JANUARY 2023

SPL026 Phase IIa trial in Major Depressive Disorder

Topline results

TSXV: DMT
OTCQB: DMTTF

Small Pharma

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SPL026 Phase IIa trial in Major Depressive Disorder

Topline results

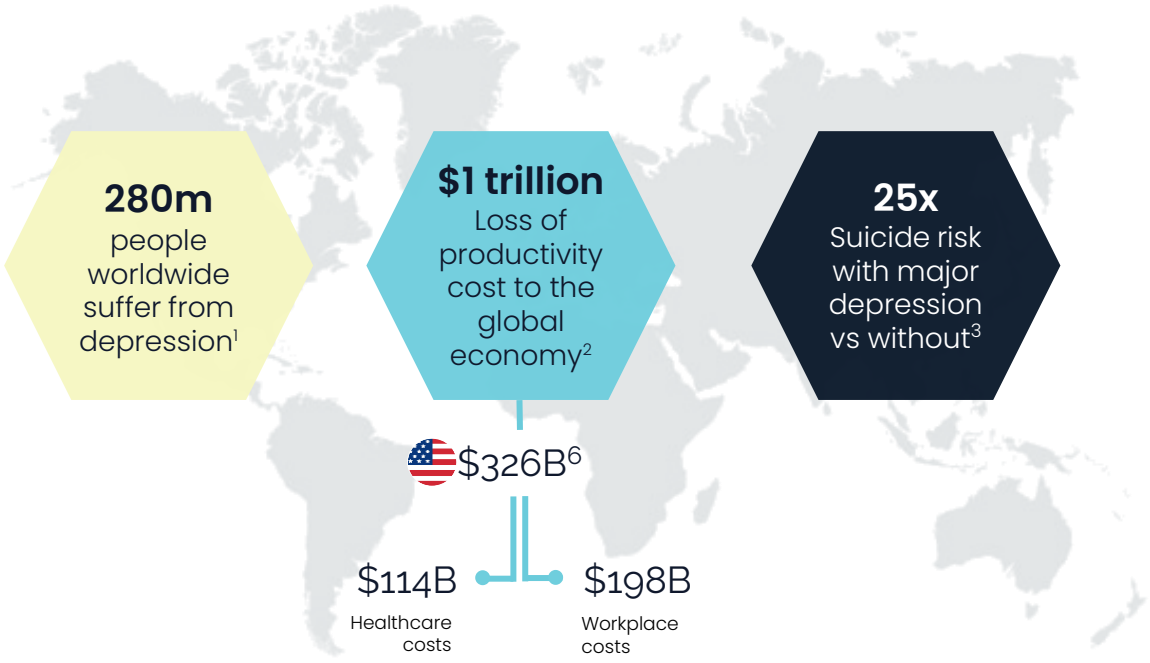
Overview	**George Tziras**, Chief Executive Officer
Trial design & results	**Carol Routledge PhD**, Chief Medical and Scientific Officer
Concluding remarks	**George Tziras**, Chief Executive Officer
Q&A	Presenters

OVERVIEW

Our focus on depression

A major contributor to the global burden of disease with critical unmet need

Global impact of depression



Human impact of depression

Major Depressive Disorder ("MDD") - a mental health disorder characterized by at least two weeks of pervasive low mood, low self-esteem, and loss of interest or pleasure in normally enjoyable activities. [1]

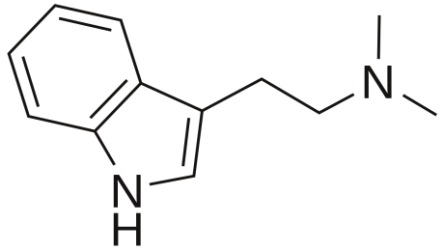
~60% Estimated time in the next decade a patient spends in depression[4]

1 in 8 Who recover from an episode of major depression remain depression-free[5]

Notes

1. WHO (2021), Depression factsheet
2. Mental health matters (2020), The Lancet Global Health
3. American Association of Suicidology, 2014
4. Judd et al (1998) A Prospective 12-Year Study of Subsyndromal and Syndromal Depressive Symptoms in Unipolar Major Depressive Disorders
5. Mitchell (2006) Depressed patients and treatment adherence
6. Greenberg PE, Fournier AA, Sisitsky T, Simes M, Berman R, Koenigsberg SH, Kessler RC. The Economic Burden of Adults with Major Depressive Disorder in the United States (2010 and 2018), Pharmacoeconomics. 2021 Jun

SPL026



Chemical compound N,N, dimethyltryptamine ("DMT") fumarate

Primary pharmacology 5-HT receptor agonist

Treatment protocol

1. **SPL026**
   - Proprietary synthetic formulation of DMT fumarate
   - Route: short intravenous ("IV") infusion

2. **Supportive psychological therapy**
   - Includes both preparation and post-dosing integration sessions with licensed therapists

