Poster No. XXXX

A Phase 3, Double-Blind, Randomized, Placebo-Controlled, Multicenter, Fixed-Dose Study of CTx-1301 (Dexmethylphenidate) in Children and Adolescents with Attention-Deficit/Hyperactivity Disorder

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OBJECTIVE

To evaluate the consistency of efficacy and safety findings for CTx-1301 in children (6-12 years) and adolescents (13-17 years) with attention-deficit/hyperactivity disorder (ADHD).

CONCLUSIONS

01 CTx-1301 demonstrated dose-related improvements in ADHD signs and symptoms in both children and adolescents, despite the limitations of a fixed-dose study design

02 The safety profile was similar across age groups and consistent with the known profile of methylphenidate products

03 These data reinforce the potential for CTx-1301 as a once-daily treatment option for patients with ADHD aged 6 years and older

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References:

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5. Childress A, et al. Poster presented at: Psych Congress; September 7-10, 2023; Nashville, TN. Poster ID: 1596317.
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Disclosures:

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Scan the QR code for additional information, including the study limitations.

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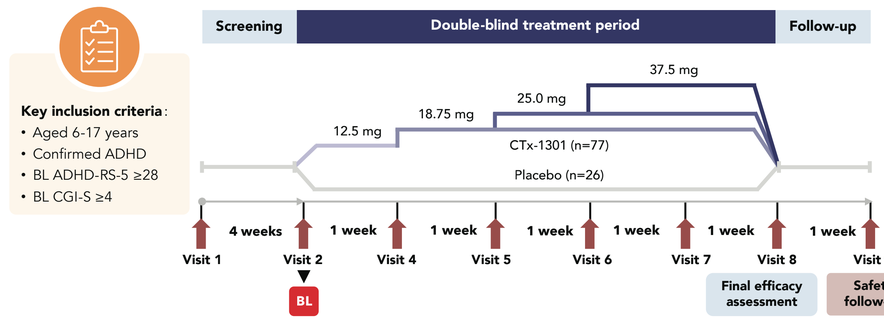
INTRODUCTION

- ADHD affects an estimated 7 million people aged <18 years in the United States[1]
- Stimulants are widely used for the treatment of ADHD in both children and adolescents[2]
  - Nonetheless, symptomatologic, physiologic, and lifestyle differences between the 2 groups warrant assessment of efficacy and safety in both populations[3,4]
- CTx-1301 is a novel, modified-release dexmethylphenidate (d-MPH) tablet that has demonstrated efficacy in the treatment of ADHD in pediatric and adult patients[5,6]
- A phase 3, fixed-dose study found that CTx-1301 at doses of 18.75, 25.0, and 37.5 mg was safe and effective for the treatment of ADHD in children and adolescents aged 6 to 17 years[6]

METHODS

Phase 3, Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose study



Key inclusion criteria:
- Aged 6-17 years
- Confirmed ADHD
- BL ADHD-RS-5 ≥28
- BL CGI-S ≥4

Primary endpoint:
- Change in ADHD-RS-5 from BL to week 5

Secondary endpoints:
- Change in CGI-S from BL to week 5
- CGI-I at week 5
- Safety and tolerability

ADHD, attention-deficit/hyperactivity disorder; ADHD-RS-5, ADHD Rating Scale, version 5; BL, baseline; CGI-I, Clinical Global Impression–Improvement; CGI-S, Clinical Global Impression-Severity.

- For this prespecified analysis, patients were stratified by age: children (6–12 years) and adolescents (13–17 years)
- Due to multiple testing, the threshold for statistical significance of efficacy measures was $p < 0.017$

