CELON PHARMA

Phase 2 trial of Falkieri (esketamine DPI) in TR bipolar depression

Topline Results

01 11 2021

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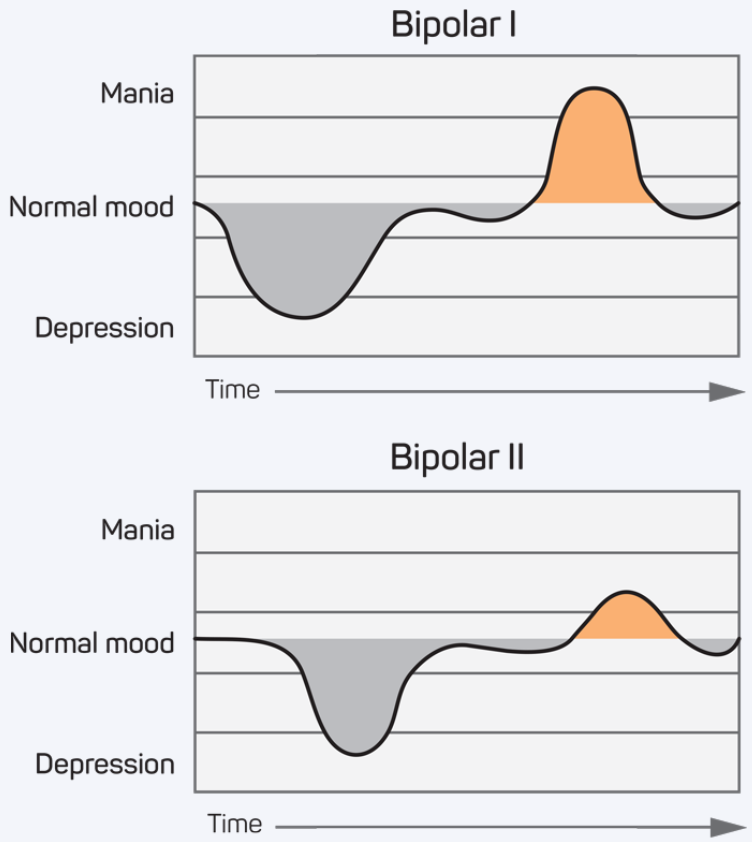
Bipolar Disorder Factsheet

- Bipolar disorder (BD) is one of the most severe psychiatric disorders affecting more than 2% of the global population (6 million adults in the US)
- It is characterised by biphasic, recurrent mood episodes of mania/hypomania and depression
- Depressive episodes are often longer than manic or hypomanic episodes
- Increased risk of other disorders (cardiovascular, obesity, diabetes, metabolic syndrome). Life-expectancy reduced by 12-15 years
- Suicide rates are 20 to 30 times higher than in general population; 6 to 7 % of patients commit suicide
- Limited treatment options for bipolar disease patients with depressive episodes



(adopted from Harvard Health Letter
https://www.health.harvard.edu/newsletter_article/Bipolar_disorder)

Bipolar disorder is a common, highly debilitating disease.

1. Vieta, E, Berk M, Schulze. TG, et al. *Bipolar disorders. Nat Rev: Dis Primer*, *4*, 18008 (2018). 2. Carvalho AF, Firth J, Vieta E. Bipolar Disorder. N Engl J Med. Jul 2;383(1):58-66, (2020). 3. Baldessarini, R.J., Vázquez, G.H. & Tondo, L. Bipolar depression: a major unsolved challenge. *Int J Bipolar Disord* 8, 1 (2020). 4. Depression and Bipolar Support Alliance. https://www.dbsalliance.org/education/bipolar-disorder/bipolar-disorder-statistics/.

