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DEVELOPING A SUPERIOR TREATMENT OPTION FOR TREATMENT-RESISTANT DEPRESSION



KETABON'S KET01 is a potential tak home treatment option for the 94 million patients suffering from treatment-resistant worldwide. This oral prolonged-release formulation of racemic ketamine has the potential to marry the robust and rapid efficacy of ketamine with superior tolerability, convenience, and accessibi compared to current treatment options.

MAJOR DEPRESSIVE DISORDER AND TREATMENT-RESISTANT DEPRESSION ARE **GLOBAL ISSUES AND INCREASING BURDEN ON SOCIETY**





Major Depressive Disorder (MDD) is a leading contributor to disability globally³. Patients with MDD who have failed two antidepressant treatments are considered to have Treatment-Resistant Depression (TRD).



Patients with TRD typically have a worse clinical perspective and greater risk of suicide than patients with MDD^{5,6}.



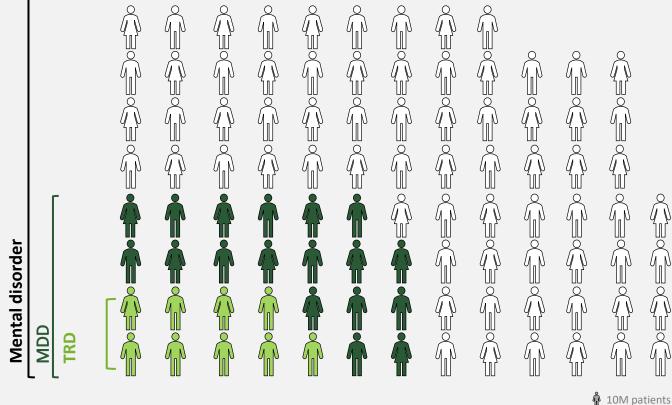
TRD patients have limited treatment options, with only one drug receiving FDA approval for TRD in the last 10 years.

94M PATIENTS WORLDWIDE SUFFER FROM TRD

Out of 970M patients worldwide suffering from a mental disorder¹,

94M

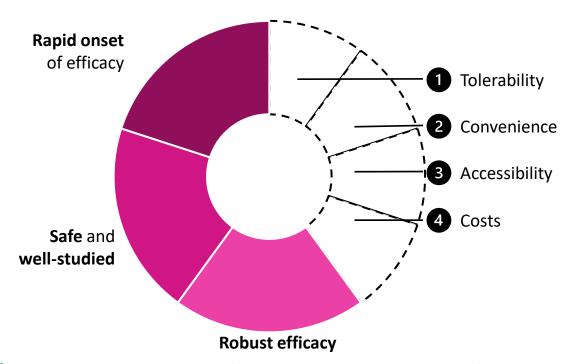
have Treatment-Resistant Depression (TRD)².





KETAMINE'S ROLE IN TODAY'S TRD TREATMENT

Advantages and outstanding challenges of FDA-approved S-ketamine treatment for TRD



KEY SHORTCOMINGS OF CURRENT KETAMINE-BASED TREATMENTS

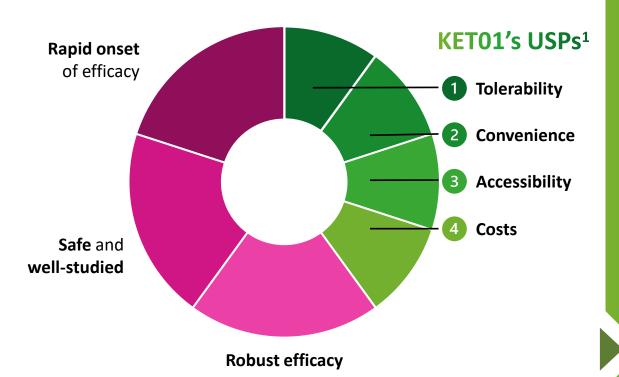
- 1 Sizeable acute side effects, especially dissociation, sedation, and cardiovascular effects¹
- 2 Strict medical supervision, i.e. patients must be monitored by a health care provider for at least two hours²
- Accessibility is limited, as only a small subpopulation of practitioners offer the therapy, which is only available through a restricted distribution system, under risk management measures²
- 4 High costs for clinics and society, reflected in UK National Institute for Health and Care Excellence (nice) decision not to recommend intranasal S-ketamine treatment³

¹ FDA's CDER review of esketamine for TRD; ² FDA press release on esketamine, 5 March 2019. ³ UK NICE final appraisal document on esketamine nasal spray for treatment-resistant depression.