RESULTS

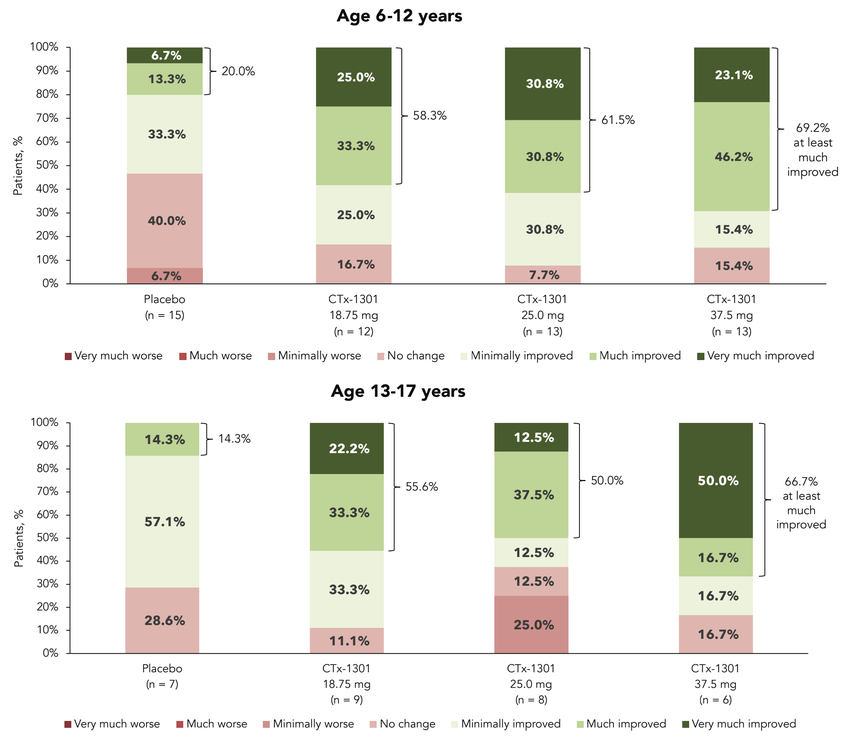
Baseline Demographics and Patient Characteristics Were Similar Among Treatment Groups Within an Age Subgroup[a]

Characteristics	Age 6-12 years				Age 13-17 years			
		CTx-1301				CTx-1301		
	Placebo (n = 16)	18.75mg (n = 16)	25.0mg (n = 16)	37.5mg (n = 16)	Placebo (n = 10)	18.75mg (n = 10)	25.0mg (n = 10)	37.5mg (n = 9)
Male sex, n (%)	9 (56.3)	9 (56.3)	9 (56.3)	8 (50.0)	8 (80.0)	4 (40.0)	7 (70.0)	8 (88.9)
Age, years	9.4 ± 2.1	9.0 ± 2.3	9.4 ± 2.5	9.1 ± 2.1	14.8 ± 1.5	15.3 ± 1.0	14.3 ± 1.2	14.6 ± 1.0
Race, n (%)								
Black/African American	8 (50.0)	9 (56.3)	6 (37.5)	11 (68.8)	5 (50.0)	3 (30.0)	6 (60.0)	3 (33.3)
White	7 (43.8)	5 (31.3)	8 (50.0)	5 (31.3)	5 (50.0)	6 (60.0)	3 (30.0)	6 (66.7)
Multiple/other	1 (6.3)	2 (12.5)	2 (12.5)	0	0	1 (10.0)	0	0
Non-Hispanic/Latino	12 (75.0)	12 (75.0)	14 (87.5)	13 (81.3)	8 (80.0)	8 (80.0)	9 (90.0)	8 (88.9)
BMI, kg/m^2	18.1 ± 2.9	18.1 ± 3.2	17.5 ± 3.2	18.8 ± 4.0	21.6 ± 3.9	22.5 ± 2.9	22.3 ± 3.4	20.6 ± 2.7
BMI Z-score	0.34 ± 0.89	0.35 ± 0.90	–0.01 ± 0.96	0.42 ± 1.37	0.28 ± 1.05	0.52 ± 0.75	0.58 ± 1.06	0.12 ± 0.84
BMI-for-age percentile	61.8 ± 26.9	60.8 ± 29.7	48.5 ± 29.4	67.0 ± 32.6	57.5 ± 34.1	66.2 ± 23.8	68.8 ± 32.0	54.2 ± 29.0
Duration of ADHD, years[b]	3.0 ± 2.6	2.7 ± 2.8	2.2 ± 2.7	2.3 ± 2.3	5.0 ± 4.0	7.8 ± 4.2	6.2 ± 3.7	6.8 ± 4.2
Age at diagnosis, years[b]	6.9 ± 2.5	6.7 ± 2.5	7.5 ± 2.1	7.3 ± 2.1	10.0 ± 3.6	7.8 ± 4.0	8.3 ± 3.6	8.4 ± 4.2
Baseline ADHD-RS-5 total score	42.9 ± 6.7	41.5 ± 7.3	42.8 ± 5.9	42.7 ± 8.1	35.4 ± 7.0	40.8 ± 8.6	37.3 ± 9.5	35.3 ± 6.5
Baseline CGI-S score	4.9 ± 0.9	4.8 ± 1.0	4.8 ± 0.8	5.0 ± 1.0	4.4 ± 0.5	4.5 ± 1.0	4.5 ± 1.0	4.4 ± 0.7

