



# INVESTOR PRESENTATION

January 2021

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# Company Highlights

## Innovative Biopharma Company

Unique revenue generating platform combining a diversified pipeline of highly innovative programs with a leading portfolio of generic products

## Largest R&D Centre in Eastern Europe

With one of the largest R&D in CEE and over 160 scientists, Celon Pharma has unique development expertise for global product R&D

## 5 Clinical Stage Programs with Large Market Opportunities

Broad pipeline of 5 clinical stage assets and multiple identified leads targeting large market opportunities in neuropsychiatry, oncology, metabolism & inflammation. Potential blockbusters with wholly owned IP

## Value Creating R&D and Commercialization Model

R&D supported by grants of >\$100m, commercial business cash flows and partnerships. Flexible and tailored commercial approach for each R&D program

## Recent Positive Ph II Readout for Falkieri

Falkieri poised to transform underserved \$10bn TRD/bipolar depression market with superior, differentiated DPI approach

## Experienced Management Team

Highly distinguished management team with track record of lab to clinic development and commercial success. Founding shareholder strongly invested in and committed to Celon Pharma

Celon Pharma is a unique profitable biopharma company with a successful R&D track record and fully-owned attractive pipeline with multiple catalysts in the near term and 9 clinical data readouts in the next 15 months.

## Corporate Overview: A Sizeable Local Player. Regional expansion plans



Warsaw-based with approx.. 500 employees (over 160 in R&D)



Listed on Warsaw stock exchange (WSE.CLN) with \$550 million market cap

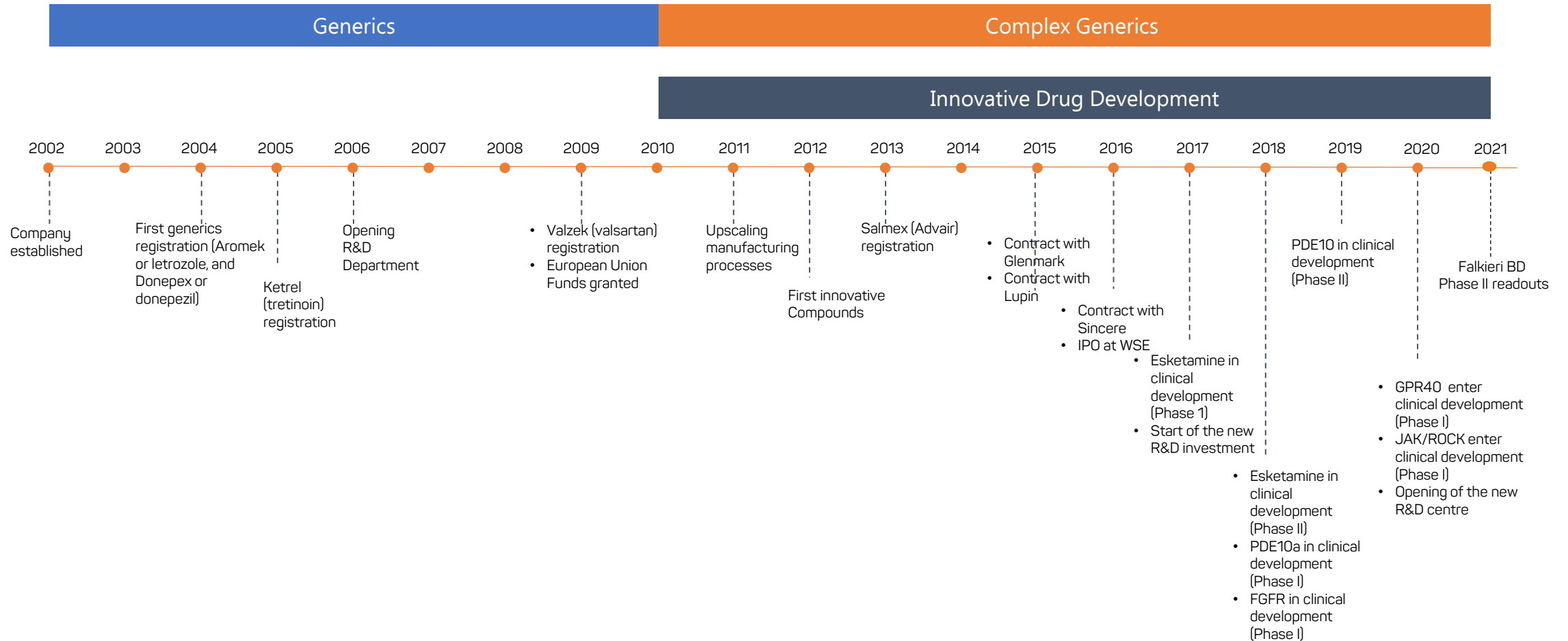


Key partners such as Mylan and Glenmark with global commercial reach



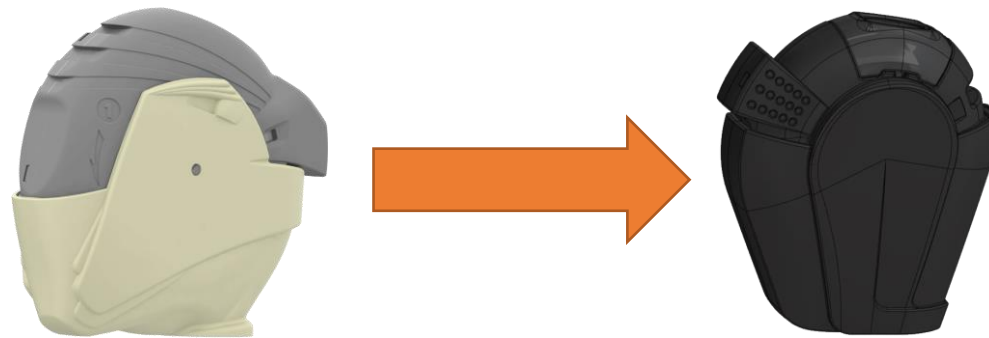
CEO Maciej Wieczorek is majority shareholder with 75% of voting rights (long term investors)

# Evolving to Create Innovative Drugs.



## Track record in Dry Powder Inhaler Technology is a Competitive Advantage

- Celon has track record in dry powder inhaler technology, relevant manufacturing expertise and capabilities as well as experience in running human factor studies
  - Salmex (Fluticasone propionate+Salmeterol) was approved in 2013
- Will leverage this expertise to develop Falkieri inhaled esketamine for at-home use
- To prevent patients from taking Falkieri recreationally its inhaler device is designed with a locking mechanism and may be monitored via a physician-controlled app.



Salmex

Falkieri

# Most Advanced Innovative R&D Projects

Indication	Molecular Target	Research	Pre-Clinical	Phase I	Phase II
Treatment-resistant Depression/Bipolar Depression	Esketamine	FALKIERI			
Schizophrenia/ Psychomotor Disorders	PDE10a Inhibitor	CPL'36			
Solid Tumors (Bladder, Lung, Gastric)	FGFR Inhibitor	CPL'110			
Diabetes/Diabetic Neuropathy	GPR40 Agonist	CPL'280			
Multiple Anti-inflammatory Indications	JAK/ROCK Inhibitor	CPL'116			

In 2021 Celon also plans to launch three new programs into the clinic: (1) MER inhibitor in solid and hematological cancers, (2) PI3K $\delta$  inhibitor for Lupus and Psoriasis and (3) an FGF agonist in diabetes.



