Supernus Pharmaceuticals

SPN-812 P302 Phase III Topline Data

December 2018

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SPN-812

Novel Non-Stimulant ADHD Product Candidate

- Viloxazine hydrochloride
  - Norepinephrine reuptake inhibitor, selective serotonin activity
  - New Chemical Entity (NCE) with five year market exclusivity
  - Previously marketed outside the U.S. as an antidepressant
- Building strong IP with expirations from 2029-2033
- Clinical data point to a well-differentiated ADHD product
- Targeted NDA filing 2H 2019, and if approved, launch 2H 2020

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SPN-812
Phase III Studies Status

	P301 N = 477	P303 N = 313	P302 N = 310	P304 N = 300
ADHD Patients	6-11 years	6-11 years	12-17 years	12-17 years
Daily Doses	100mg 200mg	200mg 400mg	200mg 400mg	400mg 600mg
Status	Completed	Completed	Completed	Topline Data 1Q 2019

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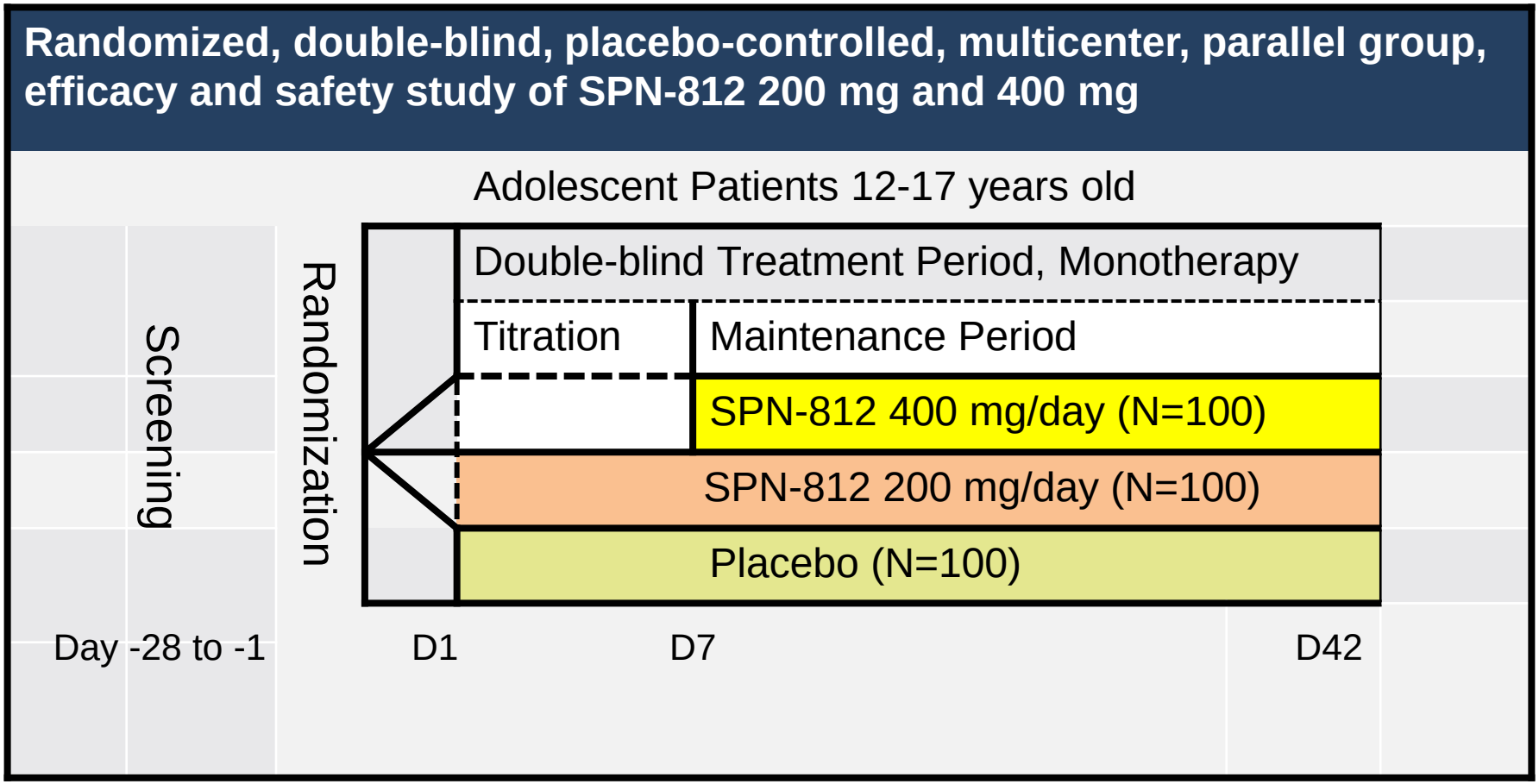
SPN-812 P302 Phase III Study Design