Treatment session: ~1¾ hrs to 2½ hrs

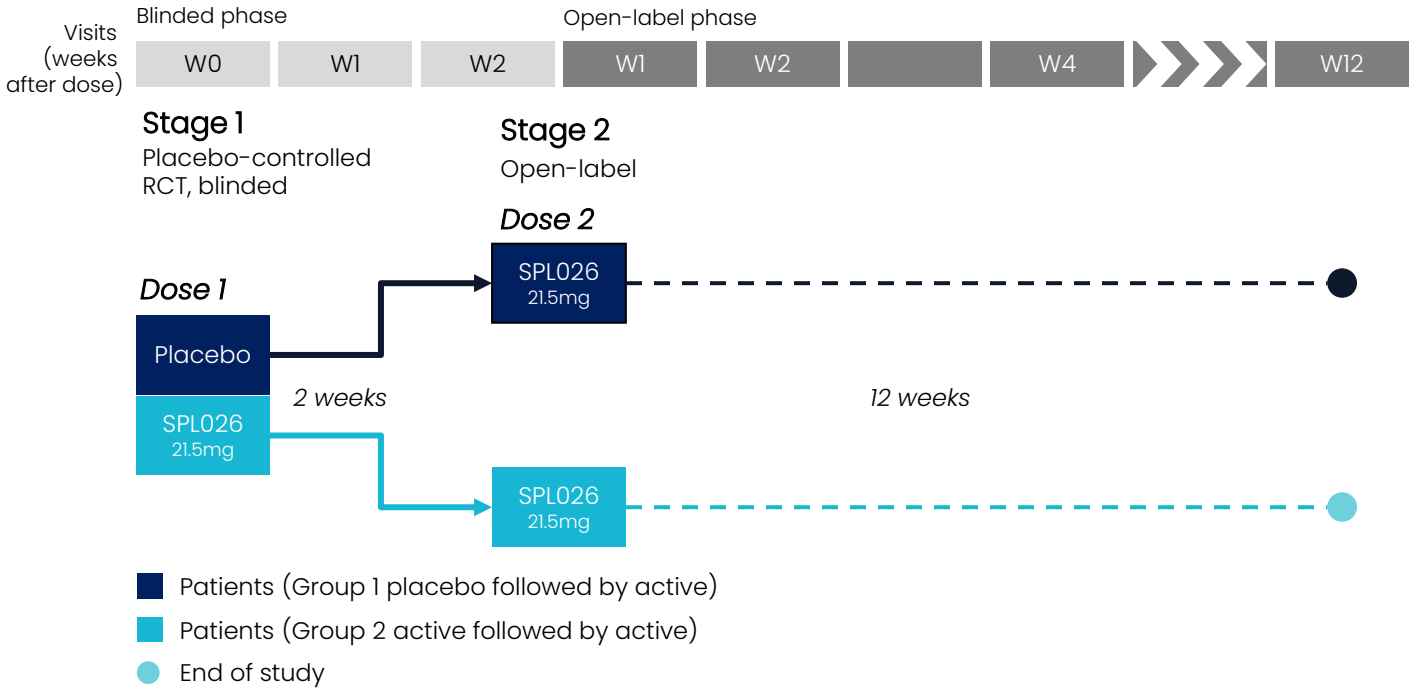
PREPARATION	DOSING	INTEGRATION THERAPY
15 MIN – 1 HR	30 MIN	1 HR+

Phase IIa trial design

Assessing the efficacy, safety and tolerability of IV SPL026 with supportive therapy for the treatment of MDD

Patients N=34
MDD patients (moderate/severe), HAMD ≥17
Not on antidepressant medication/willing to discontinue

Status
Completed Q4'22



OVERVIEW OF STUDY

- Stage 1 : Blinded, randomized, placebo-controlled
- Stage 2: Open-label

Treatment groups

- Group 1 (PA) – 1st dose: Placebo, 2nd dose: 21.5mg SPL026 (active)
- Group 2 (AA) – 1st & 2nd dose: 21.5mg SPL026
- Each treatment arm includes supportive therapy with each dose

Primary endpoint

- Difference in MADRS change from baseline at Week 2 (SPL026 vs. placebo)

Key secondary endpoint

- Efficacy as above at Week 1

Note: N = population number; HAMD = Hamilton Depression Rating Scale; MADRS = Montgomery-Asberg Depression Rating Scale; RCT = randomized controlled trial

TRIAL RESULTS

Patient demographics and baseline characteristics[1]