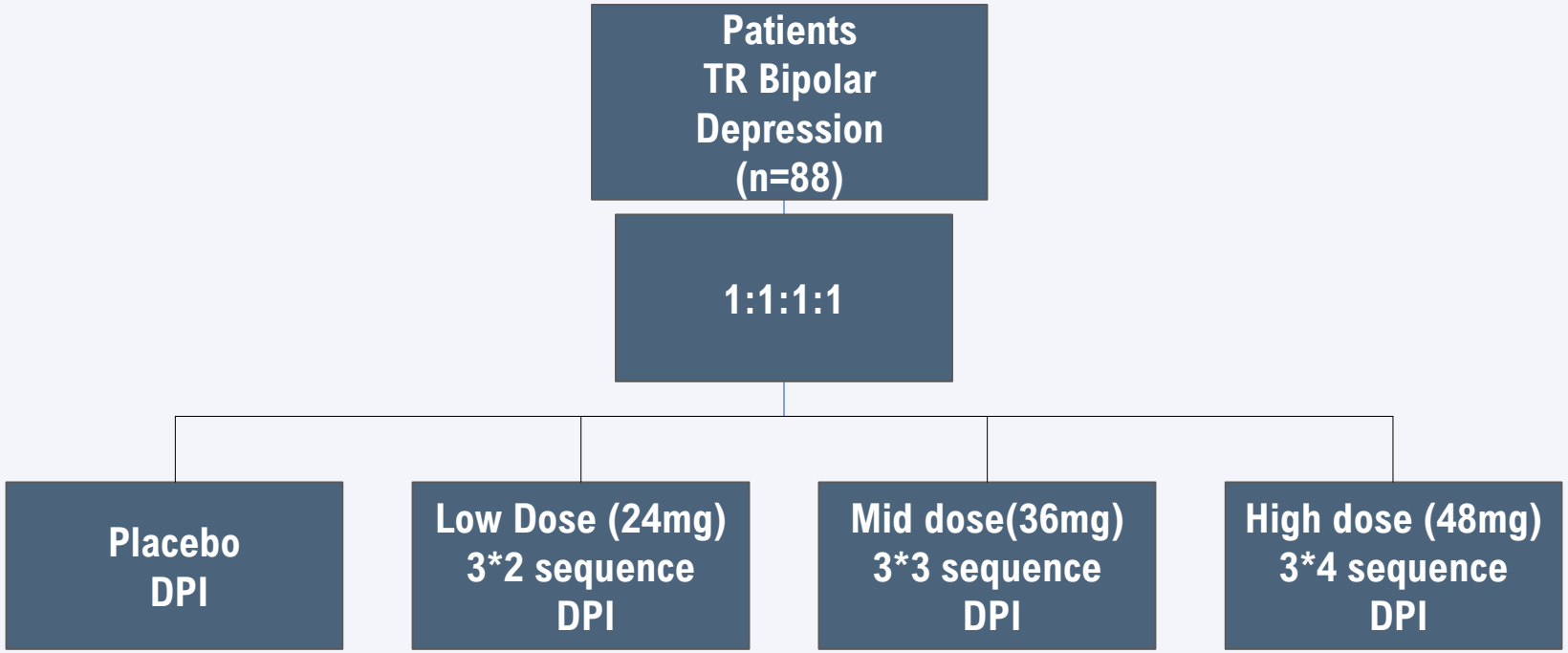
Treatment Resistant Bipolar Depression

- Small number of treatments that often fail to significantly improve symptoms and functionality
- Treatment failure rates often higher than in Major Depressive Disorder (MDD) - unipolar depression
- Treatment-resistant Bipolar Depression (TRBD)
  - no clear consensus on the TRBD definition
  - consensus shared by clinicians, similar to TR unipolar depression: inadequate response (failure to reach sustained remission) to at least two different adequate treatment trials (with at least two recommended monotherapy treatments or at least one monotherapy treatment and another combination treatment)

There are no effective therapeutic agents in TR bipolar depression, and nothing approved for acute treatment.

1. Hidalgo-Mazzei, D., Berk, M., Cipriani, A., Cleare, A., Florio, A., Dietch, D., . . . Stokes, P. (2019). Treatment-resistant and multi-therapy-resistant criteria for bipolar depression: Consensus definition. *British Journal of Psychiatry, 214*(1), 27-35. (2019).

Falkieri Phase II TR Bipolar Depression Trial - Design Summary



4 doses administered over a 14-day period, with 6 weeks of follow-up

Primary Endpoint: Change from baseline in the Montgomery-Asberg Depression Rating Scale (MADRS) total score at Week 2

Key Secondary Endpoints: Response, Remission, Safety, PK

NCT03965871: randomized, double blind, placebo controlled, multicentre study using Falkieri as an adjunctive treatment.

