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DSVR 2025

3 juillet- Paris, France

ELLIPSE

Observational study on initiation and use of Esketamine nasal spray in real-world conditions

STAND-OUT FACTOR AND KEY TAKEAWAYS

ELLIPSE is a full study designed to generate evidence of esketamine nasal spray in real world conditions

Study 5 in 1 to provide a comprehensive understanding of product utilization in everyday clinical practice

- Cross-sectional registry
- Prospective study with a 1 year core follow-up
- Long-term prospective study
- SNDS claims database matched study
- Qualitative study

Aim of the study: to inform stakeholders (patients, physicians, health authorities) on the use of esketamine in real-world conditions

Evidence dissemination

- First results (1 year of FU) published in 2025 (medical congresses)
- Manuscript planned on Q4 2025
- Final results (long-term prospective study, SNDS, and qualitative one) expected by Q4 2025

INTRODUCTION

Context

Major depressive disorder (MDD) is one of the leading causes of disability worldwide[1]. Approximately one third of patients with this disorder are considered drug resistant (TRD)[2,3].

Esketamine nasal spray was granted marketing authorization on 18-Dec-19 for the treatment of moderate to severe depressive episode which have not responded to at least two different antidepressants in the current moderate to severe depressive episode in adults in combination with a SSRI or SNRI[4,5].

On 24-June-20, the French health authorities (HAS) adopted a favourable opinion for the reimbursement of esketamine nasal spray and asked J&J to provide real world data for 2025[6] :

- describe patients' characteristics
- describe the clinical practice and condition of use of the treatment
- observe the outcome of patients under treatment in terms of effectiveness, quality of life and tolerance

ELLIPSE study was designed to address these objectives and beyond by generating a 360° approach. All patients suffering from unipolar major depressive disorder (MDD) and treated by esketamine in the participating centers were included in the prospective study.

ELLIPSE study received local ethical committee approval in September 2021 and 1st patient was included in December 2021.

Results dissemination

The first results of the ELLIPSE study were already published in medical congresses, with a comprehensive overview of patients pathways under esketamine: clinical description (cross-sectional registry), esketamine condition of use (prospective study), healthcare resources consumption (SNDS study) and patient point of view (qualitative study).

All these data will be disseminated through national and international congresses and submitted to French Health Authorities.

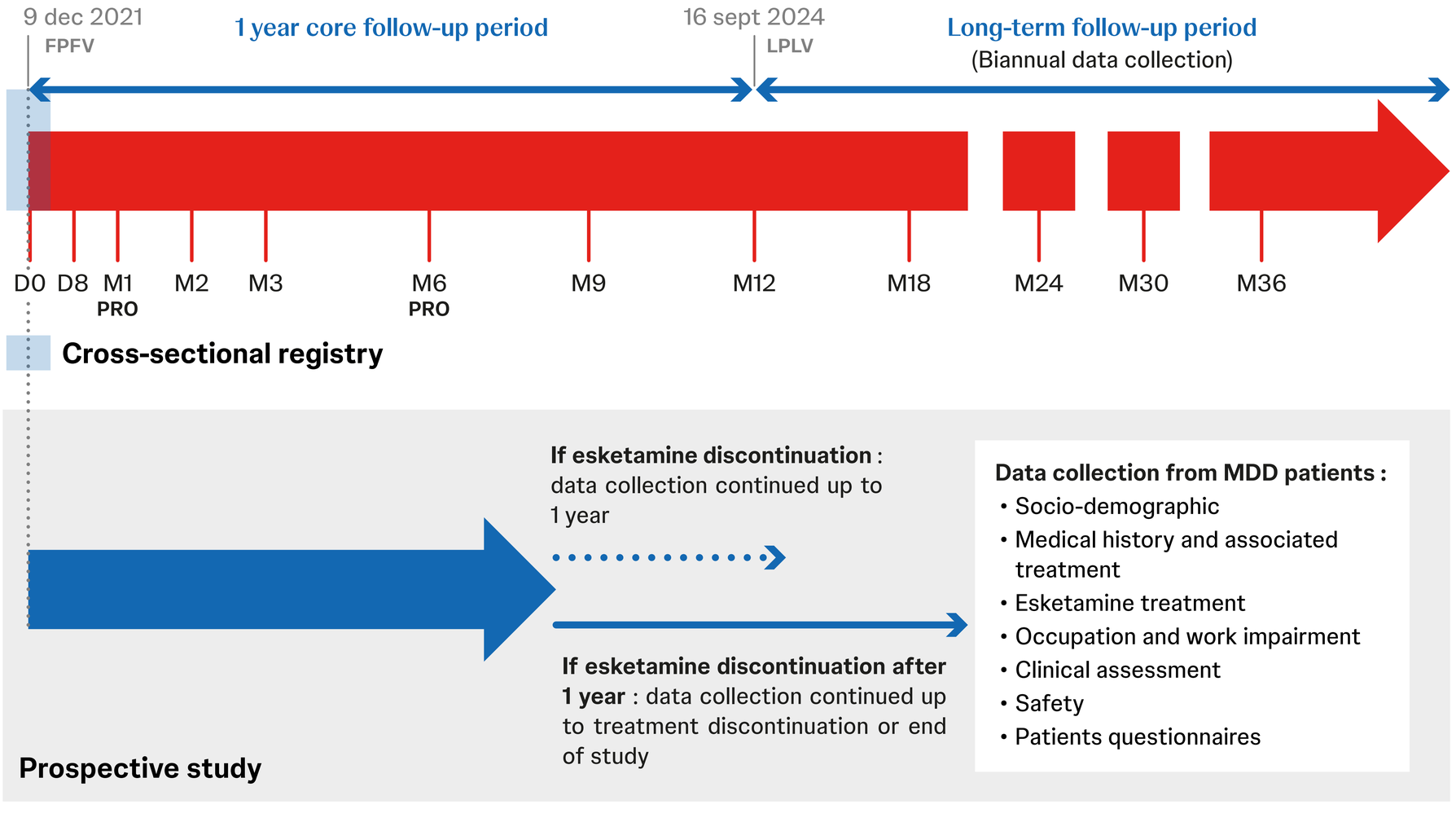
APPROACH

Patients inclusion and data collection

In the primary study, 31 French centers included **293 adults patients treated with ESK** in the cross-sectional registry to describe their socio-demographic and clinical characteristics.

200 adult patients with unipolar MDD were included in the prospective cohort to assess conditions of use, effectiveness, quality of life and safety over a 12-month period.

To date, 22 patients in the prospective cohort were still on treatment after 12 months of follow-up, allowing evaluation of long-term efficacy and safety in these patients.



Up to 5 years before esketamine initiation until end of 1 year follow-up

SNDS study (Claim database)

MDD patients from the prospective study will be probabilistically matched to the national claims database in order to describe the healthcare comsumptions and direct/indirect costs of care prior to esketamine initiation, and to assess the economic and societal impact of the patients after treatment initiation.

Qualitative study

1st interview

≃ 1 month after esketamine initiation

2nd interview

≃ 6 months after esketamine initiation

Twenty TRD patients from the prospective study took part in interviews based on the published method "IPSE"[7], collecting feedback about the administration of ESK and how it is perceived, and identifying key axes of experience.

References

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Abbreviations

FPFV: First patient first visit; **LPLV:** Last patient last visit.