# Falkieri

Esketamine smart inhaler for at-home use for treatment-resistant major depressive disorder and treatment-resistant bipolar depression



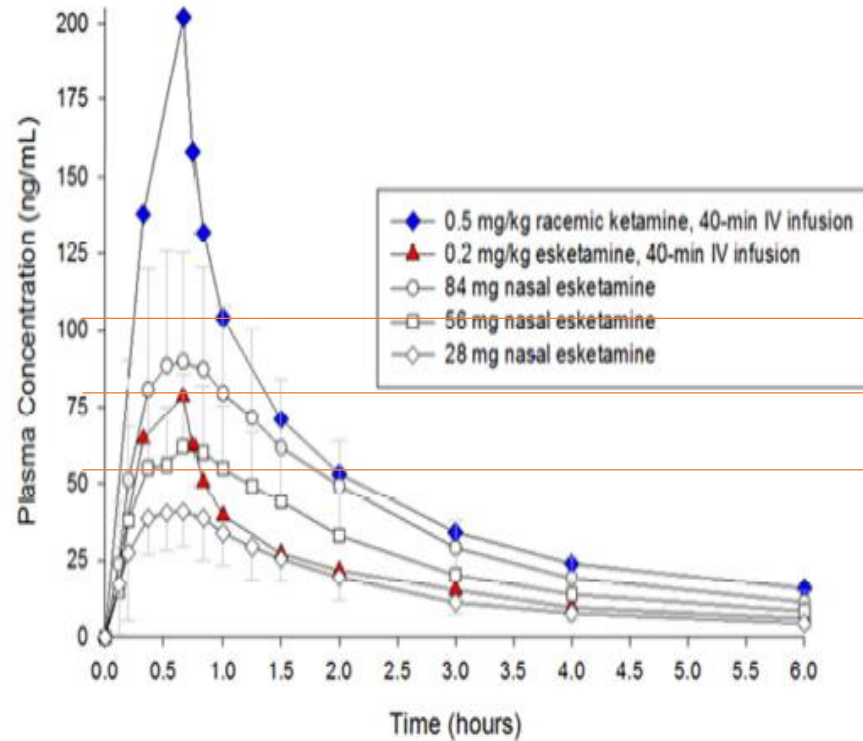
## Falkieri has been Designed to Improve on Spravato Shortcomings

	Phase of Devpt	Indication(s)	Administration	Safety	Dosing
Spravato	Approved	(1) Treatment-Resistant Depression; (2) Depressive Symptoms in Adults with Suicidal Ideation	In the clinic Both acute and maintenance		Intranasal
Falkieri	Phase II	Treatment-Resistant Depression/ Bipolar Depression*	Acute – in the clinic Maintenance - at home	Potentially more tolerable	Dry Powder Inhaler

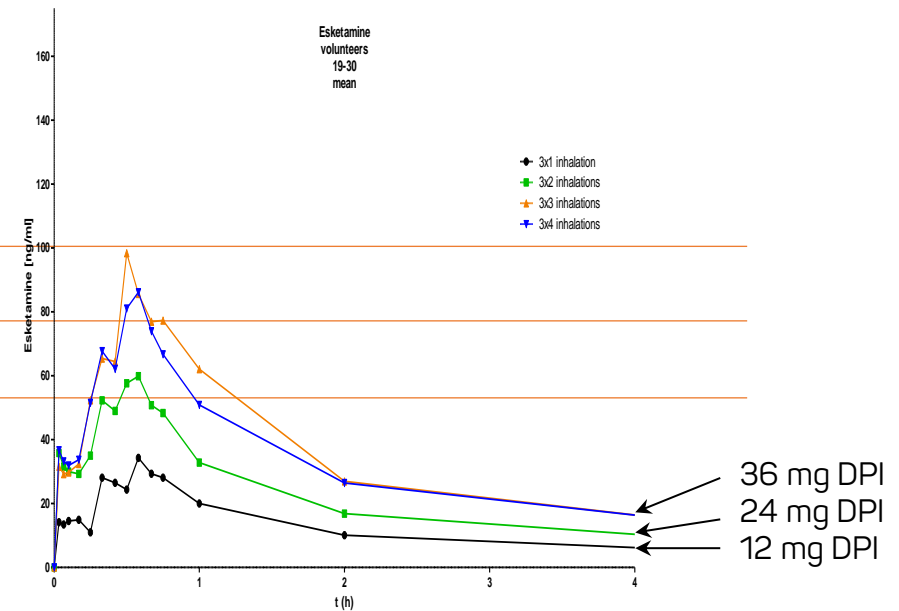
\*Falkieri is also targeting bipolar depression based on data in ~100 patients showing that the drug does not induce mania

# 30-45% Higher Bioavailability of Esketamine from DPI Falkieri vs Intranasal

Spravato (Esketamine intranasal)