Falkieri Phase 2 in TRBD - Demographics & Baseline Characteristics

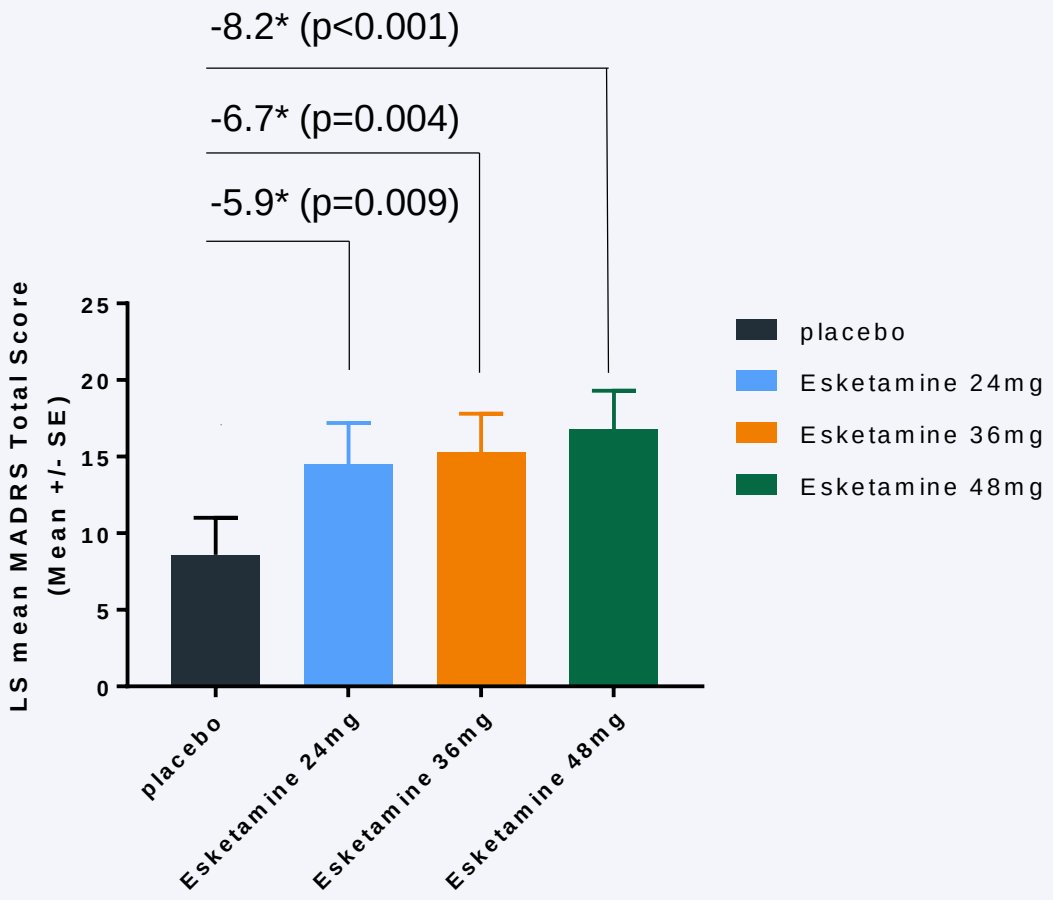
Adult patients age 18-65 years old, with depressive episode in bipolar depression
Bipolar depression was considered treatment-resistant if inadequate response to at least two therapies was observed.

		Placebo (N=22)	Esketamine		
			24 mg (N=23)	36 mg (N=21)	48 mg (N=22)
Age		44 (10.3)	40.0 (12.6)	43.2 (12.8)	42.7 (12.0)
Gender *	Female	14 (63.6 %)	16 (69.6%)	16 (76.2%)	14 (63.6%)
	Male	8 (36.4%)	7 (30.4%)	5 (23.8%)	8 (36.4%)
BMI – body mass index		28.2 (5.1)	24.7 (4.6)	27.5 (5.2)	24.6 (4.0)
Bipolar type *	Type I	16 (72.7%)	15 (65.2%)	17 (81.0%)	15 (68.2%)
	Type II	6 (27.3%)	8 (34.8%)	4 (19.0%)	7 (31.8%)
MADRS baseline score		28.6 (3.1)	28.8 (2.1)	28.4 (1.8)	28.8 (2.9)
HDRS baseline score		18.1 (2.3)	18.2 (3.4)	18.4 (3.5)	19.3 (4.5)
YMRS baseline score		2.0 (1.0)	1.3 (1.3)	1.6 (1.2)	1.3 (1.0)

If not specified [mean, (SD)] is shown
* [N, (% of patients)]

NCT03965871: randomized, double blind, placebo controlled, multicentre study using Falkieri as an adjunctive treatment.