Randomized, double-blind, placebo-controlled, multicenter, parallel group, efficacy and safety study of SPN-812 200 mg and 400 mg



SPN-812 P302 Phase III Study Design

- Primary Endpoint
  - Change from baseline on the ADHD-RS-5 scale compared to placebo
- Secondary Endpoints
  - Clinical Global Impression - Improvement (CGI-I) scale
  - Conners 3rd edition - parent, composite T-score
  - Weiss Functional Impairment Rating Scale - parent report (WFIRS-P)
- Evaluate safety & tolerability

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SPN-812 P302 Topline Results

Executive Summary

- Positive phase III results in adolescent patients 12-17 years old
  - Met primary endpoint with robust statistical significance
    - P-values ranging from <0.0091 to 0.0232
  - Sensitivity analysis confirms primary analysis
- Strong efficacy on Hyperactivity and Inattention subscales
- P302 study showed fast onset of action
  - Statistical significance as early as one week for 400mg
  - Sustained statistical significance through the end of study (week 6)

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SPN-812 P302 Topline Results

Executive Summary

- P302 met the main CGI-I secondary endpoint
- Trial showed favorable tolerability and safety profile
  - Low incidence of AE's across all doses (200mg and 400mg)
- Overall, AE's are mild leading to very low discontinuation rates
  - Discontinuation rates due to AE's of 1.9% – 4.1%

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SPN-812 P302: Met Primary Endpoint

Primary Analysis of ADHD-RS-5 based on MMRM (ITT Population)

Visit	Statistics	Placebo (N=104)	200 mg (N=94)	400 mg (N=103)
Baseline	Mean	40.5	39.9	39.4
Week 6 (EOS)	LS Mean	-11.4	-16.0	-16.5
	Effect Size		0.47	0.50
	p-value		**0.0232**	**0.0091**

MMRM = Mixed Model for Repeated Measure ITT = Intent to Treat EOS = End of Study
Effect size in P301, P303 and Phase IIb studies ranged from 0.46 to 0.63

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SPN-812 P302: Met Primary Endpoint

Efficacy Starting in Week 1

Visit	Statistics	Placebo (N=104)	200 mg (N=94)	400 mg (N=103)
Baseline	Mean	40.5	39.9	39.4
Week 1	LS Mean	-5.1	-7.1	-8.3
	p-value		0.1036	0.0085
Week 2	LS Mean	-8.0	-10.5	-12.0
	p-value		0.0702	0.0032
Week 3	LS Mean	-9.5	-12.8	-14.3
	p-value		0.0297	0.0010
Week 4	LS Mean	-10.5	-15.1	-15.9
	p-value		0.0048	0.0008
Week 5	LS Mean	-11.9	-16.7	-16.7
	p-value		0.0127	0.0102
Week 6 (EOS)	LS Mean	-11.4	-16.0	-16.5
	p-value		**0.0232**	**0.0091**

