

# ASX Announcement

12 March 2019



## **COGSTATE COMPUTERISED TESTS UTILISED AS PART OF THE OVERALL EVALUATION OF SPRAVATO™, WHICH WAS GRANTED FDA APPROVAL FOR TREATMENT RESISTANT DEPRESSION**

As announced by [The Janssen Pharmaceutical Companies of Johnson & Johnson](#), the U.S. Food and Drug Administration (FDA) has granted approval for SPRAVATO™ (esketamine) CIII nasal spray for use in conjunction with an oral antidepressant in adults with treatment-resistant depression (TRD).

SPRAVATO™ was studied in five pivotal Phase 3 trials in more than 1,700 adults with TRD, and a cognitive battery including Cogstate computerised tests was a primary outcome measure in the trials. The Cogstate tests in the battery measured attention, visual learning and memory, and executive function.

SPRAVATO™ uses the first new mechanism of action in decades to treat Major Depressive Disorder and works on the N-methyl-D-aspartate (NMDA) receptor, an ionotropic glutamate receptor in the brain. Cogstate Chief Science Officer, Dr. Paul Maruff stated, "The approval of SPRAVATO™ confirms NMDA receptor modulation to be a mechanism for accelerated improvement in severe and chronic forms of depression. This novel drug approval also provides a foundation for additional research and development by other pharmaceutical researchers evaluating compounds that are chemically similar."

"Congratulations to Janssen on the approval of this breakthrough therapy for patients suffering from treatment-resistant depression, a debilitating and potentially life-threatening disease," said Brad O'Connor, Cogstate CEO. "Our team is incredibly proud to have supported the development of this important new therapy over the many years of research."

This approval is another demonstration of the acceptability of Cogstate tests to regulatory authorities as suitable outcomes for the evaluation of cognitive safety. It further positions the company as a key partner in the development of psychopharmacologic drugs and demonstrates the utility of Cogstate technology for guiding decisions about the effects of antidepressant medications and other compounds that act on NMDA neurotransmission.

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### **About Cogstate**

Cogstate Ltd (ASX:CGS) is a leading science and technology solutions provider dedicated to optimising the measurement of cognition in clinical trials, academic research and healthcare. Cogstate provides enabling technologies and professional services for higher quality neuropsychological assessments and is a pioneer in commercialising rapid, reliable and highly sensitive computerised cognitive tests. Cogstate customers include the world's leading biopharmaceutical companies; elite sporting organisations and military; physicians and patients; renowned academic institutions and public-private partnerships. For more information, please visit [www.cogstate.com](http://www.cogstate.com).