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# Efficacy and Safety of CTx-1301 in Pediatric Subjects With ADHD: Results From a Phase 3, Randomized, Double-Blind, Placebo-Controlled Trial

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# Disclosure

## Ann Catherine Childress, MD

Potential conflict of interest with the following business, organization and individual

Name of business, organization or individual	Nature of conflict
Aadrvark, Attentive, and Sky	Consultant
Allergan, Adlon, Lilly, Sanofi, Suven, and Syndeio	Research Support
Akili and Cingulate	Advisory Board, Consultant, and Research Support
Bristol Myers Squibb	Advisory Board
Lumos and Zevra Therapeutics Inc (previously KemPharm, Inc)	Consultant and Research Support
Otsuka and Sunovion	Advisory Board, Consultant, Research Support and Writing Support
Supernus	Advisory Board, Consultant, Research Support, and Speakers Bureau
Noven and Corium	Advisory Board, Consultant, Speakers Bureau and Writing Support
Takeda	Research Support, Speakers Bureau and Writing Support
Tris Pharma and Collegium (previously Ironshore)	Advisory Board, Consultant, Research Support, Speakers Bureau and Writing Support

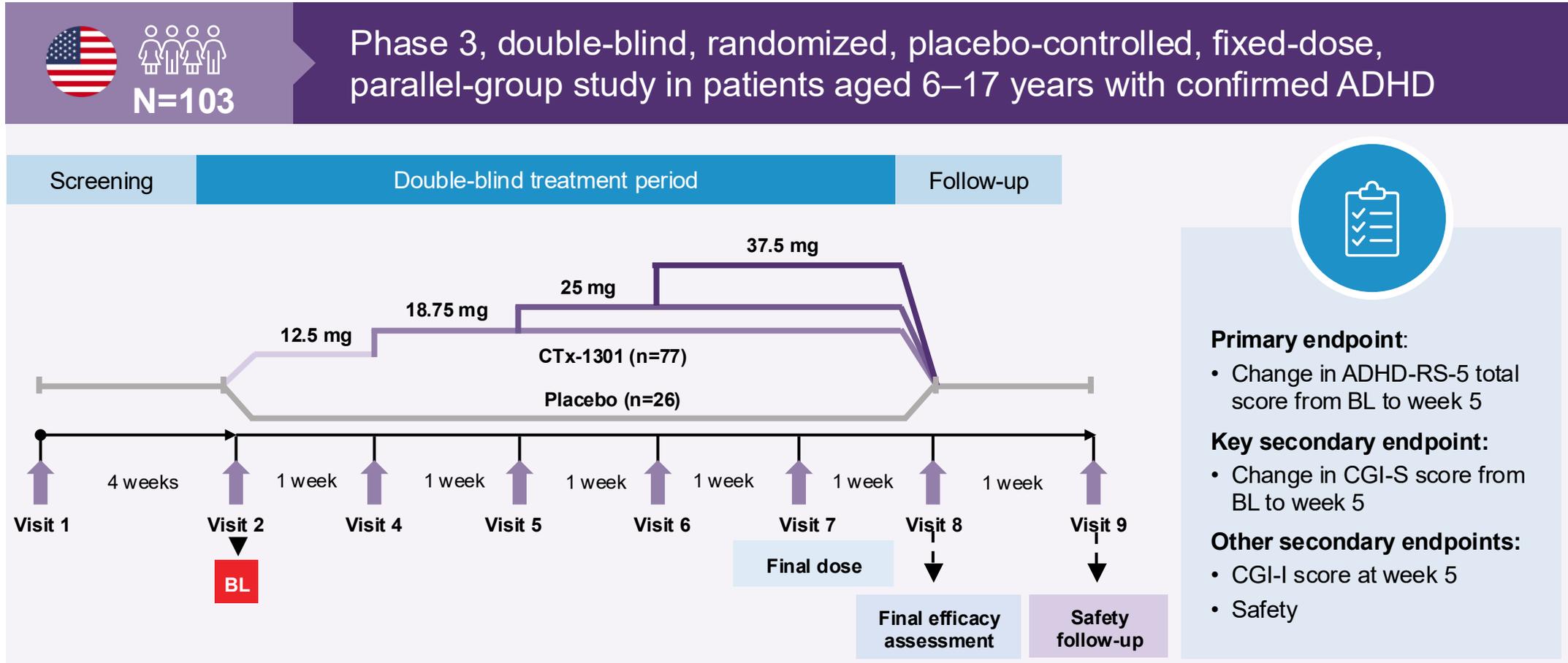
# Background and Objectives

- **Inadequately managed ADHD** contributes to significant health, social, and economic burden in children and adolescents<sup>1</sup>
- Many patients treated with long-acting stimulants experience **inadequate symptom control during the day**<sup>2</sup>
- Strategies to **improve onset and duration of treatment** are hampered by the need to take multiple medication doses per day