MMRM = Mixed Model for Repeated Measure ITT = Intent to Treat EOS = End of Study

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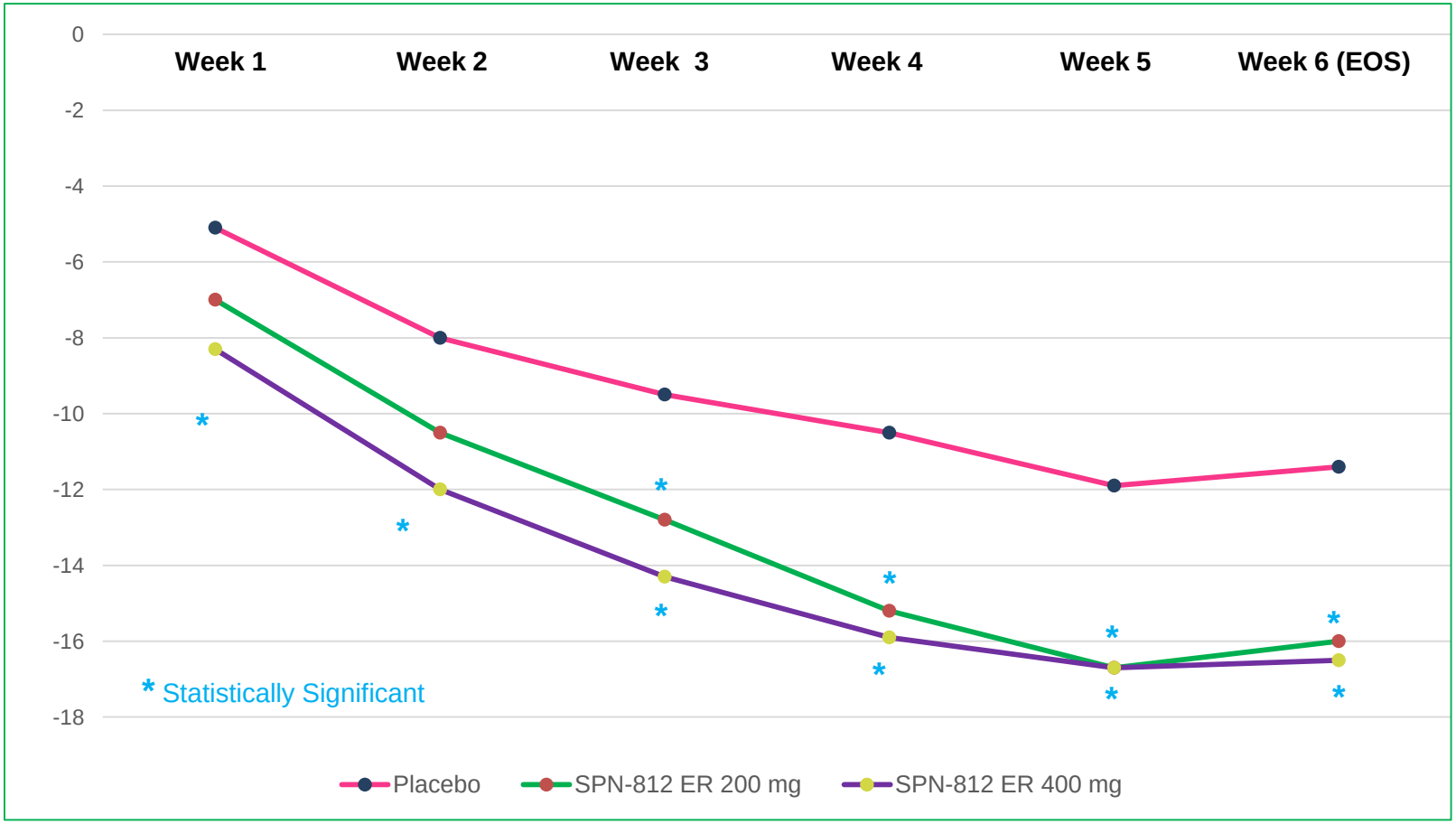
SPN-812 P302 – Efficacy Starting in Week 1

LS Mean Change from Baseline over Time – MMRM (ITT Population)



MMRM = Mixed Model for Repeated Measure ITT = Intent to Treat EOS = End of Study

SPN-812 P302: Met Primary Endpoint

Sensitivity Analysis of ADHD-RS-5 based on ANCOVA at Week 6 (EOS) Confirms Primary Analysis (ITT Population)