Falkieri Primary Efficacy Endpoint Successfully Met (Change in MADRS Total Score at Week 2)



	Placebo (N=22)	Esketamine		
		24 mg (N=23)	36 mg (N=21)	48 mg (N=22)
Mean ChfB (SD)	-7.0 (6.7)	-13.7 (8.3)	-14.6 (8.1)	-16.5 (6.4)
LS mean ChfB (SE)	-8.6 (2.4)	-14.5 (2.7)	-15.3 (2.5)	-16.8 (2.5)
LS mean difference vs placebo (SE)		**-5.9 (2.2)**	**-6.7 (2.2)**	**-8.2 (2.2)**
95% CI for LS mean difference vs placebo		-10.2 - -1.5	-11.1 - -2.2	-12.6 - -3.7
p-value vs placebo		0.009	0.004	< 0.001
Effect size (Cohens D)		0.888	1.017	1.434

ChfB: change from baseline
CI: confidence interval

Falkieri demonstrated a rapid and substantial improvement in the symptoms of depression in all tested doses.

p-value calculate from LS means. Placebo-subtracted diffirences. Based on ANCOVA analysis
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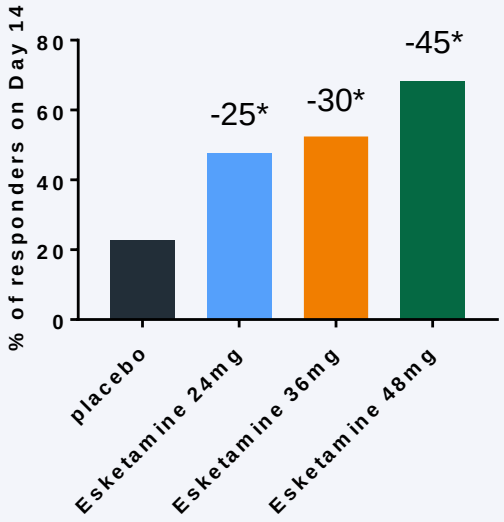
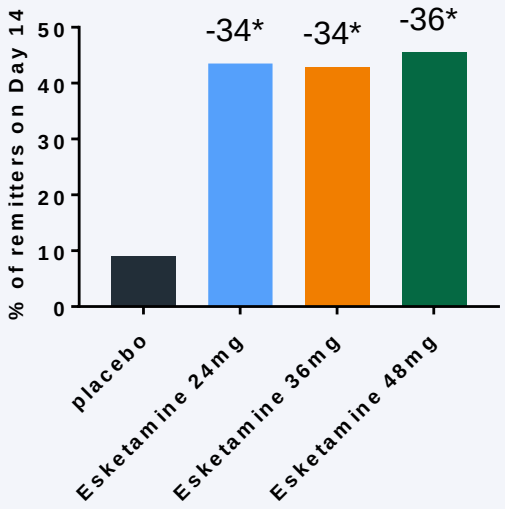
Falkieri Selected Secondary Endpoints

Response
(defined as ≥50% reduction from baseline on Day 14)