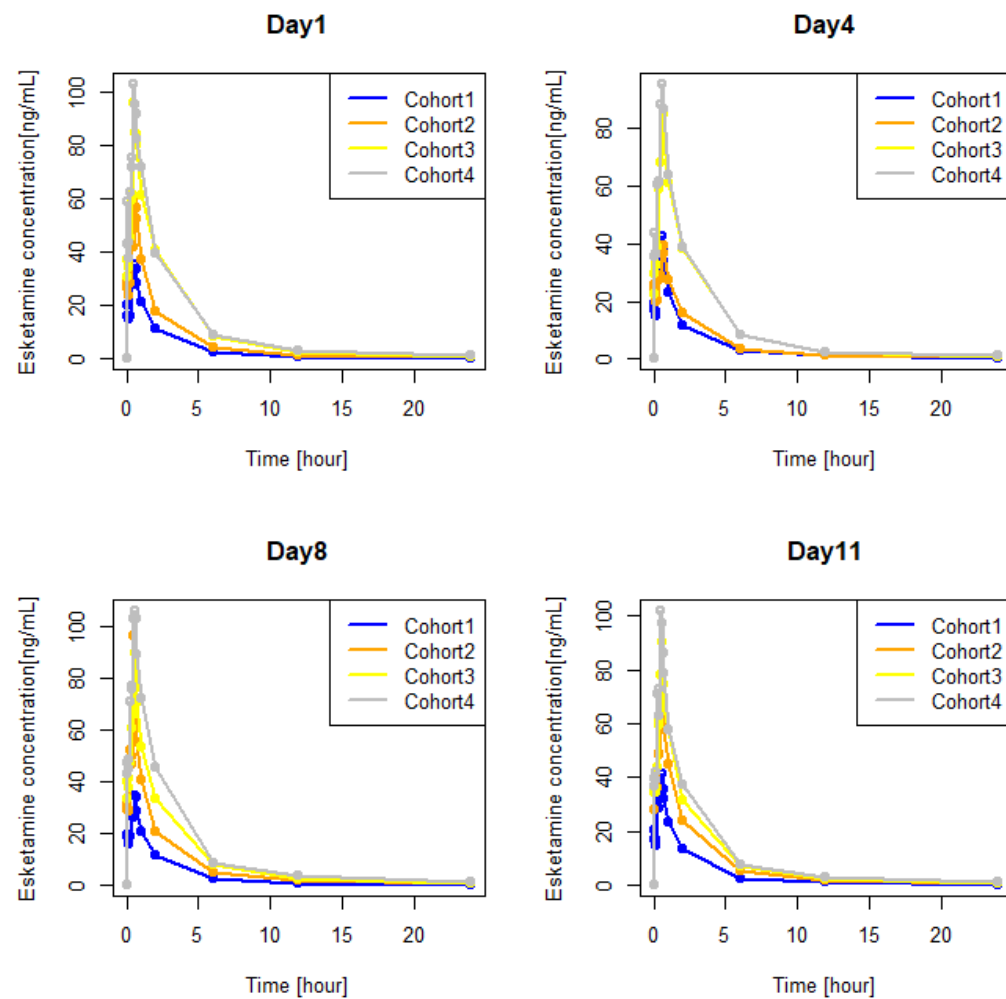


Falkieri (Esketamine DPI)



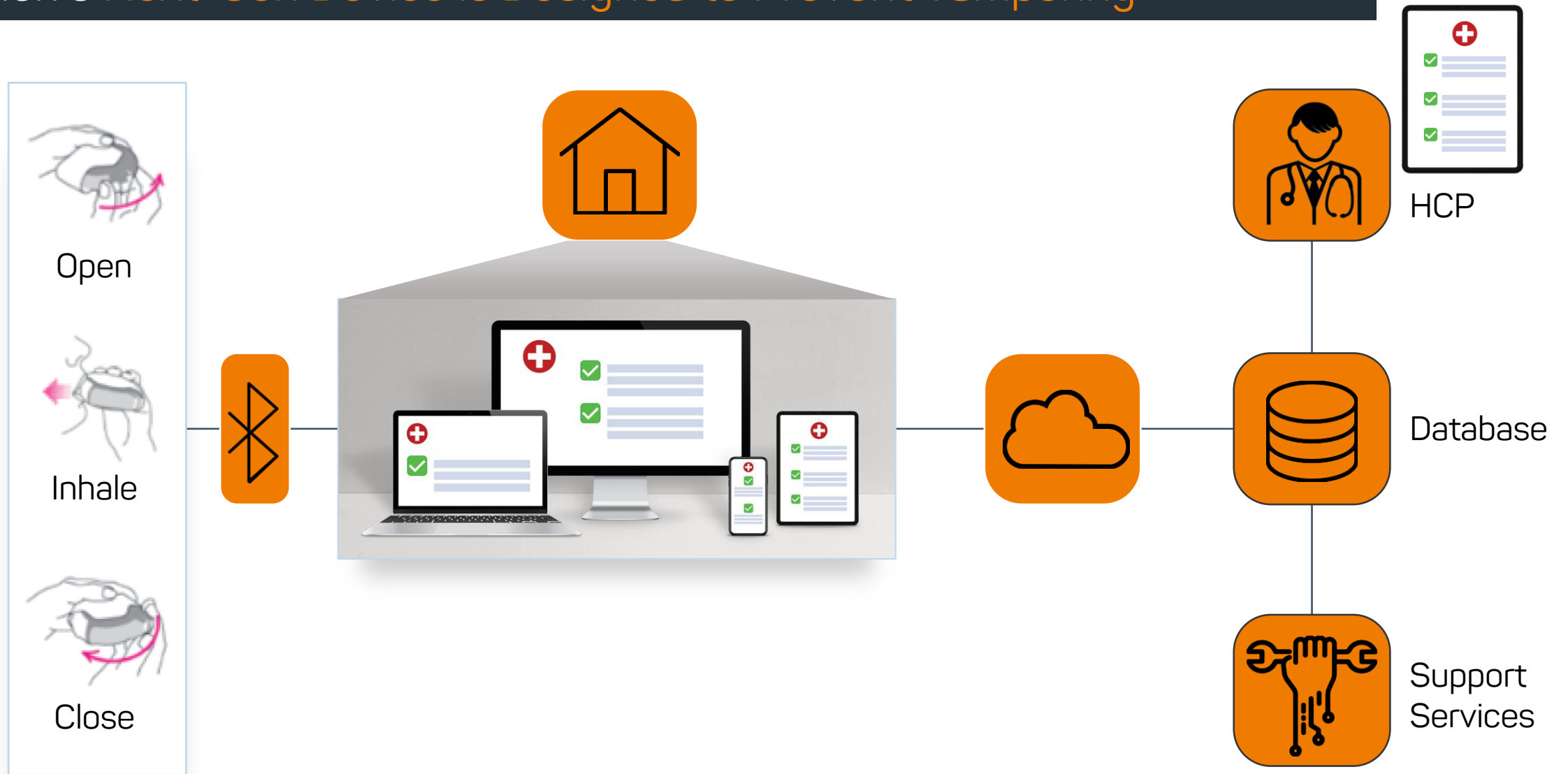
Dose is administered within a dosing sequence comprised of 3 inhalation events of 3 inhalations (puffs) per event administered within 30 minutes with a 15-minute rest period.  
The assumed treatment will include a treatment cycle of 2 weeks on/2 weeks off; 4 dosing sequences per two weeks on

# Falkieri May Deliver a More Consistent Dose to Each Patient



Phase 1 data demonstrated lower intra-subject variability of esketamine from DPI Falkieri vs intranasal Spravato (CVi 30% vs 40% for AUC)

# Falkieri's Next-Gen Device is Designed to Prevent Tampering



# Phase 2 Falkieri Trial in TR MDD Demonstrated Encouraging Results

Screened – 109 patients (19 screen failures);