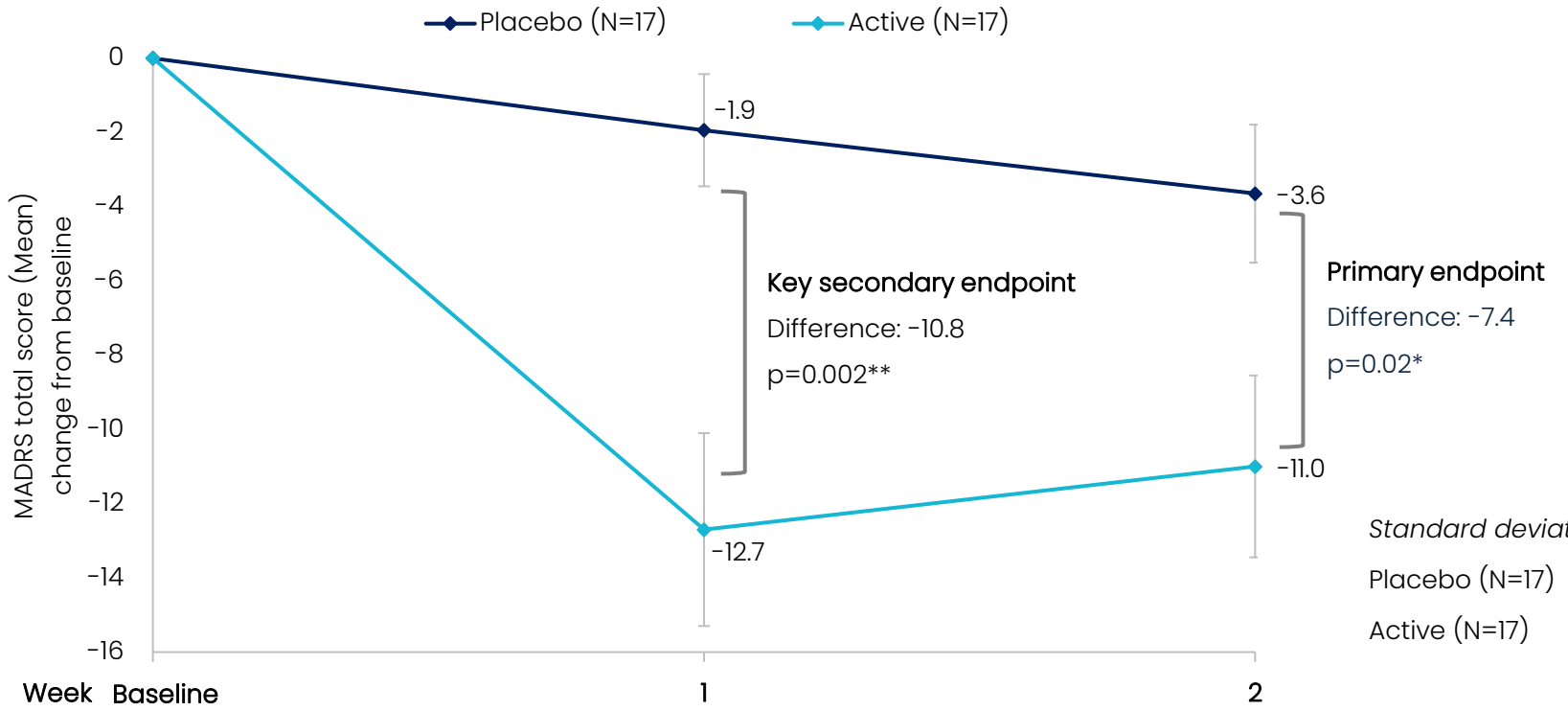
	Placebo N=17	21.5mg SPL026 (Active) N=17	All subjects N=34
Age - Mean years (SD)	33 (9.7)	32 (8.6)	33 (9.0)
Gender: % Female	35%	24%	29%
Screening HAMD – Mean (SD)	19.5 (1.9)	18.8 (1.1)	19.2 (1.6)
Baseline MADRS – Mean (SD)	26 (7.3)	26 (6.1)	26 (6.6)
Duration of illness – Mean years (SD)[2]	13.0 (9.4)	7.7 (6.8)	10.4 (8.5)
# subjects treated who received open label dose 2	16	13	29

Note: SD = standard deviation; N = population number; HAMD = Hamilton Depression Rating Scale for Depression; MADRS = Montgomery-Asberg Depression Rating Scale

1. Refers to preliminary analysis of data
2. Number of years since initial diagnosis of MDD as per patients' medical records