- **CTx-1301 is a once-daily, trimodal extended-release dexamethylphenidate** (d-MPH) tablet designed to provide rapid onset and sustained symptom relief throughout the day using Precision Timed Release™ technology<sup>3</sup>



- **Primary objective:** Efficacy of three fixed doses of CTx-1301 (18.75, 25, and 37.5 mg) versus placebo based on changes in ADHD-rating scale, version 5 (ADHD-RS-5) total score
- **Secondary objectives:** Clinical Global Impressions-Severity & Improvement (CGI-S & CGI-I), safety, and tolerability

# Study Design and Endpoints



# Patients

## Key inclusion criteria

- Patients aged 6 to 17 years
- Confirmed ADHD by DSM-5 criteria or any of the three presentations (combined, inattentive, or hyperactive/impulsive) assessed by MINI-KID
- Baseline ADHD-RS-5 score  $\geq 28$  and CGI-S score  $\geq 4$
- Body weight between the 5<sup>th</sup> and 95<sup>th</sup> percentile for the respective age and sex

## Key exclusion

- Any psychiatric diagnosis of bipolar I or II, major depressive, conduct, disruptive mood dysregulation, intellectual disability, obsessive compulsive, anxiety, or eating disorders; history of psychosis, autism spectrum disorder, Tourette's syndrome; intellectual disability; or genetic disorders with cognitive/behavioral disturbances or any other conditions deemed exclusionary by the investigator
- Evidence of any chronic CNS disease (such as tumors, inflammation, seizure disorder, vascular disorder, or other CNS-related disorders)



- All 103 patients were included in the ITT and safety populations

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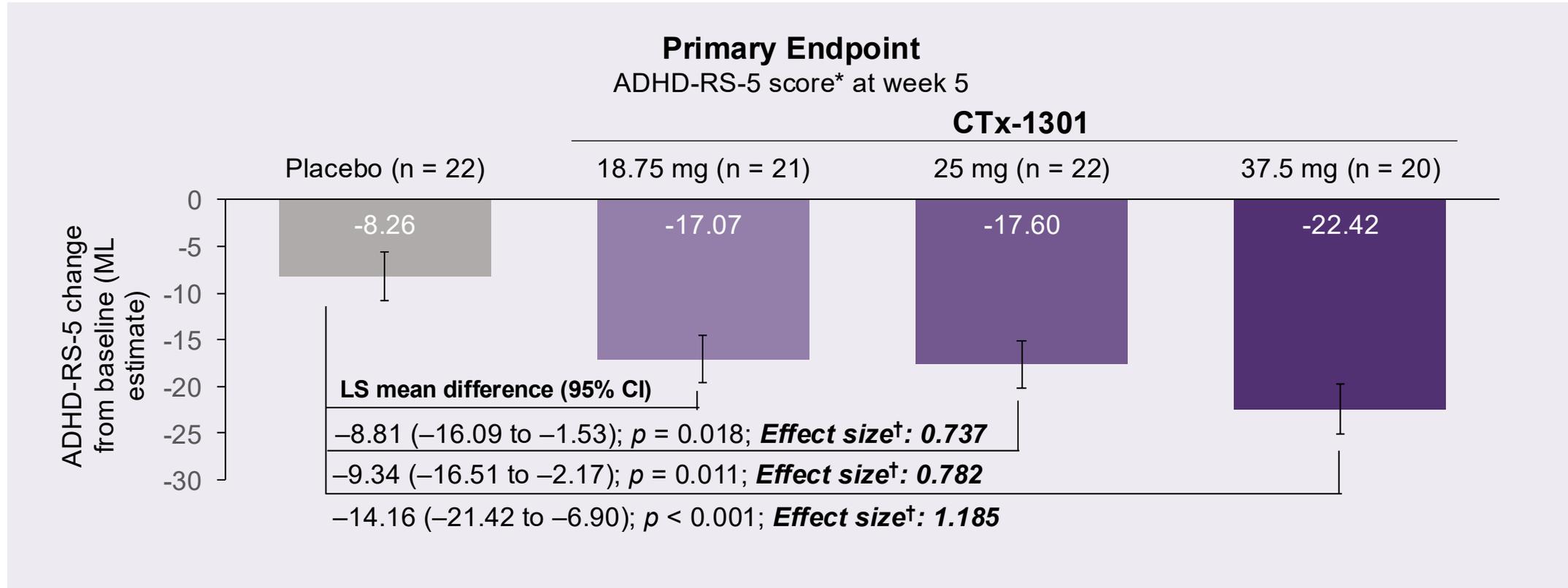
\*Missing drug concentrations, sample date/time, or incomplete dosing information were excluded from the analysis