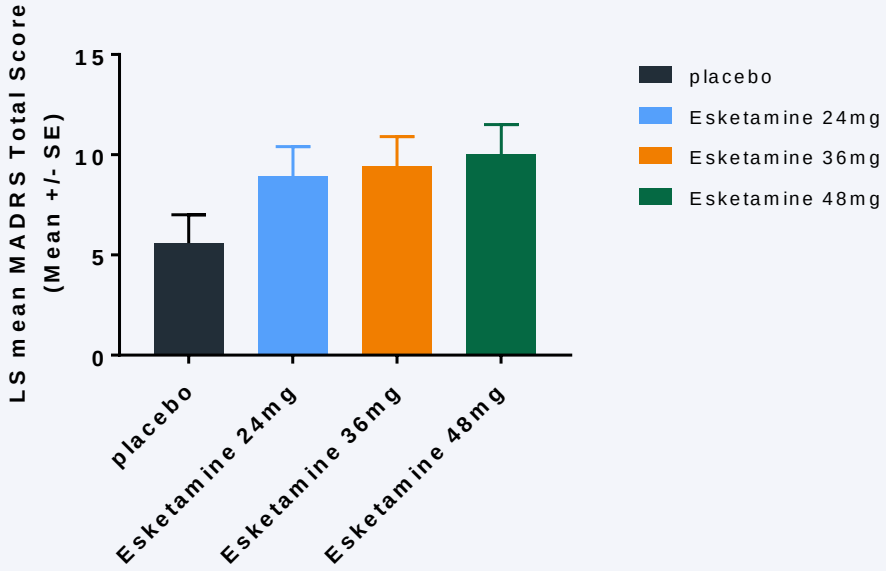


Remission
(defined as achieving MADRS total score ≤10 on Day 14)



* Placebo-subtracted difference in %

Hamilton Depression Rating Scale (HDRS)



HDRS, $p < 0.05$ at all doses

Multiple secondary efficacy endpoints robustly confirm Falkieri positive effect in TR bipolar depression.

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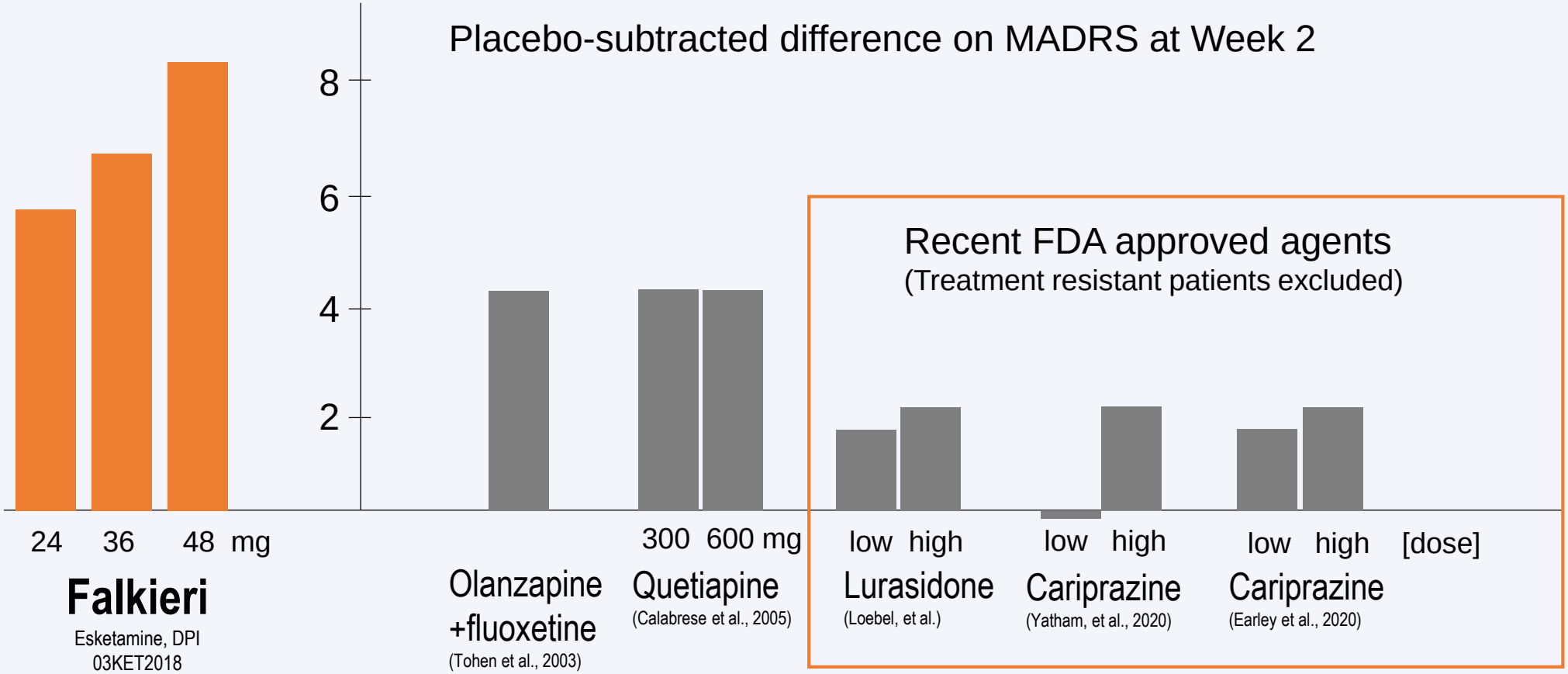
Falkieri Efficacy Data in MADRS improvement
Compares Favorably to Other Therapies



Falkieri efficacy data compare favorably to other therapeutic options.
MADRS improvement is even more profound given resistant population tested in the Falkieri study.