Primary endpoint

IV SPL026 with supportive therapy shows ***statistically significant rapid-onset antidepressant effects*** vs. placebo



n	Baseline	1	2
Placebo	17	16	17
Active	17	16	17

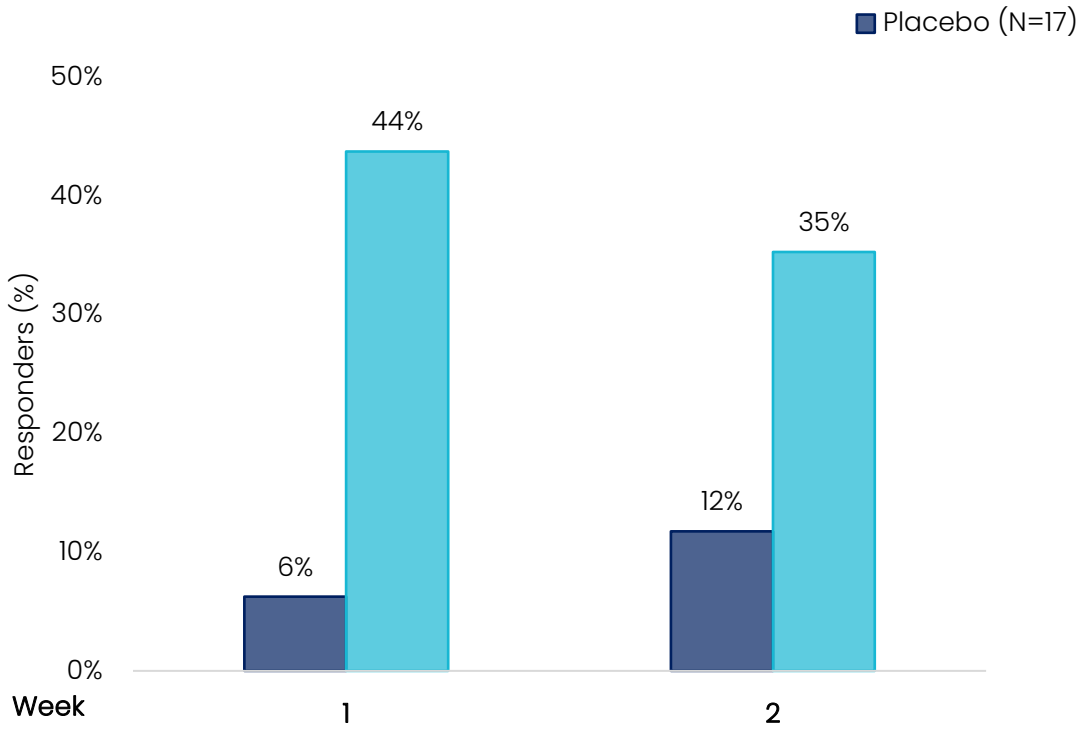
	Week 1	Week 2
Standard deviation		
Placebo (N=17)	6.0	7.7
Active (N=17)	10.4	10.1

Note: Error bars represent Standard Error Mean (SEM); MADRS = Montgomery-Asberg Depression Rating Scale; n = number of datapoints; N = population number; p = p-value; * = p<0.05; ** = p<0.01

Response & remission

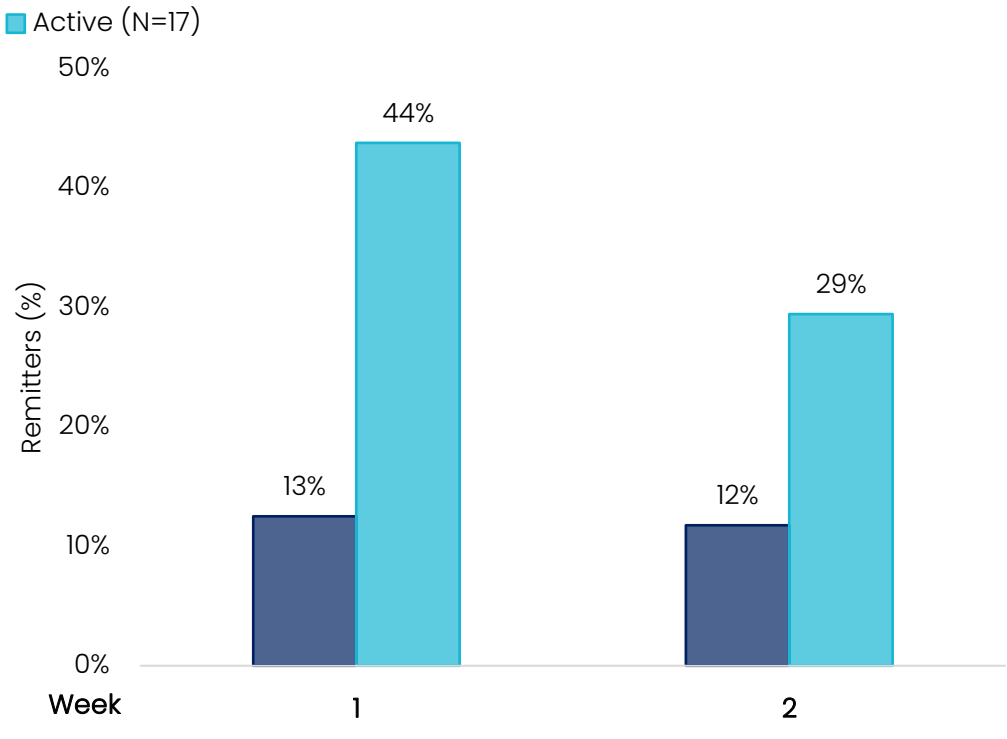
Rapid response and remission of a single dose of IV SPL026 vs. placebo