ADHD, attention-deficit/hyperactivity ; ADHD-RS-5, ADHD er rating scale, version 5; CGI-S, Clinical Global Impressions-Severity; CNS, central nervous system; DSM-5, Diagnostic and Statistical Manual of Mental Disorders - Fifth Edition; ITT, intent to treat; MINI-KID, MINI International Neuropsychiatric Interview of Children and Adolescents.

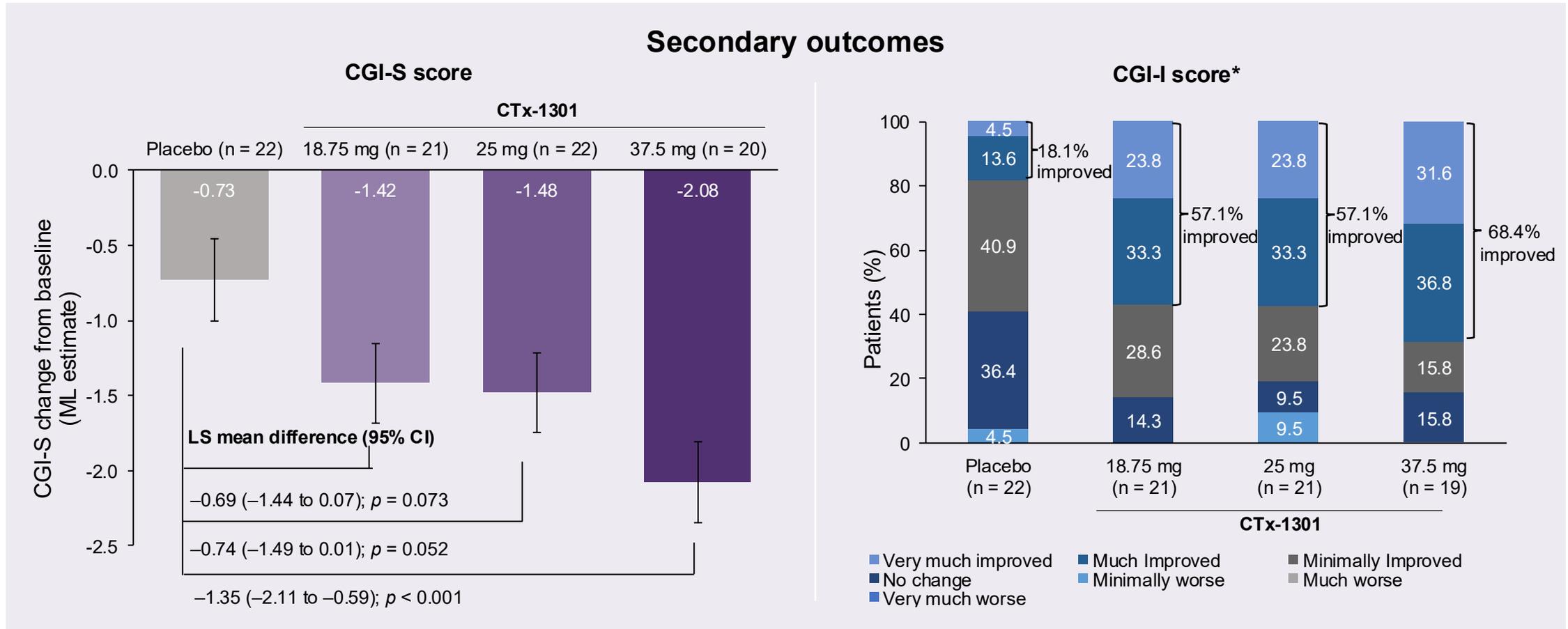
# Demographics and Baseline Characteristics Were Generally Similar Among Treatment Groups

