# ADDITIONAL DISCLOSURE DATA FOR SWITZERLAND

**Name of Sponsor/Company**: Janssen Research & Development*

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**Date**: 31 March 2020

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## Swiss marketing authorisation data

**Swiss Marketing Authorisation number:** 67103

**Swiss Marketing Authorisation date**: 25 February 2020

**Name of the preparation**: Spravato – 28 mg – nasal spray

**Name of active pharmaceutical ingredient**: Esketamine (JNJ-54135419-AAC)

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## Clinical trial data

1. **Clinical trial identification**

**Protocol No**.: ESKETINSUI2001

**Title of Study**: A Double-blind, Randomized, Placebo Controlled Study to Evaluate the Efficacy and Safety of Intranasal Esketamine for the Rapid Reduction of the Symptoms of Major Depressive Disorder, Including Suicidal Ideation, in Subjects Assessed to be at Imminent Risk for Suicide

**Study Name**: None

**EudraCT Number**: NA

**NCT No.**: NCT02133001

## 2. Protocol change history

**Protocol and Amendments:**

*Original Protocol, 17 January 2014*

*Amendment-1, 29 January 2014 –*

*Amendment-2, 18 March 2014 –*

*Amendment-3, 02 July 2014*

*Amendment-4, 11 December 2014*

*Amendment-5, 21 October 2015*

## 3. Clinical trial investigators and study centres

**Principal Investigator***:* Gerard Sanacora, MD

**Study Centres:** United States: 10 sites

## 4. Medication used

**Test Product, Dose and Mode of Administration, Batch No.**: Intranasal esketamine was supplied as a solution containing 16.14% weight/volume (w/v) esketamine hydrochloride (equivalent to 14% w/v esketamine base). The esketamine solution was supplied by the sponsor in a bidose nasal spray device. Each device delivered 16.14 mg esketamine hydrochloride (14 mg esketamine base) per 100 µL spray and contained a total of 200 µL solution. Batch numbers for intranasal esketamine formulation JNJ54135419-AAC-G005 (equivalent to 140 mg/mL G005 for nasal delivery) were: 13K08/G005 (expiry dates: November 2014 and November 2015), and 14F03/G005 (expiry date: June 2016).

**Reference Therapy, Dose and Mode of Administration, Batch No**.: Intranasal placebo was supplied as a solution containing water with a bittering agent (0.001 mg/mL denatonium benzoate) added to stimulate the taste of the intranasal esketamine solution. Placebo solution was supplied by the sponsor in a bidose nasal spray device. Each device delivered 0.1 µg of denatonium benzoate per 100 µL spray, and contained a total of 200 µL of solution. Batch numbers for intranasal placebo formulation JNJ54135419-AAC-G003 (PBO G003 for nasal delivery) were: 13H20/G003 and 13K07/G003 (expiry date: November 2014), 14G07/G003 (expiry dates; November 2015 and June 2016).

## 5. Study population

**Number of participants – planned:** 68

**Number of participants – analysed:** 68

## 6. Summary and conclusion

The results of this Phase 2a proof-of-concept study, supports the hypothesis that intranasal esketamine is an efficacious treatment for the rapid reduction of the symptoms of MDD, including suicidal ideation, in patients assessed to be at imminent risk for suicide. Intranasal esketamine 84 mg, compared to placebo, demonstrated a clinically meaningful and statistically significant rapid reduction of depressive symptoms in subjects with MDD who were assessed to be at imminent risk for suicide, as demonstrated by change from baseline in the MADRS total score at both 4 hours postodse and at Day 2 (approximately 24 hours postdose). Statistically significant improvement on MADRS-SI at 4 hours, along with evidence of potential therapeutic effect on the MADRS-SI at Day 2 and SIBAT Clinical Global Judgment of Suicide Risk at 4 hours and Day 2, suggest that esketamine 84 mg may also be efficacious treatment for the rapid reduction of suicidality in this population.

All subjects received comprehensive treatment with initial hospitalization and optimized Standard of care antidepressant medication. Despite some non-specific improvement in the placebo group, the beneficial effect of esketamine on the symptoms of MDD, as measured by the MADRS total score and the MADRS-SI item, could be distinguished at early time points as well as at the double-blind endpoint. These findings provide important new information regarding the potential use of esketamine as a treatment for the rapid reduction of the symptoms of MDD, including suicidal ideation, in patients assessed to be at imminent risk for suicide, a potentially lethal condition for which there is an unmet medical need.

Esketamine 84 mg was safe and tolerated by patients with MDD assessed to be at imminent risk for suicide, and no new safety signals emerged in this population.

## 7. Results reporting

**Date of Clinical Trial Report**: 20 January 2017

**Prepared by:** Janssen Research & Development, LLC

**Publication(s) Reference(s)**: Canuso CM, Singh JB, Fedgchin M, et al. Efficacy and safety of intranasal esketamine for the rapid reduction of symptoms of depression and suicidality in patients at imminent risk for suicide: results of a double-blind, randomized, placebo-controlled study. Am J Psychiatry. 2018;175(7):620-630

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