[a]Data are means ± SD, unless otherwise specified.
[b]Date of ADHD diagnosis recorded as start date in medical history, for incomplete diagnosis date: if day was missing, then the first of the month was used; if day and month were missing, then only year was considered.
ADHD, attention deficit/hyperactivity disorder; ADHD-RS-5, ADHD Rating Scale, version 5; BMI, body mass index; CGI-S, Clinical Global Impression-Severity; SD, standard deviation.

- Both the child (n = 64) and adolescent (n = 39) subgroups were predominantly male (54.7% and 69.2%, respectively)

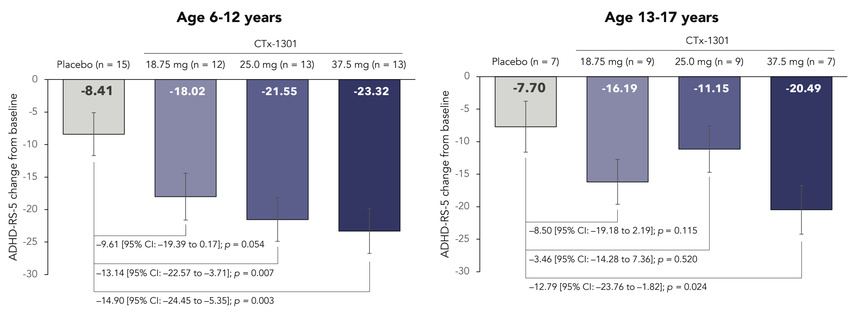
More Than Half of CTx-1301-Treated Patients Experienced Improvement in CGI-I Scores



CGI-I, Clinical Global Impression–Improvement.

- 58.3% to 69.2% of children and 50.0% to 66.7% of adolescents treated with CTx-1301 were much or very much improved per CGI-I assessment compared with 20.0% of children and 14.3% of adolescents who received placebo
- The greatest proportion of improvement was observed for the CTx-1301 37.5-mg dose group

Improvements in ADHD-RS-5 Total Score at Week 5 Were Numerically Greater With CTx-1301 vs Placebo



Data were analyzed using a mixed-effect model for repeated measures in the intent-to-treat population. Effect sizes were derived from a post hoc analysis.
ADHD-RS-5, Attention-Deficit/Hyperactivity Disorder Rating Scale, version 5; CI, confidence interval.

- Improvements were dose-dependent, with the largest mean differences observed in the CTx-1301 37.5-mg dose group for both the child and adolescent subgroups; however, lower response in adolescents receiving the 25-mg dose possibly suggests that these individuals were underdosed
- Differences between CTx-1301 and placebo were statistically significant for the 25.0-mg and 37.5-mg dose groups in the child subgroup ($p = 0.007$ and $p = 0.003$, respectively)

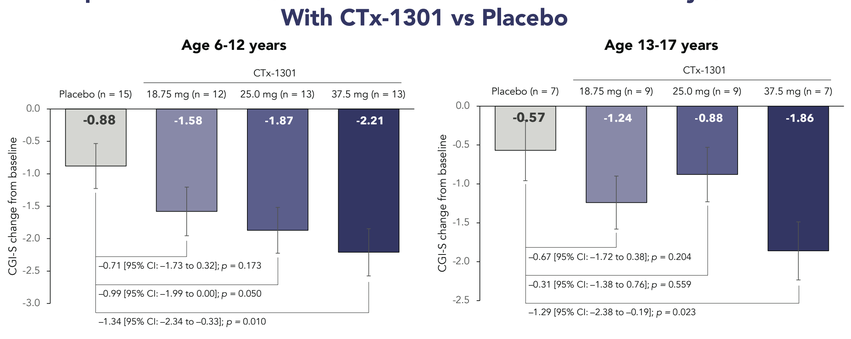
No Significant Differences in Treatment-Emergent Adverse Events (TEAEs) Were Observed in Age Subgroups

