Supernus Pharmaceuticals

SPN-812

Topline Results – ADHD Phase III Study in Adults (P306)

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SPN-812 Phase III Adult Study

	P306 N = 374	Study Design
ADHD Patients	Adults	Randomized, double-blind, two arm placebo-controlled study
Daily Doses	200mg to 600mg	Starting dose of 200mg on week 1, 400mg on week 2, followed by flexible dosing between 200mg and 600mg per day.
Primary Endpoint	Change from baseline to end of study on ADHD Investigator Symptom Rating Scale (AISRS) total score compared to placebo.	

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SPN-812 Phase III Adult Study: Fast Onset of Action

Efficacy Starting as Early as Week 2 – Primary Endpoint

Primary Endpoint			
Visit	**Statistics**	Placebo (N=179)	200mg to 600mg[1] (N=175)
Baseline	Mean	37.6	38.5
Week 1	p-value		0.2941
Week 2	p-value		0.0397
Week 3	p-value		0.0005
Week 4	p-value		0.0014
Week 5	p-value	*	*
Week 6 (EOS)	LS Mean	-11.7	-15.5
	p-value		0.0040

Primary Analysis of AISRS. EOS = End of Study

*Per study design, at Week 5 no patient visit was conducted, and no data were collected.
[1] 200mg on week 1, 400mg on week 2, followed by flexible dose administration to 600mg.

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SPN-812 Phase III Adult Study: Fast Onset of Action

Efficacy Starting as Early as Week 2 – Secondary Endpoint

Clinical Global Impression - Severity Score (CGI-S)			
Visit	**Statistics**	Placebo (N=179)	200mg to 600mg[1] (N=175)
Baseline	Mean	4.6	4.6
Week 1	p-value		0.1833
Week 2	p-value		0.0203
Week 3	p-value		<0.0001
Week 4	p-value		0.0004
Week 5	p-value	*	*
Week 6 (EOS)	LS Mean	-1.0	-1.4
	p-value		0.0023

EOS = End of Study
*Per study design, at Week 5 no patient visit was conducted, and no data were collected.
[1] 200mg on week 1, 400mg on week 2, followed by flexible dose administration to 600mg.

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SPN-812 Phase III Adult Study

Significant Reduction in Inattention Subscale

Inattention Subscale			
Visit	**Statistics**	Placebo (N=179)	200mg to 600mg[1] (N=175)
Baseline	Mean	21.1	21.5
Week 1	p-value		0.1127
Week 2	p-value		0.0113
Week 3	p-value		0.0003
Week 4	p-value		0.0006
Week 5	p-value	*	*
Week 6 (EOS)	LS Mean	-6.1	-8.5
	p-value		0.0015

EOS = End of Study
*Per study design, at Week 5 no patient visit was conducted, and no data were collected.
[1] 200mg on week 1, 400mg on week 2, followed by flexible dose administration to 600mg.

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SPN-812 Phase III Adult Study

Significant Reduction in Hyperactivity/Impulsivity Subscale

Hyperactivity/Impulsivity Subscale			
Visit	**Statistics**	Placebo (N=179)	200mg to 600mg[1] (N=175)
Baseline	Mean	16.5	17.0
Week 1	p-value		0.9991
Week 2	p-value		0.3478
Week 3	p-value		0.0073
Week 4	p-value		0.0236
Week 5	p-value	*	*
Week 6 (EOS)	LS Mean	-5.8	-7.2
	p-value		0.0380

EOS = End of Study
*Per study design, at Week 5 no patient visit was conducted, and no data were collected.
[1] 200mg on week 1, 400mg on week 2, followed by flexible dose administration to 600mg.

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SPN-812 Phase III Adult Study

Summary of Treatment Related Adverse Events (Safety Population)

Number (%) of Patients - Treatment Related AEs with ≥ 5% Incidence

P306	Placebo (N=183)	SPN-812 (N=189)
Insomnia	9 (4.9)	43 (22.8)
Fatigue	5 (2.7)	22 (11.6)
Decreased appetite	4 (2.2)	19 (10.1)
Nausea	4 (2.2)	19 (10.1)
Headache	9 (4.9)	17 (9.0)
Dry mouth	4 (2.2)	17 (9.0)
Discontinuation due to AEs	9 (4.9)	17 (9.0)

AEs = Adverse Events

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