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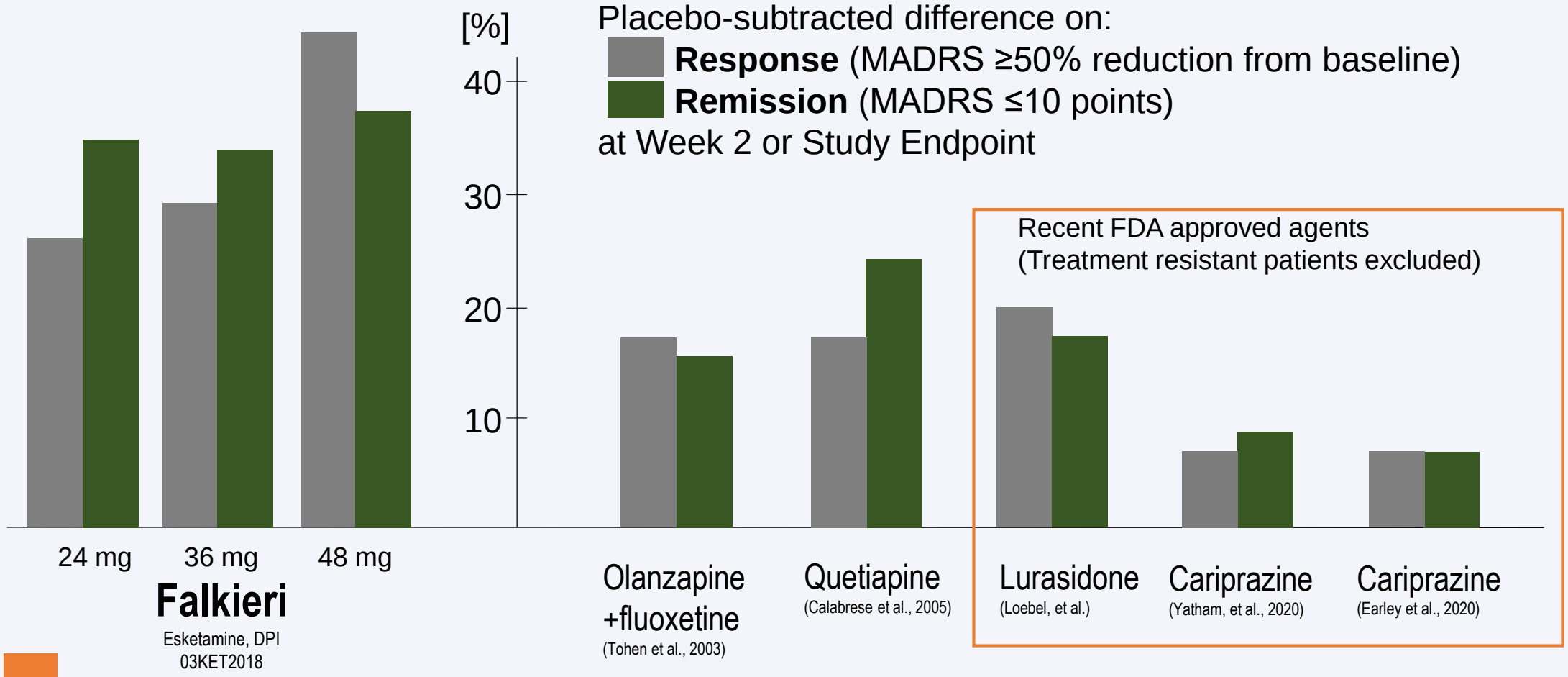
Falkieri Efficacy Data in Achieving **RESPONSE and REMISSION**
Compares Favorably to Other Therapeutic Options



Falkieri efficacy data compare favorably to other agents.
Both response and remission rates for Falkieri exceed those for other agents.