Characteristics	Age 6-12 years, n (%)				Age 13-17 years, n (%)			
		CTx-1301				CTx-1301		
	Placebo (n = 16)	18.75 mg (n = 16)	25.0 mg (n = 16)	37.5 mg (n = 16)	Placebo (n = 10)	18.75 mg (n = 10)	25.0 mg (n = 10)	37.5mg (n = 9)
Any TEAE	7 (43.8)	8 (50.0)	7 (43.8)	10 (62.5)	3 (30.0)	5 (50.0)	2 (20.0)	7 (77.8)
Serious TEAEs	0	0	0	0	0	0	0	0
Study drug-related TEAEs[a]	3 (18.8)	7 (43.8)	5 (31.3)	8 (50.0)	3 (30.0)	4 (40.0)	2 (20.0)	7 (77.8)
Most common TEAEs[b]								
Decreased appetite	0	1 (6.3)	3 (18.8)	3 (18.8)	0	2 (20.0)	2 (20.0)	4 (44.4)
Upper abdominal pain	1 (6.3)	1 (6.3)	1 (6.3)	3 (18.8)	1 (10.0)	0	0	1 (11.1)
Headache	1 (6.3)	2 (12.5)	0	1 (6.3)	2 (20.0)	1 (10.0)	0	0
BP increased	0	1 (6.3)	0	1 (6.3)	1 (10.0)	0	0	1 (11.1)
Tachycardia	0	1 (6.3)	1 (6.3)	0	0	0	1 (10.0)	1 (11.1)
Nasopharyngitis	1 (6.3)	0	0	1 (6.3)	1 (10.0)	0	0	0
URTI	0	1 (6.3)	1 (6.3)	0	0	0	0	1 (11.1)
Palpitations	0	0	1 (6.3)	1 (6.3)	0	0	0	0
TEAEs leading to study drug withdrawal[c]	0	0	0	1 (6.3)	1 (10.0)	1 (10.0)	0	0
Chest pain	0	0	0	1 (6.3)	0	0	0	0
Headache	0	0	0	0	0	1 (10.0)	0	0
Joint stiffness	0	0	0	0	1 (10.0)	0	0	0

[a]TEAEs that were assessed by the investigator as "possibly related" or "definitely related" to study drug or for which the relationship to study drug was missing.
[b]TEAEs that occurred in 2 or more patients per age group.
[c]All TEAEs leading to study drug withdrawal were considered at least possibly related to study drug.
BP, blood pressure; TEAE, treatment-emergent adverse events; URTI, upper respiratory tract infection.

- All TEAEs were mild or moderate in severity and no serious TEAEs were reported
- The frequency of TEAEs was numerically lower in the adolescent group
- Weight decreased dose-dependently in the 13–17-year age group, but only slight decreases occurred among 6–12-year-olds (see **Supplementary Materials**)
- Slight changes in blood pressure and heart rate were observed; however, no notable shifts from normal at baseline to low or high values occurred during the study
- No clinically relevant findings or trends across treatment groups were observed for clinical laboratory results, height and weight z-scores, electrocardiogram parameters, or physical examination findings

Improvements in CGI-S Score at Week 5 Were Numerically Greater With CTx-1301 vs Placebo



CGI-S, Clinical Global Impression-Severity; CI, confidence interval.

- Improvements were dose-dependent, with the largest mean differences observed in the CTx-1301 37.5-mg dose group for both the child and adolescent subgroups; however, lower response in adolescents receiving the 25-mg dose possibly suggests that these individuals were underdosed
- Differences between CTx-1301 and placebo were statistically significant for the 37.5-mg dose in the child subgroup ($p = 0.010$)