Visit	Statistics	Placebo (N=104)	200 mg (N=94)	400 mg (N=103)
Baseline	Mean	40.5	39.9	39.4
Week 6 (EOS)	LS Mean	-11.7	-16.4	-17.0
	p-value		**0.0163**	**0.0055**

ANCOVA = Analysis of Covariance
ITT = Intent to Treat EOS = End of Study

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SPN-812 P302: Met Secondary Endpoint

Analysis of Observed Global Improvement Score (CGI-I) at Week 6 (EOS)

Visit	Statistics	Placebo (N=104)	200 mg (N=94)	400 mg (N=103)
Baseline	Mean	4.6	4.6	4.6
Week 6 (EOS)	LS Mean	3.0	2.5	2.4
	p-value		**0.0042**	**0.0003**

EOS = End of study

SPN-812 P302
Significant Reduction in Hyperactivity and Inattention

Analysis in ADHD-RS-5 Inattention and Hyperactivity/Impulsivity Subscales

Visit	Statistics	Placebo (N=104)	200 mg (N=94)	400 mg (N=103)
ADHD-RS-5 Hyperactivity/Impulsivity				
Baseline	Mean	18.1	17.7	17.9
Week 6 (EOS)	LS Mean	-5.1	-7.7	-8.4
	p-value		**0.0069**	**0.0005**
ADHD-RS-5 Inattention				
Baseline	Mean	22.4	22.2	21.5
Week 6 (EOS)	LS Mean	-6.6	-8.7	-8.7
	p-value		**0.0424**	**0.0390**

EOS = End of Study

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SPN-812 P302
Well Tolerated

Number (%) of Patients Reporting Common AEs (≥ 5% and greater than placebo)

	Placebo (N=104)	200 mg (N=99)	400 mg (N=105)	Overall SPN-812 (N=204)
Somnolence	8 (7.7)	13 (13.1)	15 (14.3)	28 (13.7)
Headache	10 (9.6)	10 (10.1)	13 (12.4)	23 (11.3)
Decreased appetite	0	5 (5.1)	9 (8.6)	14 (6.9)
Nausea	3 (2.9)	7 (7.1)	7 (6.7)	14 (6.9)
Fatigue	1 (1.0)	4 (4.0)	6 (5.7)	10 (4.9)
Discontinuation Due to AE's	**0**	**4 (4.1)**	**2 (1.9)**	**6 (2.9)**

SPN-812 P302
Well Tolerated

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

	Placebo (N=104)	200 mg (N=99)	400 mg (N=105)	Overall SPN-812 (N=204)
Somnolence	7 (6.7)	13 (13.1)	15 (14.3)	28 (13.7)
Decreased appetite	0	5 (5.1)	9 (8.6)	14 (6.9)
Fatigue	1 (1.0)	4 (4.0)	6 (5.7)	10 (4.9)
Headache	7 (6.7)	3 (3.0)	7 (6.7)	10 (4.9)
Nausea	3 (2.9)	5 (5.1)	5 (4.8)	10 (4.9)

SPN-812 P302 Topline Results
Executive Summary

- Third positive phase III trial for SPN-812 in ADHD
  - First trial in adolescents 12-17 years old
  - Consistent with results from two phase III trials (P301 and P303) in children 6-11 years old
- Clinical data point to a well-differentiated ADHD product
  - Strong efficacy with robust statistical significance
    - Efficacy on both Hyperactivity and Inattention
  - Fast onset of action
    - Works as early as the first week
  - Very well tolerated
- Topline data from P304 adolescent trial in 1Q 2019
- Targeted NDA filing 2H 2019, and if approved, launch 2H 2020

Supernus® Pharmaceuticals

Positioned For Continued Strong Growth

Growth Potential for Existing Products

Potential Peak Sales for Oxtellar XR® and Trokendi XR® >$500M

Innovative Late Stage Portfolio in Psychiatry

SPN-812	**Well Differentiated Novel Non-Stimulant**
SPN-810	**First Product to be Developed for Impulsive Aggression**
SPN-604	**Novel Product for Bipolar Disorder**

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