The data for other treatments measured at timepoint between Week 2 and 8 depending on the data availability.
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Falkieri Safety Profile in Bipolar Depression

- No deaths, no serious side effects, no suicides, no discontinuations due to adverse events, no mania induction at any time point, no sedation
- No dose related adverse events (% of subjects with adverse events: Placebo – 27.3%, Esk24 – 39.1%, Esk36 – 23.8%, Esk48 – 27.3%),

Adverse events occurring in ≥ 5% of patients

No.	Adverse Events	Overall (N=88)	Placebo (N=22)	Esketamine		
				24 mg (N=23)	36 mg (N=21)	48 mg (N=22)
1	Dizziness	18 (20.5%)	2 (9.1%)	9 (39.1%)	3 (14.3%)	4 (18.2%)
2	Feeling abnormal	13 (14.8%)	2 (9.1%)	6 (26.1%)	3 (14.3%)	2 (9.1%)
3	Euphoric mood	7 (8.0%)	0 (0.0%)	4 (17.4%)	2 (9.5%)	1 (4.5%)

[N, (% of patients)]

Clean safety profile. High study completion rates.

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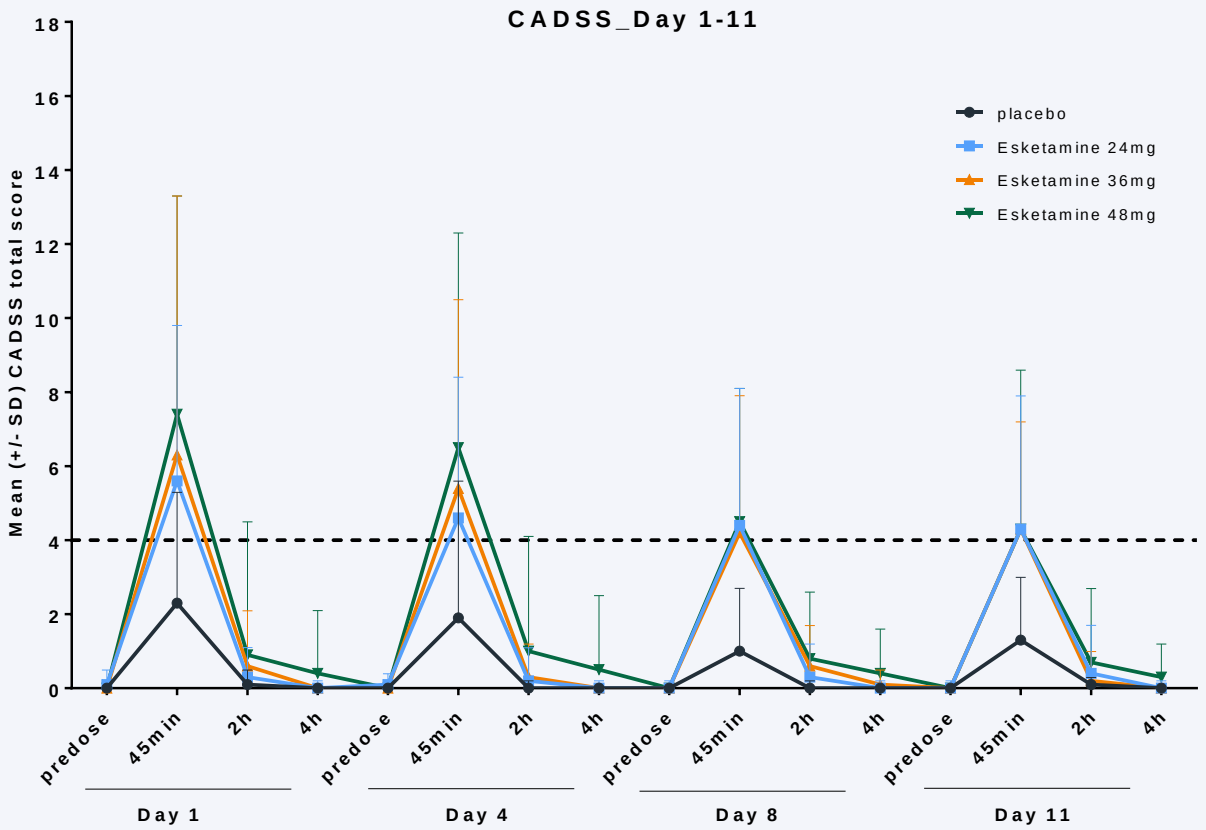
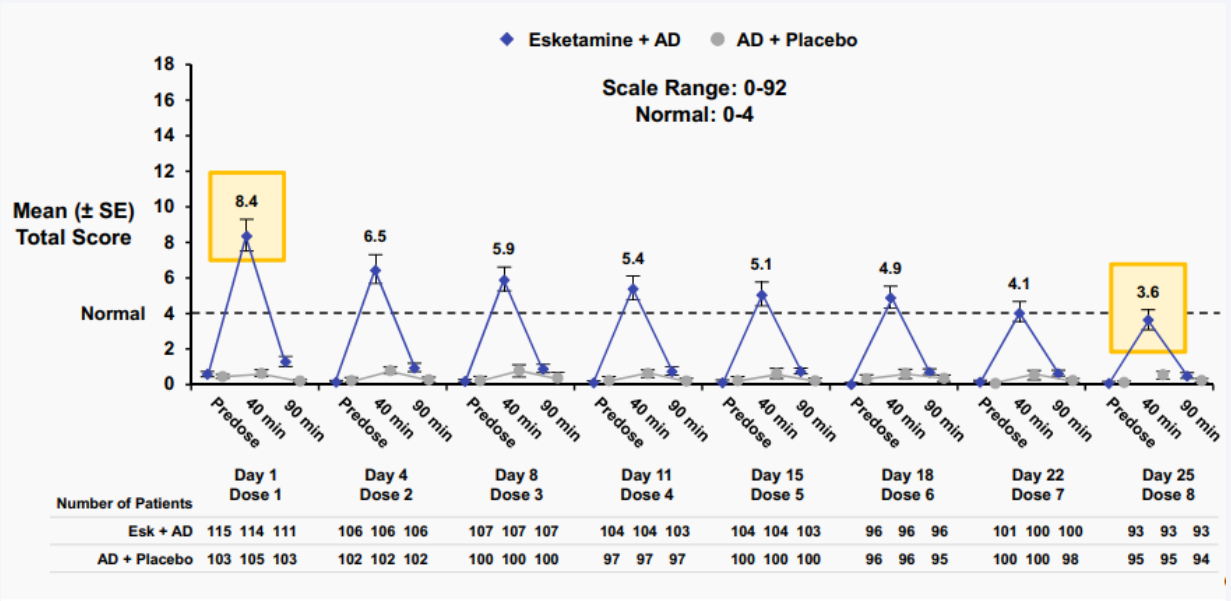
Falkieri Safety Profile. Dissociation.