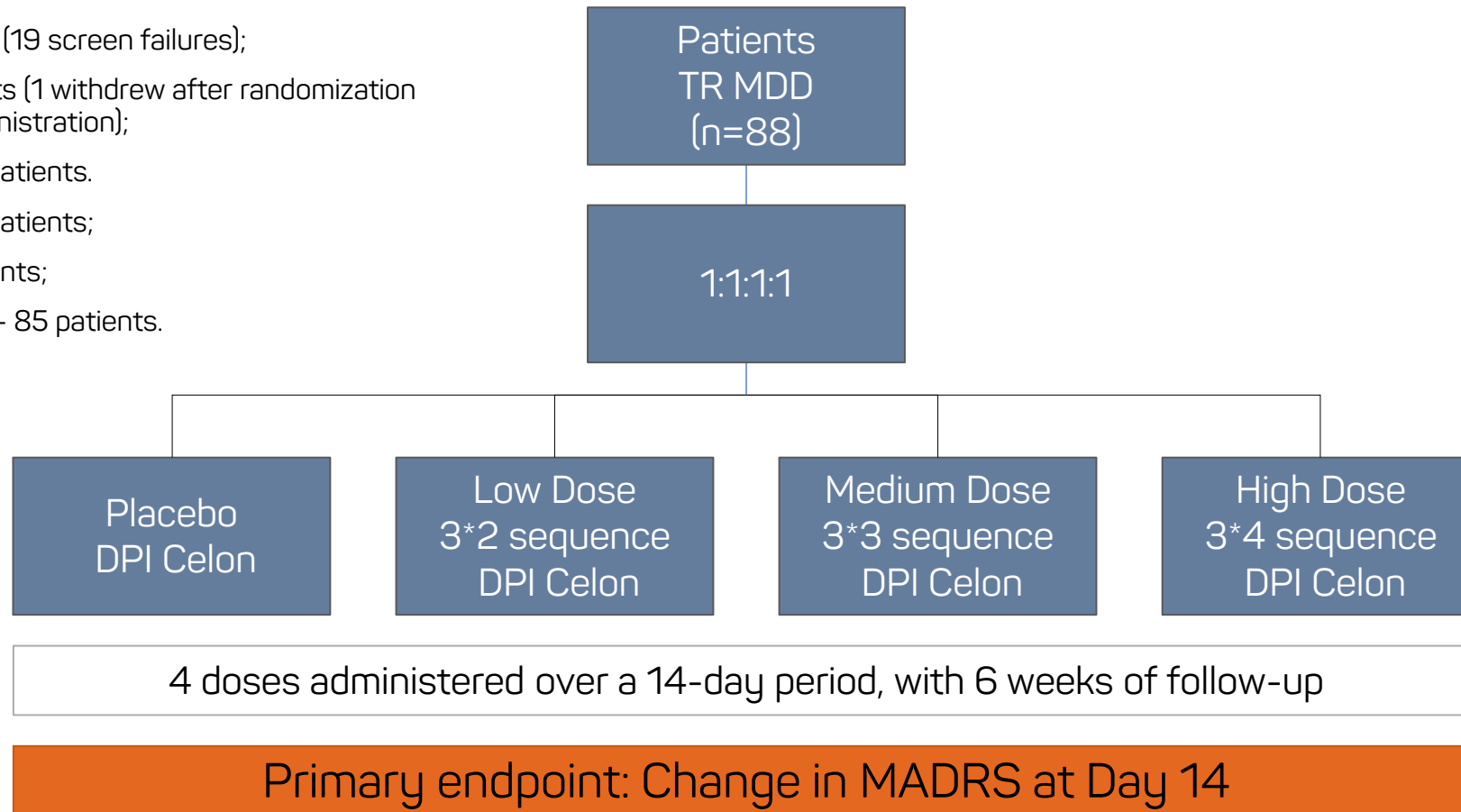
Randomized – 90 patients (1 withdrew after randomization but before first IMP administration);

Day 14 completed – 85 patients.

Safety Population – 89 patients;

ITT Population – 89 patients;

Per Protocol Population – 85 patients.



Generated good safety data and signals of efficacy in low dose and high dose arms.

# Falkieri May Offer a Competitive Safety Profile to Spravato

Number and % of patients with TEAE observed  
(only TEAE observed in  $\geq 5\%$  of patients)

No.	TEAE	Overall (%) N=89	Placebo N=22	Esketamine Low dose N=22	Esketamine Medium dose N=23	Esketamine High dose N=22
1	Feeling abnormal	5 (5.6%)	0 (0.0%)	1 (4.5%)	2 (8.7%)	2 (9.1%)
2	Feeling of relaxation	6 (6.7%)	1 (4.5%)	2 (9.1%)	1 (4.3%)	2 (9.1%)
3	Dizziness	21 (23.6%)	3 (13.6%)	3 (13.6%)	7 (30.4 %)	8 (36.4%)
4	Headache	16 (18.0%)	7 (31.8%)	2 (9.1%)	4 (17.4%)	3 (13.6%)
5	Somnolence	5 (5.6%)	2 (9.1%)	0 (0%)	1 (4.3%)	2 (9.1%)
6	Anxiety	7 (7.9%)	2 (9.1%)	1 (4.5%)	2 (8.7%)	2 (9.1 %)
7	Euphoric mood	5 (5.6%)	0 (0.0%)	1 (4.5%)	1 (4.3%)	3 (13.6%)

Spravato (Phase III studies)

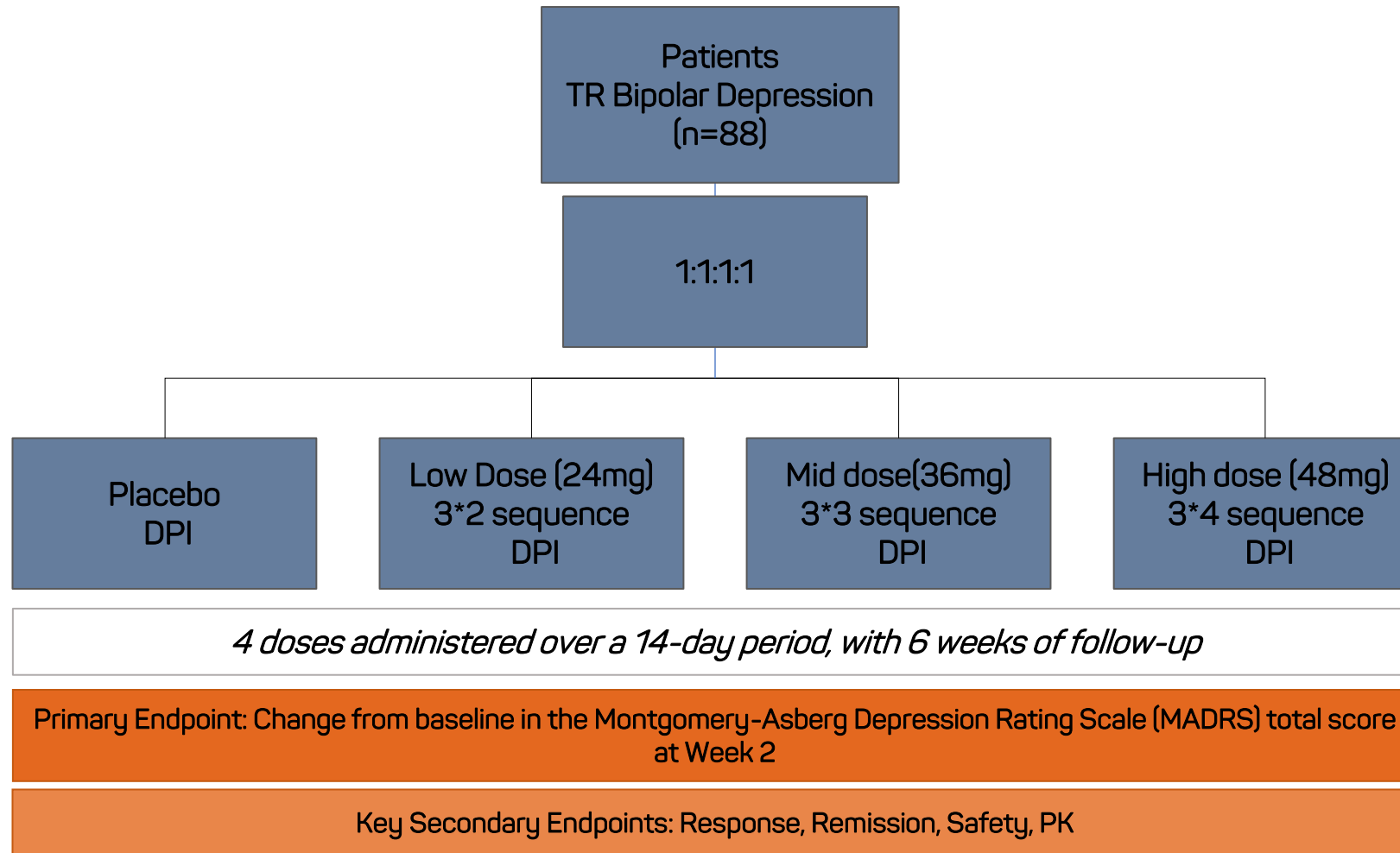
Most Common Adverse Events (2:5%)  
Short-term Phase 3 Studies

