



Cingulate Inc.

Developing Next-Generation Therapeutics to Address Unmet Needs in Billion Dollar Markets

August 2024



Forward-Looking Statements

This presentation contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include all statements, other than statements of historical fact, regarding our current views and assumptions with respect to future events regarding our business, including statements with respect to our plans, assumptions, expectations, beliefs and objectives with respect to product development, clinical studies, clinical and regulatory timelines, market opportunity, competitive position, business strategies, potential growth opportunities and other statements that are predictive in nature.

These statements are generally identified by the use of such words as “may,” “could,” “should,” “would,” “believe,” “anticipate,” “forecast,” “estimate,” “expect,” “intend,” “plan,” “continue,” “outlook,” “will,” “potential” and similar statements of a future or forward-looking nature. Readers are cautioned that any forward-looking information provided by us or on our behalf is not a guarantee of future performance. Actual results may differ materially from those contained in these forward-looking statements as a result of various factors disclosed in our filings with the Securities and Exchange Commission (SEC), including the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2023. All forward-looking statements speak only as of the date on which they are made, and we undertake no duty to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

Boosters

Efficacy

Cost (s)

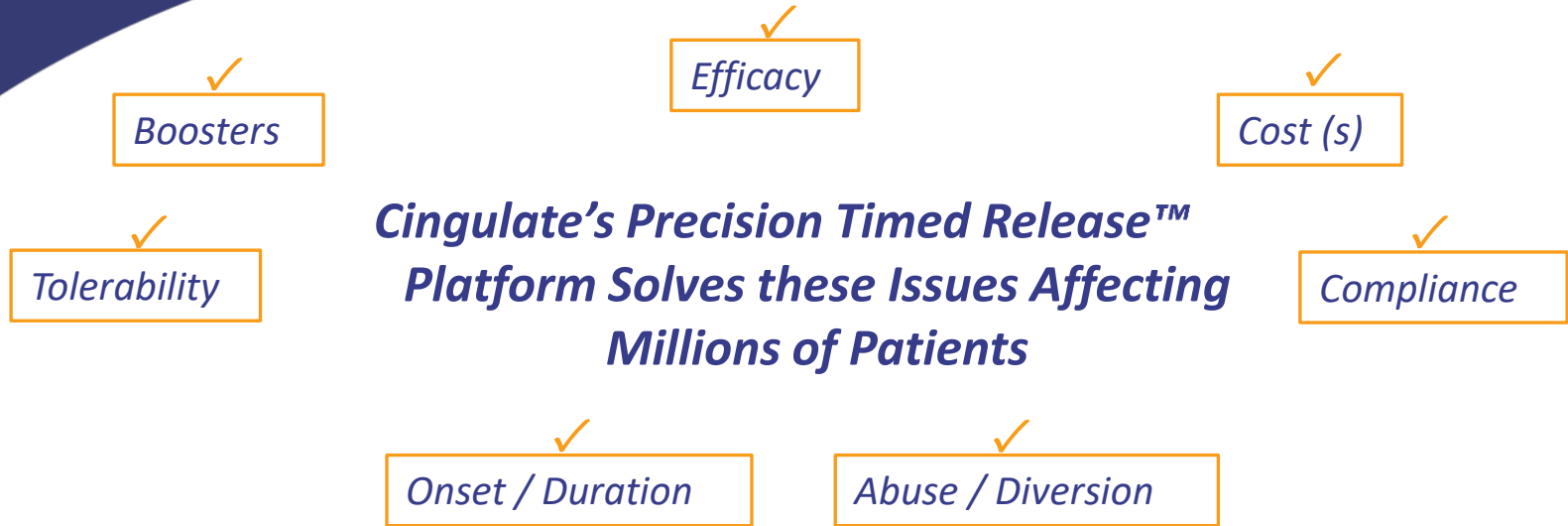
Tolerability

Current Medication Options Do Not
Deliver Acceptable Outcomes for
Patients, Providers, and Payors

Compliance

Onset / Duration

Abuse / Diversion



Why Cingulate (Nasdaq: CING)

Completed & Near-Term Catalysts (CTx-1301)

- Indegene Commercialization Partnership Agreement Executed, dovetailing with...
- US License Discussions
- Unprecedented Phase 3 Adult Data
- Phase 3 Clinical Development Complete
- Planned NDA Submission in 1H'25

