KURZPROTOKOLL
Escape-TRD

Öffentlicher Titel	Phase III Studie zu Esketamin Nasenspray gegenüber Quetiapin Retardpräparat bei behandlungsresistenter Depression
Wissenschaftl. Titel	A randomized, open-label,rater-blinded,active-controlled, international, multicenter study to evaluate the efficacy, safety and tolerability of flexibly dosed Esketamine Nasal Spray compared with Quetiapine Extended-Release in adult and elderly participants with Treatment-resistant Major Depressive Disorder who are continuing a selective Serotonin Reuptake Inhibitor/serotonin-Norepinephrine Reuptake inhibitor
Kurztitel	Escape-TRD
Studienart	multizentrisch, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Psyche: Affektive Störungen: Depression
Einschlusskriterien	- At screening, each participant must meet Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5) diagnostic criteria for single-episode major depressive disorder (MDD) or recurrent MDD, without psychotic features, based on clinical assessment and confirmed by the Mini International Neuropsychiatric Interview (MINI) - At screening and baseline, each participant must have an Inventory of Depressive Symptomatology - Clinician-rated, 30 item (IDS-C30) total score of greater than or equal to (>=) 34 - Must be on a current antidepressive treatment that includes an selective serotonin reuptake inhibitor (SSRI)/ serotonin-norepinephrine reuptake inhibitor (SNRI) at screening that resulted in nonresponse (less than 25% improvement of symptoms) after having been given at an adequate dosage (based on antidepressive dosages from SmPC [or local equivalent, if applicable]) for an adequate duration of at least 6 weeks and having been uptitrated to the maximum tolerated dose; however, at screening the participant must show signs of minimal clinical improvement to be eligible for the study. Clinical improvement of a participant on their current AD treatment will be retrospectively evaluated in a qualified psychiatric interview performed by an experienced clinician. At baseline (Day 1) prior to randomization, the investigator will evaluate any changes in the participant's signs/symptoms of depression since the screening assessment and confirm that the inclusion criteria for the current AD treatment are still met (that is nonresponse and minimal clinical improvement) - The current antidepressive treatment, was immediately preceded by nonresponse to at least 1 but not more than 5 different, consecutive treatments (all within the current moderate to severe antidepressive episode) with anti-depressants (ADs) taken at an adequate dosage for an adequate duration of at least 6 weeks and must be documented - Must have been treated with at least 2 different antidepressive substance classes among the treatments taken at an adequate dosage for an adequate duration of at least 6 weeks resulting in nonresponse in the current moderate to severe depressive episode (including the current treatment with an selective serotonin reuptake inhibitor/serotonin-norepinephrine reuptake inhibitor [SSRI/SNRI]) - Must be on a single oral SSRI/SNRI on Day 1 prior to randomization
Ausschlusskriterien	- Received treatment with esketamine or ketamine in the current moderate to severe depressive episode - Received treatment with quetiapine extended- or immediate-release in the current moderate to severe depressive episode of a dose higher than 50 milligram per day (mg/day) - Had depressive symptoms in the current moderate to severe depressive episode that previously did not respond to an adequate course of treatment with electroconvulsive therapy (ECT), defined as at least 7 treatments with unilateral/bilateral ECT

	- Has no signs of clinical improvement at all or with a significant improvement on their current AD treatment that includes an SSRI/SNRI as determined at screening by an experienced clinician during the qualified psychiatric interview - Received vagal nerve stimulation or has received deep brain stimulation in the current episode of depression - has a current or prior DSM-5 diagnosis of a psychotic disorder or MDD with psychotic features, bipolar or related disorders (confirmed by the Mini International Neuropsychiatric Interview [MINI]), obsessive compulsive disorder (current only), intellectual disability (DSM-5 diagnostic codes 317, 318.0, 318.1, 318.2, 315.8, and 319), autism spectrum disorder, borderline personality disorder, or antisocial personality disorder, histrionic personality disorder, or narcissistic personality disorder - age at onset of first episode of MDD was more than or equal to (>=) 55 years - has homicidal ideation or intent, per the investigator's clinical judgment; or has suicidal ideation with some intent to act within 1 month prior to screening, per the investigator's clinical judgment; or based on the Columbia-Suicide Severity Rating Scale (C-SSRS), corresponding to a response of "Yes" on Item 4 (active suicidal ideation with some intent to act, without specific plan) or Item 5 (active suicidal ideation with specific plan and intent) for suicidal ideation, or a history of suicidal behavior within the past year prior to screening. Participants reporting suicidal ideation with intent to act or suicidal behavior prior to the start of the acute phase should also be excluded
Alter	18 - 74 Jahre
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Sponsor	Janssen Research & Development
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04338321 (primäres Register) EudraCT 2019-002992-33