Characteristics	Placebo	CTx-1301		
	(n = 26)	18.75 mg (n = 26)	25 mg (n = 26)	37.5 mg (n = 25)
<b>Age, mean ± SD, years</b>	11.5 ± 3.3	11.4 ± 3.6	11.3 ± 3.2	11.0 ± 3.2
<b>Male sex, n (%)</b>	17 (65.4)	13 (50.0)	16 (61.5)	16 (64.0)
<b>Race, n (%)</b>				
Black or African American	13 (50.0)	12 (46.2)	12 (46.2)	14 (56.0)
White	12 (46.2)	11 (42.3)	11 (42.3)	11 (44.0)
Multiple	1 (3.8)	3 (11.5)	2 (7.7)	0
Asian	0	0	1 (3.8)	0
<b>Duration of ADHD, mean ± SD, years*</b>	3.8 ± 3.3	4.6 ± 4.2	3.7 ± 3.6	3.9 ± 3.7
<b>Prior stimulant use, n (%)</b>				
Mixed amphetamine salts	7 (26.9)	7 (26.9)	4 (15.4)	3 (12.0)
Methylphenidate	3 (11.5)	3 (11.5)	4 (15.4)	2 (8.0)
Methylphenidate HCL	4 (15.4)	4 (15.4)	1 (3.8)	3 (12.0)
Lisdexamfetamine	6 (23.1)	3 (11.5)	0	2 (8.0)
d-MPH	0	1 (3.8)	2 (7.7)	1 (4.0)
Amphetamine	0	1 (3.8)	0	0
d-MPH/serdexmethylphenidate	0	1 (3.8)	0	0
<b>BL ADHD-RS-5 total score, mean ± SD</b>	40.0 ± 7.6	41.2 ± 7.7	40.7 ± 7.8	40.0 ± 8.3
<b>BL CGI-S score, mean ± SD</b>	4.7 ± 0.8	4.7 ± 1.0	4.7 ± 0.8	4.8 ± 0.9

# CTx-1301 Significantly Improved ADHD-RS-5 Score Compared With Placebo



# CTx-1301 Improved CGI-S and Greater Proportion of Patients Demonstrated Improvement Based on CGI-I Scores Compared to Placebo



# Safety Profile

Category	Placebo	CTx-1301		
	(n = 26)	18.75 mg (n = 26)	25 mg (n = 26)	37.5 mg (n = 25)
<b>Any TEAE, n (%)</b>	10 (38.5)	13 (50.0)	9 (34.6)	17 (68.0)
Mild	5 (19.2)	11 (42.3)	5 (19.2)	11 (44.0)
Moderate	5 (19.2)	2 (7.7)	4 (15.4)	6 (24.0)
Severe	0	0	0	0
<b>Serious TEAEs, n (%)</b>	0	0	0	0
<b>TEAEs leading to study drug withdrawal*, n (%)</b>	1 (3.8)	1 (3.8)	0	1 (4.0)
<b>Most common TEAEs†, n (%)</b>				
Decreased appetite	0	3 (11.5)	5 (19.2)	7 (28.0)
Upper abdominal pain	2 (7.7)	1 (3.8)	1 (3.8)	4 (16.0)
Headache	3 (11.5)	3 (11.5)	0	1 (4.0)
BP increased	1 (3.8)	1 (3.8)	0	2 (8.0)
Tachycardia	0	1 (3.8)	2 (7.7)	1 (4.0)
Nasopharyngitis	2 (7.7)	0	0	1 (4.0)
URTI	0	1 (3.8)	1 (3.8)	1 (4.0)

- CTx-1301 demonstrated a favorable safety profile, with no serious TEAEs
- No clinically relevant findings for clinical laboratory measurements, vital signs, or physical examinations

# Summary



CTx-1301 demonstrated consistent **dose-dependent efficacy** in improving ADHD symptoms in children and adolescents



The 37.5-mg dose demonstrated the **largest effect size and symptom reduction**; effect sizes were substantial considering the fixed-dose study design



CTx-1301 showed **favorable safety profile** for all three dosage strengths

The study findings demonstrated the efficacy and safety of CTx-1301 for the treatment of ADHD in pediatric patients