Responders (%) (≥50% MADRS reduction from baseline)



Responders (n)	16	16	17	17

Remitters (%) (MADRS score ≤10)

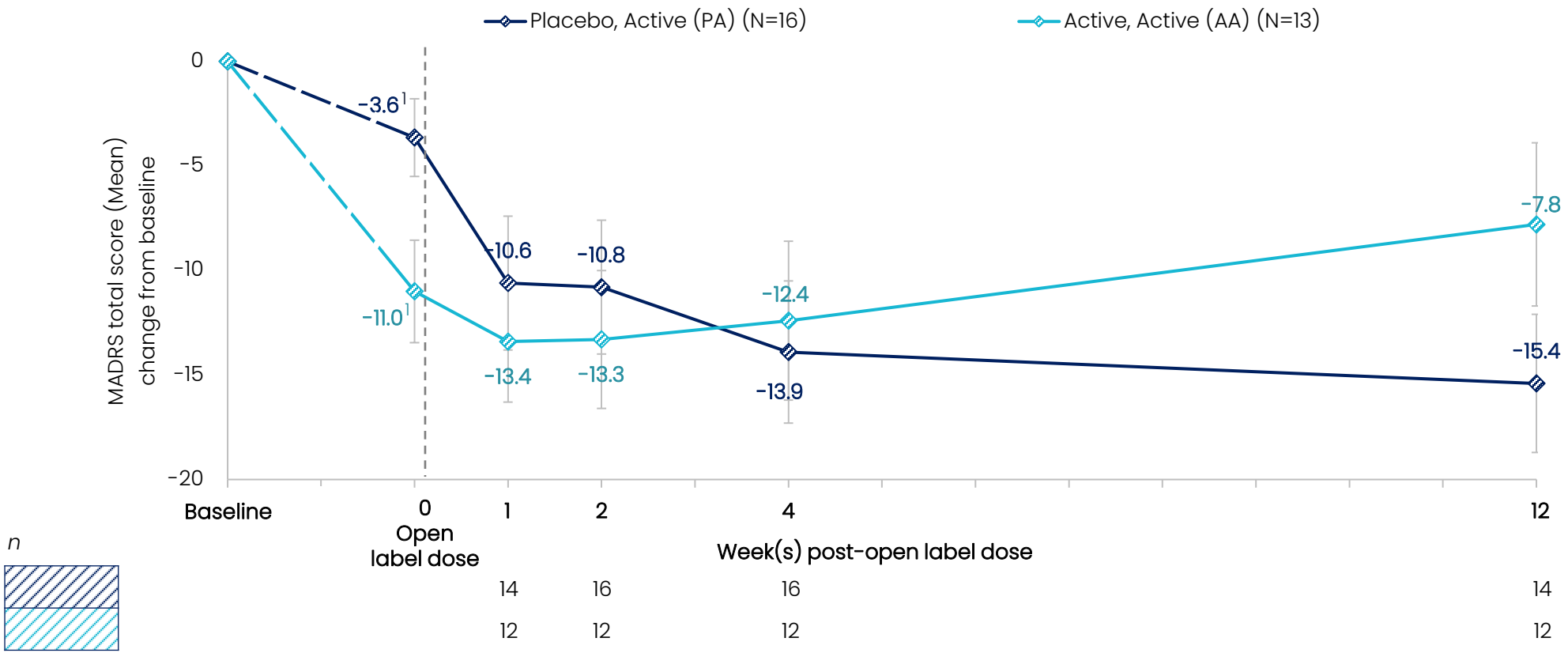


Remitters (n)	16	16	17	17

Note: MADRS = Montgomery-Asberg Depression Rating Scale; n = number of datapoints; N = population number

Change in MADRS over time

One and two dose regimens of IV SPL026 with supportive therapy show ***durable reduction in depression symptoms***