Falkieri bipolar TR depression



SPRAVATO

CADSS total score over time
TRANSFORM-2 (3002)



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CADSS data consistent with findings from unipolar depression Phase 2 study.
Dissociation is mild and transient, stabilizing after the first two administrations at the score 4.
CADSS - Clinician-Administered Dissociative States Scale.

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Falkieri - Differentiated Product Profile

	Phase of Devpt.	Indication(s)	Administration	Dosing
Spravato	Approved	(1) Treatment-Resistant Unipolar Depression	In the clinic	Intranasal
Falkieri	Phase II	(1)Treatment-Resistant Unipolar Depression (2)Bipolar Depression	Acute – in the clinic Maintenance - At home	Dry Powder Inhaler (potentially more predictable pharmacokinetics)

Falkieri represents new therapeutic option with clear differentation on safety and efficacy and potential for at-home use.

Falkieri Key Takeaways

- Rapid, substantial and significant improvement in treatment-resistant bipolar depression
- Met primary endpoint – highly statistically significant improvement on MADRS versus placebo at Week 2
- Well tolerated and safe treatment with a safety profile consistent with the previously completed study in MDD, with no mania induction

What's next ?

- Six week follow-up data in TR bipolar depression expected H1 2021
- Positive results sufficient to initiate discussions with the FDA/EMA regarding the pivotal Phase 3 registrational trials
- Continuation of partnering talks in accordance with the strategy for innovative drugs portfolio.

Unique opportunity in a high unmet need illness with no acute treatment options.

THANK YOU!

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