... WHICH KET01 HAS THE POTENTIAL TO OVERCOME



KET01 AS FULL-CIRCLE TREATMENT OPTION



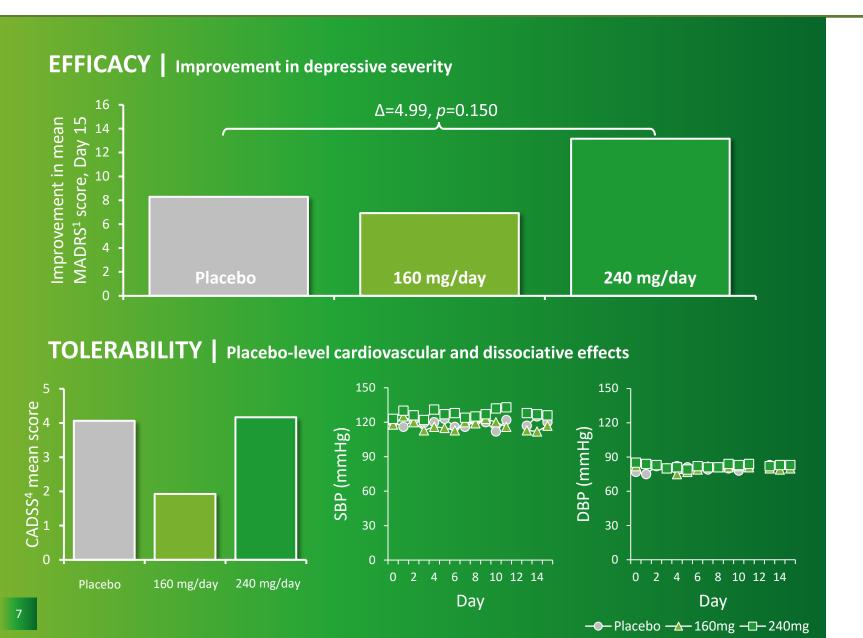
KEY FEATURES OF KETABON'S KET01,

compared to currently available therapy options

- 1 Limited acute side effects, i.e. placebo-level dissociative and cardiovascular effects, suggest vastly improved tolerability
- Take-at-home treatment potential, leading to improved patient convenience and potentially compliance
- 3 Increased accessibility for those patients who cannot accommodate to have regular clinic visits while potentially unable to work or drive until the next day.
- 4 Potential for cost savings of up to 70% of the current total cost of ketamine treatment with high potential of being fully reimbursed.

KET01 IS A POTENTIAL FIRST-LINE TREATMENT OPTION FOR TRD





Highest studied dose (240 mg/day) KET01 associated with a numerical and clinically meaningful improvement in MADRS² scores, reflecting depressive severity, after 7 days (Δ =5.67) and 15 days (Δ =4.99, primary endpoint), respectively^{1,3}.

Placebo-level effects on dissociation measured by CADSS scale and blood pressure effects, suggesting superior tolerability³ compared with other esketamine and ketamine treatments for depression

¹ Data from a 2-week, randomized, placebo-controlled study of inpatients with TRD (N=27)

²Montgomery—Åsberg Depression Rating Scale, a validated diagnostic questionnaire which psychiatrists use to measure the severity of depressive episodes patients with mood disorders; ² note that the study was terminated prematurely because of recruitment issues during COVID and was therefore underpowered; ³ compared to intranasal S-ketamine; ⁴ CADSS is a structured clinical interview to assess present-state dissociative symptoms rated by clinicians. CADSS mean score at each day with an assessment while on study drug; DBP: diastolic blood pressure; SBP: systolic blood pressure



STRONG IP PROTECTION IN EUROPE AND US





 Patents
 US 10335379B2
 EP 3131533B1

 granted:
 US 11103467B2
 EP 3272338B1

 Under
 US 20210386691A1
 EP 3287124A1

 examination:
 US 20200121619A1
 EP 3641742A1

EXCLUSIVITY GRANTED FOR KET01 UNTIL 2035 IN US AND KEY EU COUNTRIES



HMNC BRAIN HEALTH & DEVELCO PHARMA JOINT VENTURE MERGES EXPERTISE IN PSYCHIATRY WITH FORMULATION KNOW-HOW



KETABON'S LEADERSHIP TEAM



Dr. Maximilian Döbler, Co-CEOManaging Director, Ketabon GmbH
Chief Business Officer, HMNC Brain Health





Dr. Hans Eriksson, CMOChief Medical Officer, HMNC Brain Health



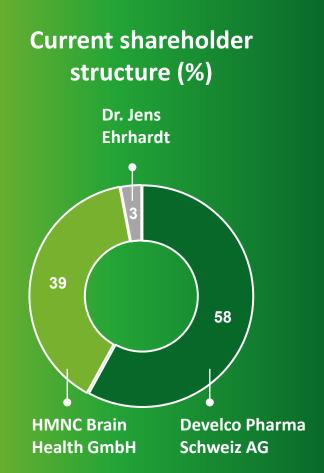


Dr. Markus Zimmer, Co-CEO

Managing Director, Ketabon GmbH

Member of the Board of Directors, Helmadis







CONTACT

Ketabon GmbH

Wilhelm-Wagenfeld-Straße 20 80807 Munich, Germany

Katharina Schwabe

info@ketabon.health
+49 151 23 14 61 87