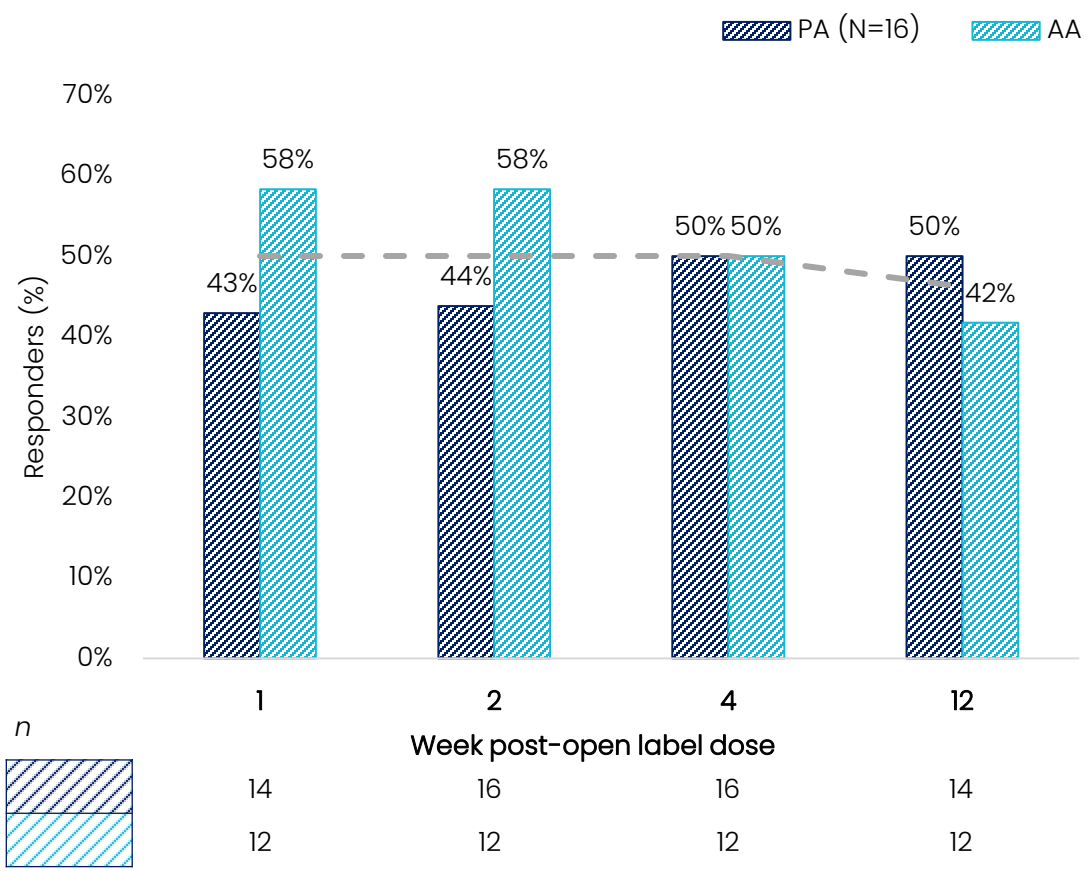
Note: Dashed lines on chart represent blinded phase. Lines are illustrative not representative of data in this phase; Error bars represent Standard Error Mean (SEM); MADRS = Montgomery-Asberg Depression Rating Scale; n = number of datapoints; N = population number