	Pooled TRANSFORM-1/2 (Age 18-64)	
	Esk + AD N=346 %	AD + Placebo N=222 %
<b>Total percent of patients with TEAE</b>	<b>87.0</b>	<b>64.4</b>
<b>Nausea</b>	<b>28.3</b>	<b>8.6</b>
<b>Dissociation</b>	<b>26.6</b>	<b>3.6</b>
<b>Dizziness</b>	<b>23.7</b>	<b>6.8</b>
<b>Vertigo</b>	<b>22.5</b>	<b>2.3</b>
<b>Headache</b>	<b>20.2</b>	<b>17.1</b>
<b>Dysgeusia</b>	<b>18.8</b>	<b>13.5</b>
<b>Somnolence</b>	<b>17.3</b>	<b>9.0</b>
<b>Paresthesia</b>	<b>12.4</b>	<b>1.8</b>
<b>Hypoesthesia</b>	<b>11.0</b>	<b>1.4</b>
<b>Hypoesthesia oral</b>	<b>10.7</b>	<b>1.4</b>
<b>Vomiting</b>	<b>9.2</b>	<b>1.8</b>
<b>Vision blurred</b>	<b>9.0</b>	<b>1.4</b>
<b>Anxiety</b>	<b>9.0</b>	<b>5.4</b>
<b>Blood pressure increased</b>	<b>8.7</b>	<b>2.3</b>
<b>Insomnia</b>	<b>8.4</b>	<b>7.2</b>
<b>Fatigue</b>	<b>7.2</b>	<b>5.0</b>

Phase 3 design to encompass home setting conditions to validate safe utilization.

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# Falkieri Phase II TR Bipolar Depression Trial - Design Summary



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)

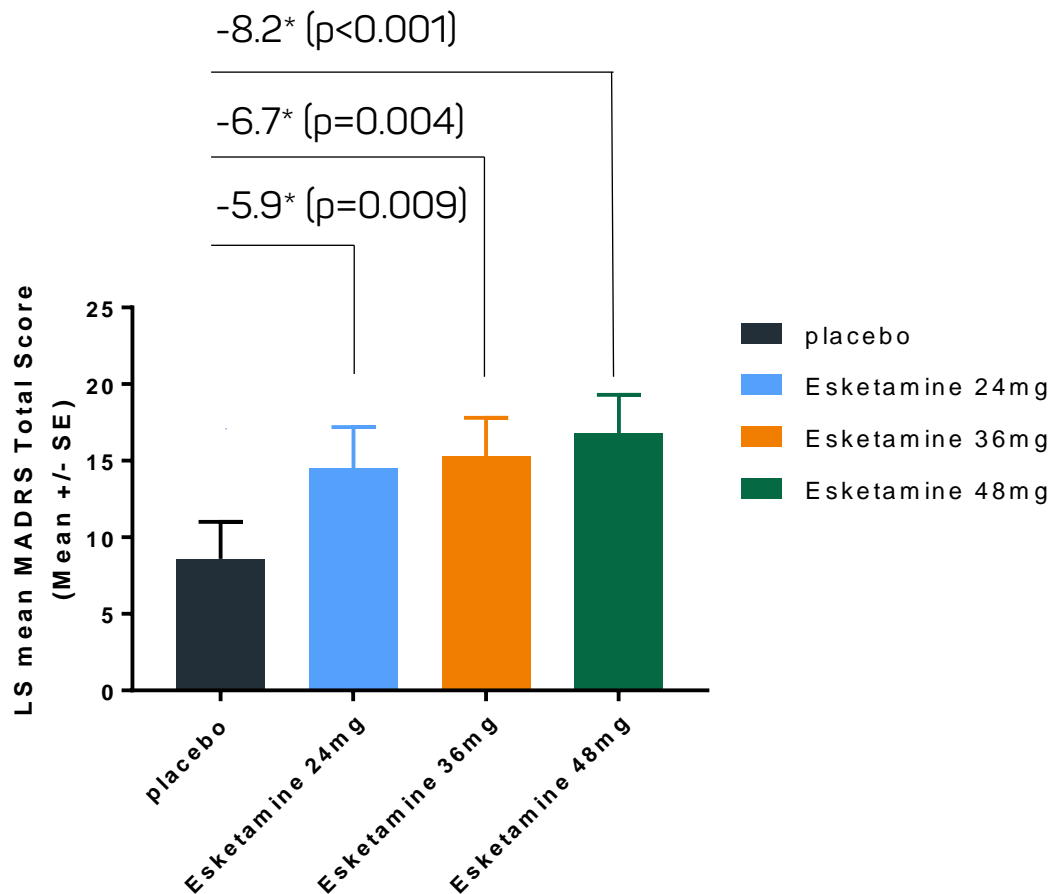
If not specified [mean, (SD)] is shown

\* [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

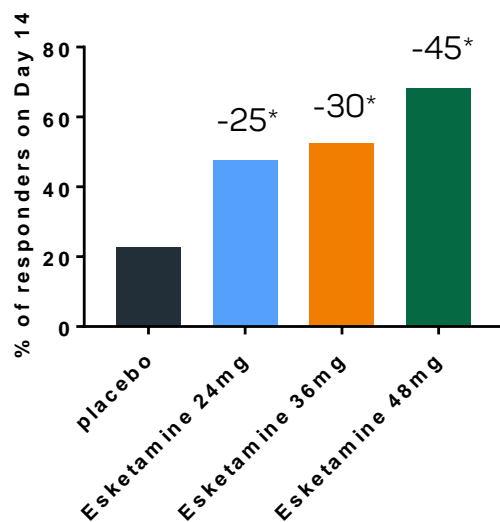
ChfB: change from baseline  
CI: confidence interval

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

# Falkieri Selected Secondary Endpoints

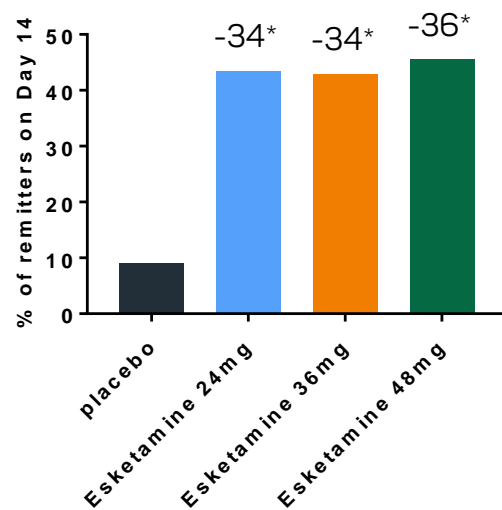
## Response

(defined as  $\geq 50\%$  reduction from baseline on Day 14)

