Based on its suggested mechanisms of action and promising cognitive effects, GV-971 could help diversify the portfolio of treatments for this terrible disease." said Eric Reiman, MD, Executive Director of Banner Alzheimer's Institute. "Additional studies are needed to further clarify and confirm its promising biological and clinical effects."

"The trial of GV-971 consistently showed a cognitive benefit, it has promise as a new therapy for Alzheimer's disease," said Jeffrey Cummings, MD, Professor of Neurology at the Cleveland Clinic Lou Ruvo Center for Brain Health. "We look forward to the future global development of GV-971."

Green Valley Pharmaceuticals have submitted New Drug and Marketing Authorization applications to the CFDA in Oct. 16, 2018 and plans to conduct global trials in the near future.

"We are very grateful to our patients and their families for their support," said Songtao Lv, CEO and Chairman of Green Valley Pharmaceuticals Co., Ltd. "We look forward to continuing on this journey with them—together with private and public partners of Green Valley, we are striving to make Alzheimer's disease a distant memory."

About Green Valley

Green Valley is an innovation-driven pharmaceutical company committed to researching and developing drugs that patients are yearning for. The company focuses its primary efforts on developing carbohydrate drugs for patients with complex chronic diseases in areas of central nervous system, cardiovascular, and oncology. Founded in 1997 and headquartered in Shanghai with over 1500 staffs on board, Green Valley's business presence in China covers more than 31 provinces/municipals including 2 GMP manufacturing sites and has achieved more than $700 million in revenue in the previous fiscal year. The company's product Salvianolate is a top 10 drug for cardiovascular disease in China. The new drug registration application and marketing authorization application for GV-971 has been recently submitted to CFDA for treatment of Alzheimer's disease.

For more information about Green Valley, please visit http://www.shgvp.com/En

Forward Looking Statement

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