1. Represents Week 2 endpoint of both treatment groups in the blinded phase taken prior to receiving open label dose

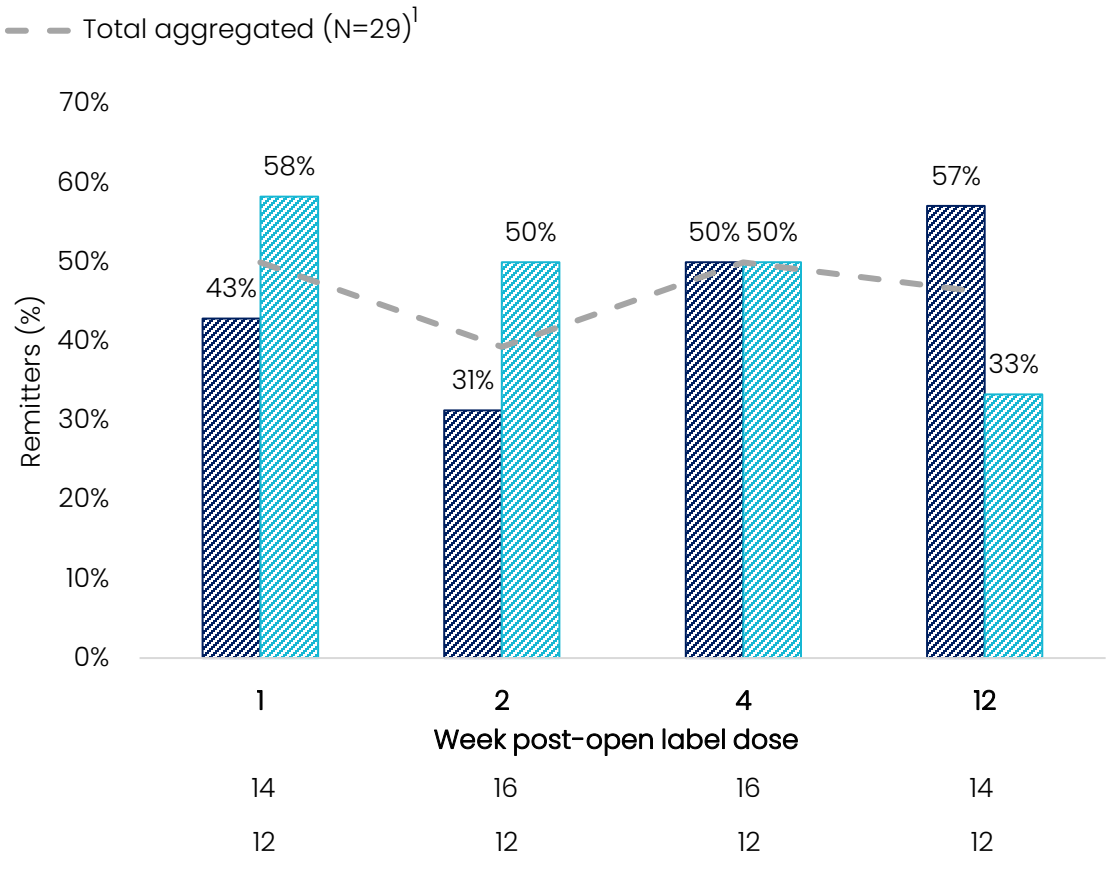
Response & remission

Durable response and remission in one and two dose SPL026 regimens

Responders (%) (≥50% MADRS reduction from baseline)



Remitters (%) (MADRS score ≤10)



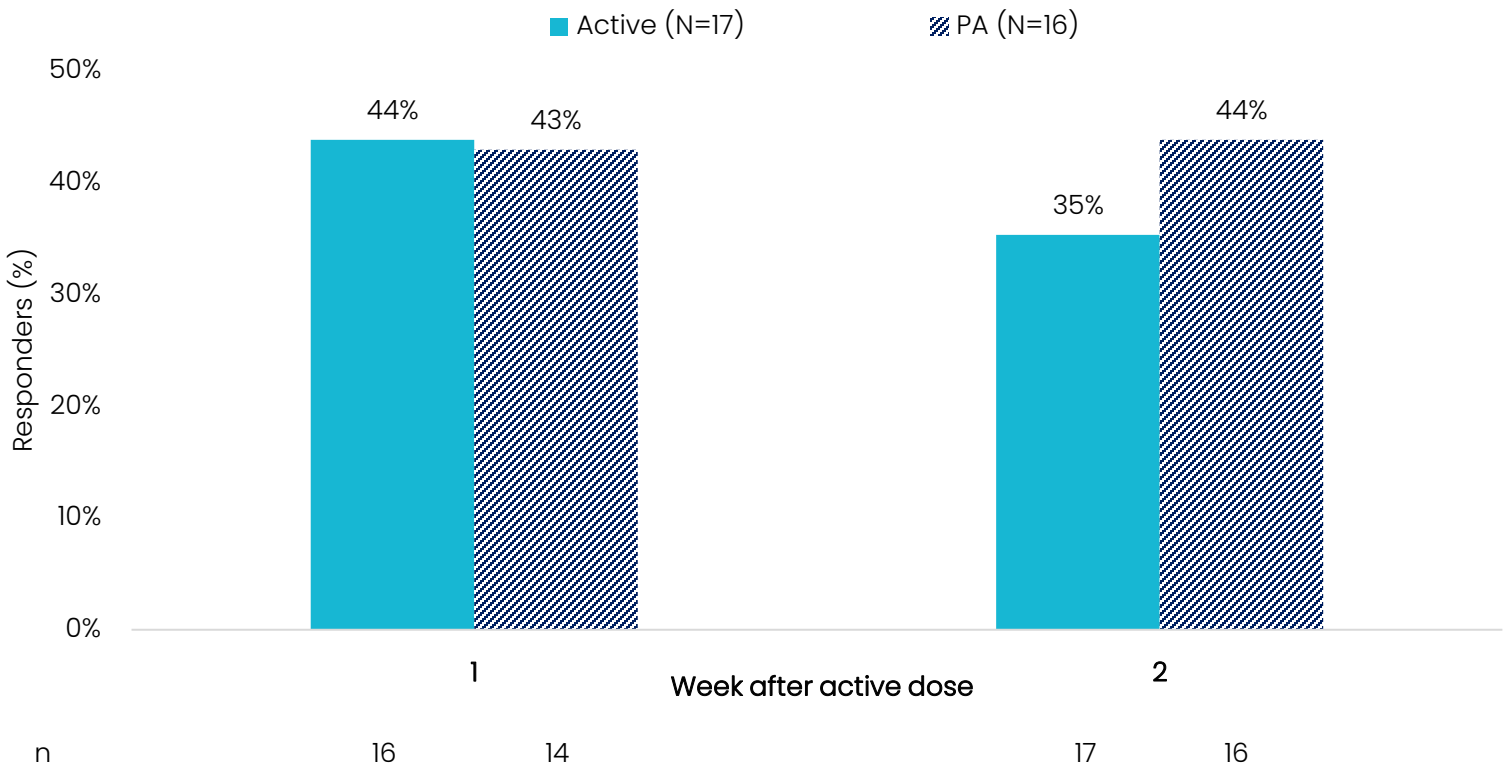
Note: PA = 1st dose: Placebo, 2nd dose: Active; AA – 1st & 2nd dose: Active; MADRS = Montgomery-Asberg Depression Rating Scale; n = number of datapoints; N = population number

