Braincells, Inc. Announces the Successful Completion of a Multiple Ascending Dose Study of BCI-838, a Group II mGluR2/3 Antagonist, and the Company's Plans for a Proof-of-Concept Study in Patients with Treatment-Resistant Depression

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SAN DIEGO, Nov. 5, 2012 /PRNewswire/ -- BrainCells, Inc. (BCI), a leading biotechnology company developing novel compounds for the treatment of central nervous system (CNS) diseases, announced the successful completion of their Phase 1 multiple ascending dose (MAD) study of BCI-838, the oral prodrug for the company's Group II mGluR2/3 antagonist, BCI-632. BCI will advance the clinical development program of the compound by initiating a Proof-of-Concept (PoC) study in patients with treatment-resistant depression (TRD) in early 2013.

The MAD study evaluated BCI-838 for safety, tolerability, pharmacokinetics and pharmacodynamic effect in healthy male and female subjects. Three different dose levels of BCI-838 were administered orally once daily for 7 days. The study's pharmacokinetic results indicate that all 3 doses of BCI-838 met or exceeded exposures of BCI-632 expected for the treatment of TRD. BCI-838 showed a favorable safety profile with no treatment-related trends in clinical laboratory results, vital sign measurements, 12 lead ECG results, or physical examination findings. In addition, the drug was well-tolerated within and up to the dose levels predicted for efficacy. Adverse events (AEs), which were mild to moderate in intensity, were transient, and resolved without sequelae. As a pharmacodynamic endpoint, quantitative electroencephalograms (qEEG) were included on day 1 and day 7 of the study. At all 3 dose levels, significant changes in several frequency bands were observed at both time points indicative of the drug's brain penetration and engagement of its target.

"BCI-632's biological activity triggers changes in the brain through a mechanism similar to that for ketamine, an intravenous drug which has shown remarkable efficacy in treating patients with TRD. Since ketamine is associated with a number of unwanted side effects such as short-term dissociation and psychosis, BCI-838 has th
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