



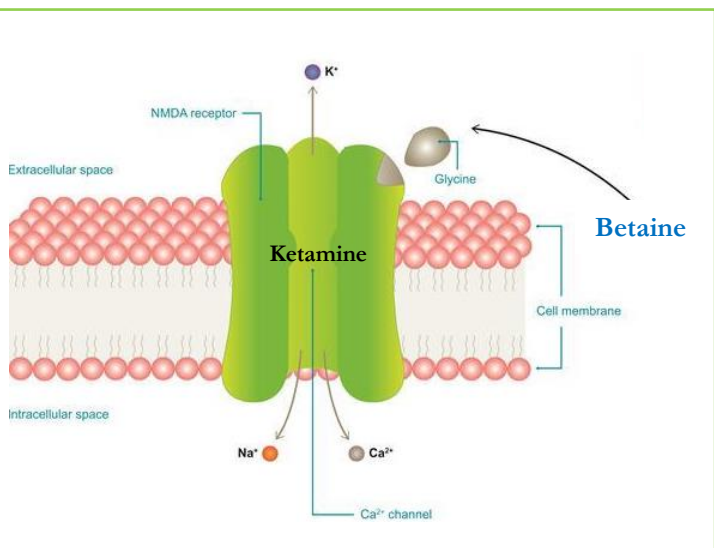
A novel method to enhance the efficacy and safety of ketamine in treating neuropsychiatric disorders

Invention Description

The present invention relates to a method for enhancing the antidepressant effect of ketamine while reducing its psychotomimetic side effects and abuse potential, achieved through the combination with betaine.

Mechanism of action (MOA)

Betaine, which possesses anti-inflammatory and antioxidant properties, acts as a partial agonist at the NMDA receptor glycine binding site.



Preclinical efficacy

Enhancing

- antidepressant effect
- analgesic effect

Reducing

- reinforcing efficacy
- motor incoordination
- cognitive impairment
- prepulse inhibition deficits

Patent granted

Taiwan

Japan, US,
Canada, Israel,
Europe

Application

China

Expiration

2038-01-01

Beta-K (Betaine / Ketamine)

Take-at-home treatment

Higher efficacy for depression and pain

Lower risk for abuse potential and cognitive deficits

Potential indications for neuropsychiatric disorders

Depression

Bipolar disorder

Anxiety

Post-traumatic stress disorder

Obsessive-Compulsive Disorder

Substance use disorder

Other potential indications and usage

Prevention of Ischemia-reperfusion injury from organ transplantation

Treatment of levodopa-induced dyskinesia

Treatment of Status Epilepticus

Treatment of Amyotrophic Lateral Sclerosis

Treatment of Fibromyalgia

Treatment of Complex Regional Pain Syndrome

Treatment of Rett Syndrome

Comparison of key features of the proposed product, Beta-K, with other global products

Product	SPRAVATO® (esketamine)	R-107 (Ketamine)	KET01 (Ketamine)	FREE001 Rapamycin/Ketamine	VTS-K (Aspirin /Ketamine)	Beta-K (Betaine/Ketamine)
Company	Janssen	Douglas Pharmaceuticals	Ketabon GmbH	Freedom Biosciences	Vitalis Analgesics	N/A
Formulation	Nasal spray	Oral prolonged release	Oral prolonged release	Oral rapamycin prior to ketamine (0.5 mg/kg, IV)	Oral Aspirin/ketamine	To be determined
Onset for anti- depression	Day 1- 7	Within 1 week	Day 4	Peaking at 24 h	Uncertainty	Uncertainty
Efficacy for depression	High	Low	Low	Prolong effect with rapamycin	Low	High
Efficacy for Pain relief	High	Low	Uncertainty	Uncertainty	Low	Extremely high
Dissociative States	Severe	Low	Low	Severe	Low	Extremely low
Abuse potential	High	Medium	Medium	Low	Low	Extremely low
Patent status	Granted (US)	Granted (US)	Granted (US, EU)	Pending	Pending	Granted (5 countries and EU)