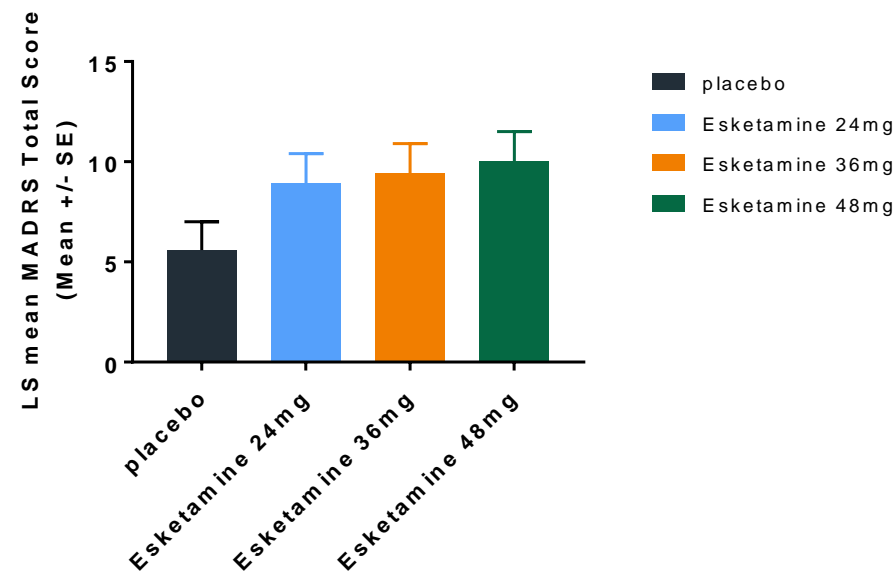


## Remission

(defined as achieving MADRS total score  $\leq 10$  on Day 14)



## Hamilton Depression Rating Scale (HDRS)



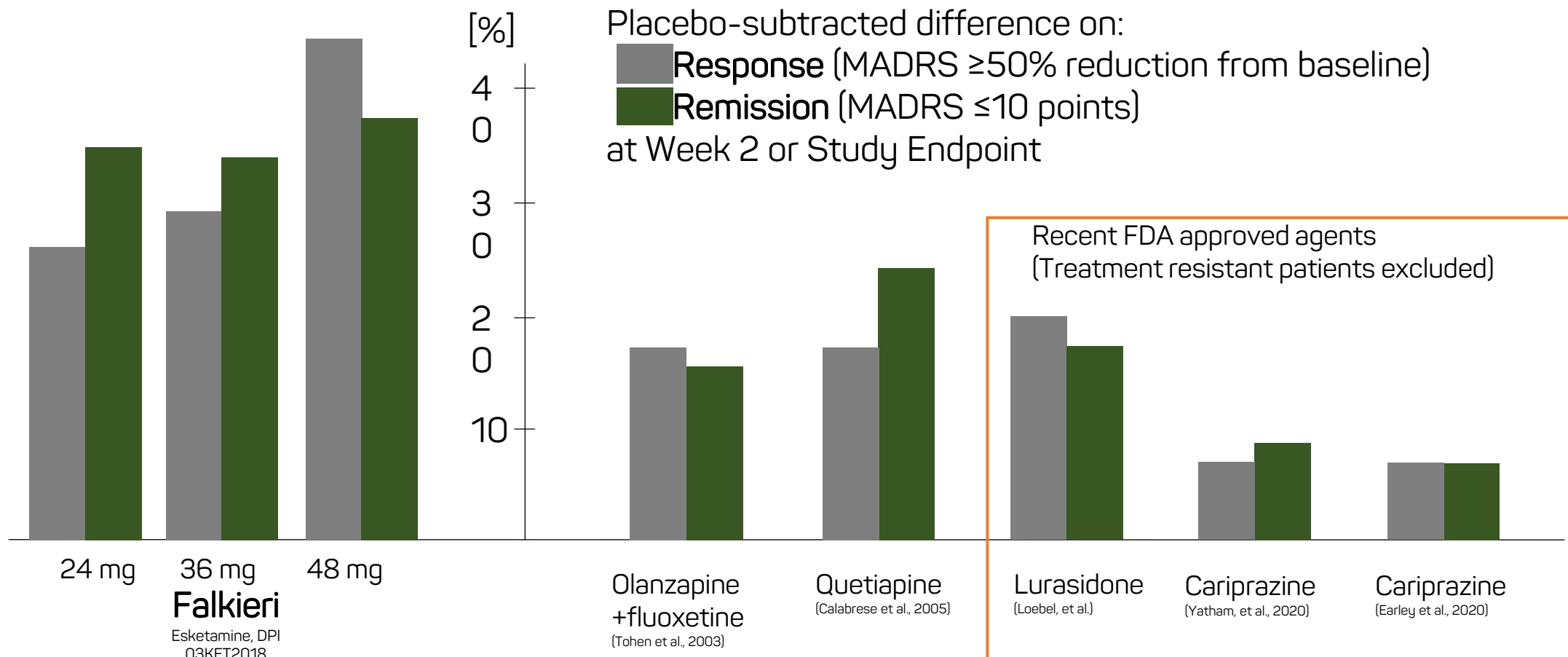
\* Placebo-subtracted difference in %

HDRS,  $p < 0.05$  at all doses

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

# 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.

## 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  $\geq 5\%$  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)]