1. Refers to mean aggregated outcomes of all patients receiving an active dose in the open label phase

Response: Single dose comparison

No apparent difference in rapid onset antidepressant effects of a single SPL026 dose in the blinded and open label phases

The graph represents % responders at Week 1 and Week 2 in the group receiving a single blinded SPL026 dose (active) vs. the group receiving a single open label SPL026 dose following placebo (PA)



Note: PA = 1st dose: Placebo, 2nd dose: Active; n = number of datapoints; N = population number; Responder = ≥50% MADRS reduction from baseline

Safety and adverse events[1]

Favorable safety and tolerability profile

- No drug-related Serious Adverse Events including suicidal ideation or behavior
- 100% of Adverse Events ("AEs") deemed possibly related to treatment were mild to moderate in severity
- The most commonly reported AEs were infusion site pain or reaction, nausea and mild to moderate anxiety
- Majority of AEs (~80%) resolved during dosing visit
- No clinically significant safety concerns, including no concerns with vital signs, ECG or clinical laboratory findings in any treatment group

AEs possibly related to treatment	Blinded phase (to Day 14)		Total study
	Active	Placebo	All subjects
Infusion site pain or reaction	7	3	17
Musculoskeletal and connective tissue disorder	1		2
Nausea	3		6
Headache	1		2
Anxiety	2		5
Insomnia		1	3
Restlessness			2
Other[2]	5		10
Total mild and moderate	**19**	**4**	**47**
Total severe	**0**	**0**	**0**
Total	**19**	**4**	**47**

Note: AEs = Adverse Events; n = number of datapoints; N = population number

1. Refers to preliminary analysis of data
2. Refers to AEs incident possibly related to treatment equal to 1 and includes: disturbance in attention, paresthesia, pseudo-hallucination, hypertension, pallor, tinnitus, depression, patient dissatisfaction with treatment, night sweats, visual snow syndrome

First placebo-controlled trial demonstrating efficacy of a short-duration psychedelic with supportive therapy in MDD

PHASE IIA MET PRIMARY ENDPOINT

- Primary endpoint met with a statistically significant -7.4 point difference between SPL026 (21.5mg) and placebo at two-weeks post-dose, as measured by MADRS change from baseline (p=0.02)

RAPID & DURABLE ANTIDEPRESSANT EFFECT

- Rapid onset antidepressant effects demonstrated at one-week post-dose with a statistically significant difference in MADRS of -10.8 versus placebo (p=0.002)
- Durable antidepressant effect with a 57% remission rate at 12-weeks following a single SPL026 dose[1] with supportive therapy
- No apparent differences identified in antidepressant effect between a one and two dose regimen of SPL026

FAVORABLE SAFETY PROFILE

- SPL026 data suggested a favorable safety profile and was well-tolerated
- No drug-related Serious Adverse Events
- 47 Adverse Events deemed possibly related to treatment, all reported to be mild or moderate, and majority resolved during dosing visit

Note: p = p-value; MADRS = Montgomery-Asberg Depression Rating Scale

1. Refers to 12-weeks following the open label dose

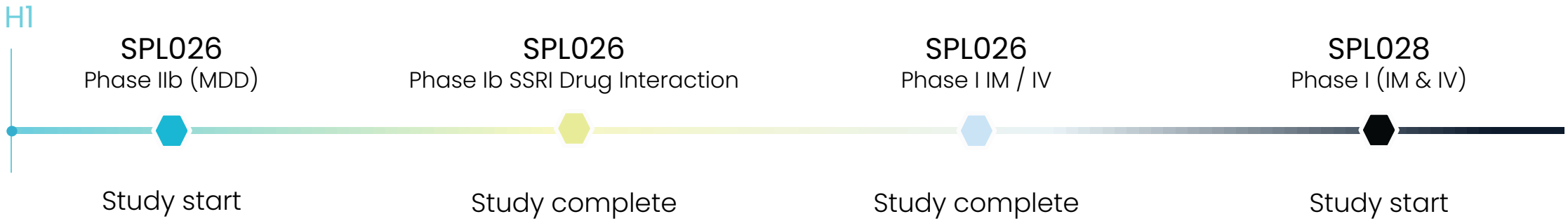
CONCLUDING REMARKS

Multiple meaningful R&D catalysts expected in 2023

Financial overview

Cash raised	Cash position	Common shares outstanding	Fully diluted shares outstanding
~C$63m	~C$22.7m	321.6m	348.9m
2021	Nov 22[1]	Jan 23	Jan 23

Expected key milestones in 2023[2]



Note
1. Refers to latest quarterly results
2. Milestone timelines refer to calendar year

Q&A

THANK YOU