ASX Announcement

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CogState Tests Again Used in Successful Phase 2 Schizophrenia Study

Successful results released by EnVivo Pharmaceuticals follows last month's results released by Targacept, Inc. with both companies using CogState as a primary endpoint in successful Phase 2 clinical trials

CogState Ltd (ASX: CGS) today announced that its computerized tests of cognition were successfully used as the primary endpoint by EnVivo Pharmaceuticals to determine the effectiveness of their drug EVP-6124 to improve cognitive function in patients suffering from schizophrenia.

Today's announcement follows the announcement on 11 April 2011 that CogState tests were used successfully by Targacept, Inc. to determine the effectiveness of their drug TC-5619 to improve cognition in patients suffering from schizophrenia.

CogState CEO, Brad O'Connor commented, "The results released by both EnVivo and Targacept further validate the effectiveness of the CogState technology in assessing cognitive change in schizophrenia. We are very pleased to see the positive results in an area where, historically, companies have found it very difficult to achieve signals of cognitive change."

Overnight in the United States, EnVivo Pharmaceuticals announced positive topline results of its randomized, placebo-controlled Phase 2b clinical trial of EVP-6124, its potent, orally bioavailable and selective alpha-7 agonist, in patients with schizophrenia. The data showed that EVP-6124 had a clinically meaningful and statistically significant impact on patients' overall cognition - the trial's pre-specified primary endpoint - when taken in combination with second-generation antipsychotics and as measured by the full CogState overall cognitive index, or "OCI" ($p=0.05$ for all patients treated with EVP-6124 versus placebo.) This positive effect on the OCI was supported by a strong positive trend for improved cognition on the MCCB Battery of cognition tests, which were conducted on all U.S. patients in the trial.

Additionally, results from this Phase 2b trial demonstrated that patients treated with EVP-6124 showed clinically meaningful and statistically significant effects in key secondary endpoints: improvement in clinical function (as assessed by the Schizophrenia Cognition Rating Scale (SCoRS)) and reduction of the negative symptoms of schizophrenia (as measured by the Negative Symptom Scale of the Positive and Negative Symptoms Scale (PANSS)). Importantly, EVP-6124 was generally safe and well-tolerated over the trial's three-month dosing period.

Schizophrenia is a psychiatric disorder that affects approximately 2.4 million Americans, or about one percent of the adult population, and is usually diagnosed between the ages of 15 and 35 years old. Symptoms of schizophrenia include positive and negative symptoms as well as cognitive impairment. "Positive" symptoms include hallucinations, delusions and paranoia. "Negative" symptoms include loss of motivation and interest in everyday activities, blunting of emotion, decrease in speech, and social withdrawal. Increasingly, cognitive impairments such as difficulty paying attention, memory loss and problems processing information and making decisions are also recognized as core disabling symptoms of the disease. The overall annual cost of schizophrenia in the U.S. is more than $62 billion according to a study published in the Journal of Clinical Psychiatry.

"We are extremely excited by these data, which show a compelling and positive impact on a wide range of schizophrenia patients' cognitive functions as measured by the CogState overall cognition index. Additionally, the ability of EVP-6124 to reduce schizophrenia's debilitating negative symptoms further illustrates the drug's promise and broad potential," said Kees Been, president and chief executive officer of EnVivo Pharmaceuticals. "There are no currently approved therapies to treat cognitive and negative symptoms of the disease, so the opportunity to potentially address both cognition and negative symptoms is exciting and something that we will carefully evaluate as we move forward into later stages of development."

About the EVP-6124 Phase 2b Clinical Trial

This Phase 2b trial evaluated the safety and efficacy of two doses of EVP-6124 (0.3 mg and 1.0 mg per day) versus placebo in chronic schizophrenia patients on stable second-generation antipsychotic drugs (except clozapine). Each patient was treated for three months and a total of 319 patients were enrolled in the U.S., Russia, Ukraine and Serbia. The trial's primary endpoint was overall cognition as measured by the CogState overall cognitive index and important secondary endpoints included cognition as assessed by the MCCB battery, clinical function (as measured by the SCoRS) and positive and negative symptoms (measured by PANSS). Safety and tolerability were also assessed.

About EnVivo Pharmaceuticals

The EnVivo Pharmaceuticals group, consisting of EnVivo Pharmaceuticals, Inc., located in Watertown, MA, and its subsidiaries, is a drug discovery and development company working to convert its world-class pipeline into a broad range of central nervous system (CNS) therapies and deliver novel treatments to patients. EnVivo's focus is on building an integrated company that leverages novel mechanisms of action to treat CNS diseases like schizophrenia and Alzheimer's disease by altering the progression of disease and providing improvement in cognitive and overall function. EnVivo's lead product is an alpha-7 nicotinic acetylcholine receptor agonist currently in Phase 2b clinical trials for the treatment of cognitive impairment in Alzheimer's disease and schizophrenia. The company's other programs include an epigenetics program based on Histone Deacetylase inhibition (HDACi), which is in preparation for Phase 2 studies, and several preclinical programs including Gamma Secretase Modulators for Alzheimer's disease and PDE10 inhibitors for the positive and negative symptoms of schizophrenia, both of which are expected to enter the clinic this year. For more information about EnVivo, please visit www.envivopharma.com.

About CogState

CogState Ltd (ASX: CGS) specialises in the development and commercialisation of rapid, computerised tests of cognition (brain function). To date, CogState has commercialised its technology in two markets – clinical drug trials and concussion management in sport.

In the clinical drug trial market, CogState technology and associated services are used by pharmaceutical and biotechnology companies to quantify the effect of drugs or other interventions on human subjects participating in clinical trials. Since sales into the clinical trials market began in 2004, CogState has secured agreements with top pharmaceutical companies including Pfizer, AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Merck, Johnson & Johnson, Novartis, Lundbeck, Dainippon Sumitomo, Otsuka, and Servier.

In the area of sports related concussion, CogState's technology has been used by a number of highly regarded institutions and sporting organisations around the world for almost 10 years. Current users include, University of Notre Dame, University of Michigan, English Rugby League, English Jockey Club, and a number of national and international Rugby League and Rugby Union clubs. In Australia, both the AFL and NRL have mandated computerised cognitive testing, using CogState, within the last month.

CogState has established a joint venture in the USA, called Axon Sports, to market its concussion management technology. Axon Sports has an exclusive license to market and sell the CogState technology in the area of sports and related concussions within North America (USA, Canada, Mexico).

For further information:

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