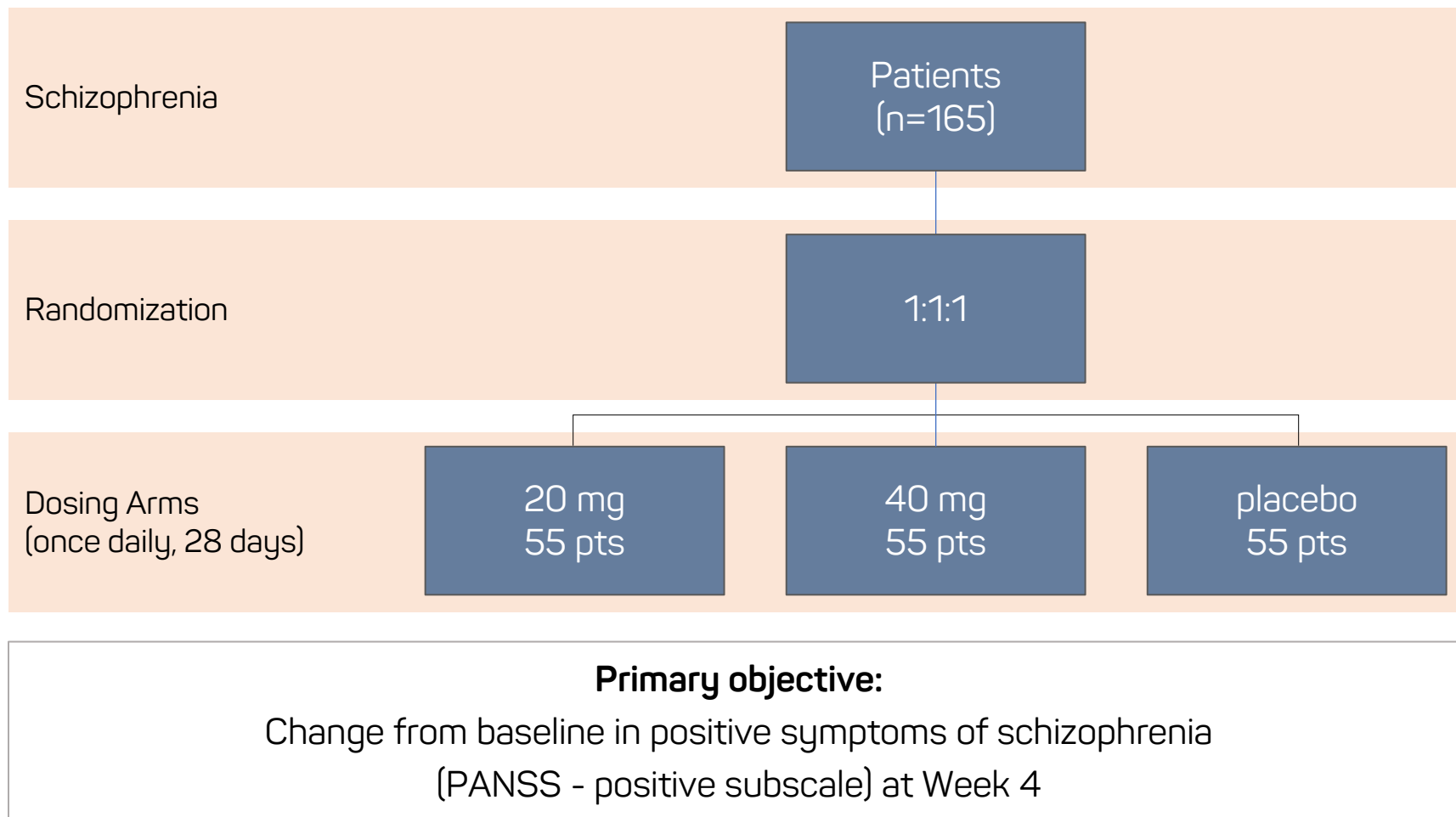
Clean safety profile. High study completion rates.



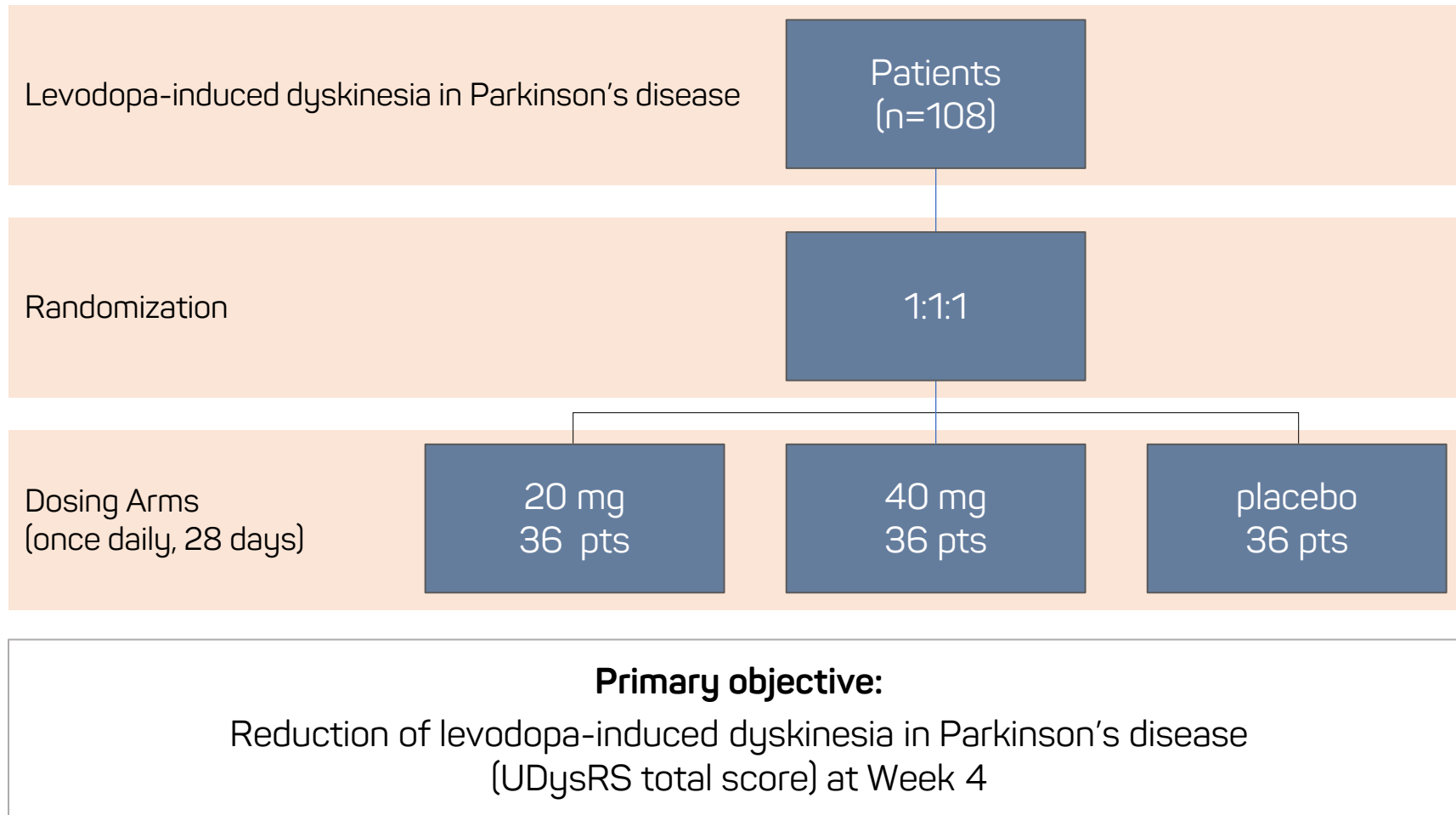
# PDE10a Inhibitor (CPL'36)

For treatment of schizophrenia and psychomotor disorders (dyskinesias)-aimed to overcome pharmacological and safety deficiencies of prior compounds

## Phase 2 – PoC Schizophrenia Study Underway



## Phase 2 – PoC Levodopa-Induced Dyskinesia in Parkinson's Disease Underway





# JAK/ROCK Inhibitor (CPL'116)

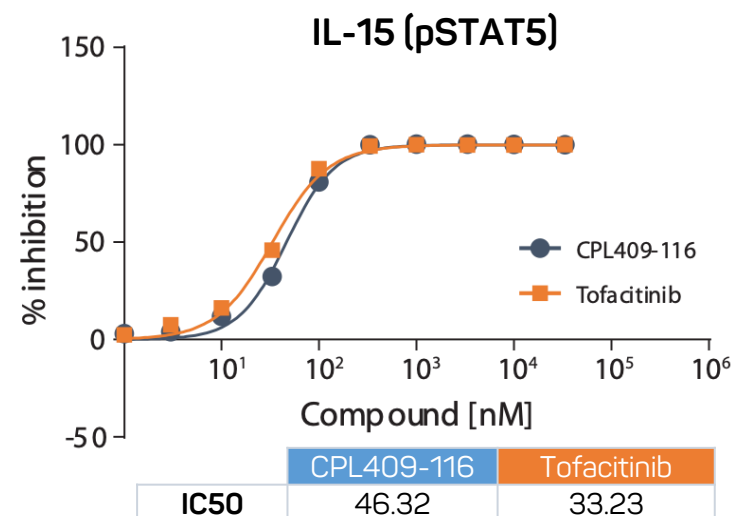
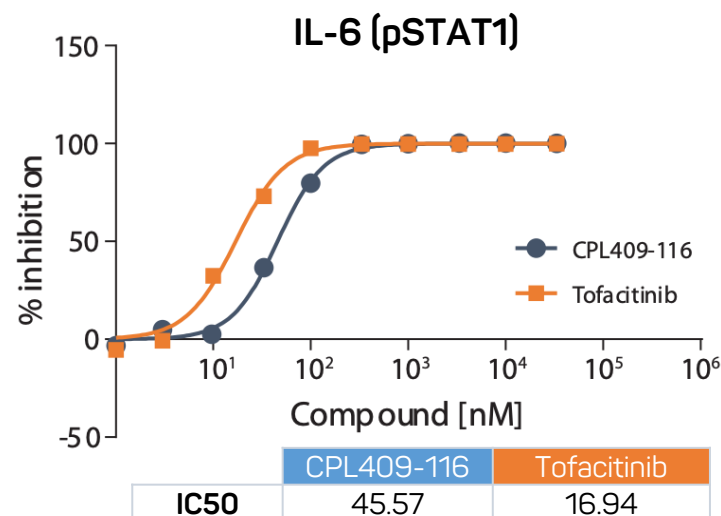
Anti-inflammatory and anti-fibrotic effects with potential for new therapeutic indications such as IPF and pulmonary hypertension as well as autoimmune disease, oncology and diabetes.



# CPL'116 JAK/ROCK Program -Entering Phase 1

- Program combines a selective JAK inhibitor (JAK1=JAK3>JAK2) with a selective ROCK inhibitor to generate both anti-inflammatory and anti-fibrotic effects with potential for new therapeutic indications such as IPF and pulmonary hypertension **as well as autoimmune disease, oncology and diabetes.**
- Well elucidated MOA: anti-contractile agent and potent vasorelaxant
- Blocks IL-6 and IL-15 cytokine signaling in human PMBC *ex-vivo*, with similar potency as tofacitinib, but less preference for JAK2
- Toxicology profile is more favorable than other JAK inhibitors
- Tested in multiple animal models for RA, Psoriasis and Lupus, with consistent efficacy

## CPL409116 blocks cytokine signalling in human PBMC



	IC50 [nM]	
	CPL409116	Tofacitinib
JAK1	0,95	2,46
JAK2	5,36	2,23
JAK3	0,87	1,30
TYK2	63	39

	IC50 [nM]	
	CPL409116*	Fasudil
ROCK1	10	4533
ROCK2	5,9	4592

The key differentiation of dual JAK/ROCK inhibition is augmenting selective and potent JAK inhibition with the anti-fibrotic activity from ROCK to expand into conditions such as IPF and Pulmonary Hypertension as well as Autoimmune Disease, Oncology and Diabetes

# Anticipated 2021/2022 News Flow

1Q 2021

Falkieri – Phase 2 results in Treatment-resistant Bipolar Depression  
CPL'280 (GPR40) – Phase 1 completed in healthy volunteers  
CPL'280 (GPR40) – PoC Phase 2 in diabetes starts

2Q 2021

CPL'116 (JAK/ROCK) – Final Phase 1 results  
Falkieri – Phase 3 regulatory feedback

3Q/4Q  
2021

CPL'110 (FGFR) – Phase 1/1b results in solid tumors  
CPL'110 (FGFR) – Phase 2/2b (of key importance) in indication of 2 selected tumors  
CPL'280 (GPR40) – PoC Phase 2 results in diabetes

1Q 2022

CPL '36 (PDE10a) – Key Phase 2 results (Schizophrenia and PD)  
CPL'116 (JAK/ROCK) – Results of Phase 2 PoC in RA and selected AI disease.

# Experienced Management Team



## Maciek Wieczorek (PhD)

PhD CEO, President of The Management Board  
Celon Pharma S.A.

- Mr. Wieczorek is Founder and President of the Management Board of Celon Pharma S.A.
- He has a PhD in medical biology at the Medical University of Lodz (PL)
- Mr. Wieczorek received a scholarship of New University of Lisbon in Portugal, while he also completed MBA at the Warsaw School of Economics and the University of Minnesota
- He has many years of experience in managing pharmaceutical companies and is the inventor or co-inventor of several patent applications for classic chemical and biotechnological drugs, as well as the driving force for the launch of several of the best-selling drugs in Poland



## Jacek Glinka

Vice President of The Management Board Celon  
Pharma S.A.

- Mr. Glinka has 20+ years experience in the pharmaceutical industry
- For many years, he headed one of the largest Polish pharmaceutical companies Polpharma S.A where Mr. Glinka led the company's business and sales success, including its international expansion
- Afterwards, Mr. Glinka built a sales business in Europe for Mylan as President for Europe, where he led impressive growth from EUR 1 billion to nearly EUR 4 billion, both through organic growth and acquisition
- Mr. Glinka has extensive experience in conducting in and out licensing transactions



## Iwona Giedronowicz

CFO

- In the years 1997-2001 Iwona Giedronowicz held the position of Head of Accounting at Finanspol
- After that, she was chief accountant at Tebodin Poland Sp. z o.o. with its registered seat in Warsaw (2005-2010), chief accountant at Celon Pharma Sp. z o.o. (in the years 2010-2012) and chief accountant at Celon Services Sp. z o.o. in 2012
- Currently, Ms. Giedronowicz performs the functions of Member of the Board at Celon Pharma S.A. and is the Company's CFO
- She graduated the Faculty of Economics, Finance and Accounting at the University of Warsaw.
- Ms. Giedronowicz is a member in the list of tax advisers maintained by the National Chamber of Tax Advisers since 2007

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Broad pipeline of 5 clinical stage assets and multiple identified leads targeting large market opportunities in neuropsychiatry, oncology, metabolism & inflammation. Potential blockbusters with wholly owned IP

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R&D supported by grants of >\$100m, commercial business cash flows and partnerships. Flexible and tailored commercial approach for each R&D program

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Highly distinguished management team with track record of lab to clinic development and commercial success. Founding shareholder strongly invested in and committed to Celon Pharma

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