Multiple Long-Term Revenue Streams

- PTR™ Platform: CING Assets & Out license Value
- ADHD Market \$20+ Bn in US
- Anxiety Market \$5+ Bn in US
- Ex-US License Opportunities
- IP & Exclusivity: First LOE in 2035

Experienced Leadership Team

- Proven C-Suite and Management team possessing big and small pharma expertise
- Seasoned Board of Directors – Pharma, Securities, PubCo, Finance, M&A, PRMA
- Indegene Commercial Partnership provides instant launch and scalable commercial readiness

Multiple Near-Term Milestones Expected



ADHD

CTx-1301

CTx-1302

- Complete Phase 3 Clinical Development Plan
- Complete Registration Batches for NDA Filing
- Ex-US Licensing

- NDA Preparation
- Registration Stability Data
- US Licensing BD&L

- File CTx-1301 New Drug Application
- Prepare CTx-1302 IND

Anxiety

CTx-2103

- Ex-US Licensing

- Manufacture IND-enabling clinical study supply

- Prepare & File CTx-2103 IND

- FDA Pre-IND Meeting

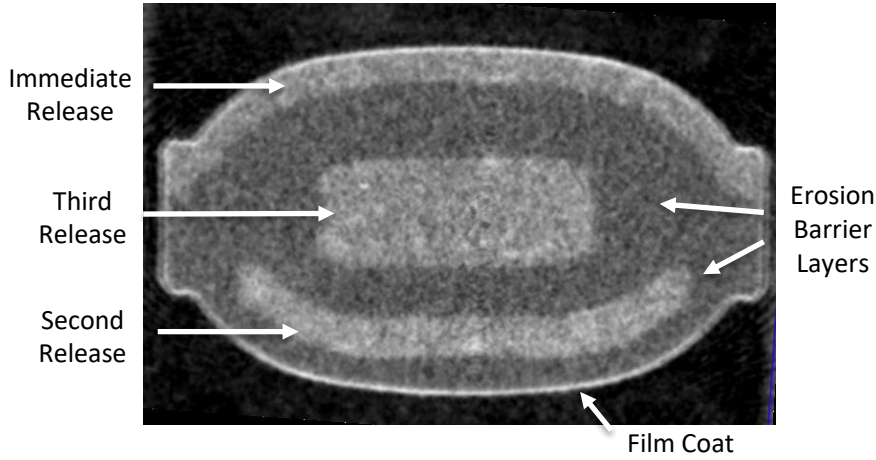
PTR™ Platform

- Manufacturing Operations Expanded for Current and Future PTR™ Platform Assets

- Pursue out license opportunity for PTR™ Platform
- Expand CING – BDD Partnership
- Expand BD&L Activities w/ PTR™

Next-Generation Medications in Billion-Dollar Markets

Precision Timed Release™ (PTR™) Platform Unlocks the Possibility for 'True' Once-daily, Multi-dose Tablets



[See the PTR™ Platform in Action @ Cingulate.com](https://www.cingulate.com)

PTR Facilitates a Potential Pipeline Addressing Multiple Indications

Identified Targets for PTR™ Platform Pipeline

In Development

- ADHD (CTX-1301, 1302)
- Anxiety (CTX-2103)

Near-Term Targets Identified

- Insomnia
- Depression
- Bipolar Disorder
- Movement Disorders
- Cardiovascular Disorders
- Xerostomia (dry mouth)

Future Therapeutic Areas

- Migraine
- Hypothyroidism
- Oral Oncology Medicines
- Psychosis
- Alzheimer's Disease
- Pain (Non-Opioid)



The Cingulate Solution for Patients & Providers

ADHD



CTx-1301



CTx-1302

Targeting Treatment of ADHD - \$20+Bn US Market Opportunity

Frequently diagnosed, chronic pattern interfering with functioning / development

17 Million US ADHD Patients
11M Adults & 6M Children/Adolescents

Stimulants 90% of Prescriptions

80 Million Prescriptions per Year¹

Methylphenidates

- Ritalin® / LA
- Concerta®
- Focalin® / XR
- CTx-1301 (d-MPH)

Amphetamines

- Vyvanse®
- Adderall® / XR
- Dexedrine®
- CTx-1302 (d-AMP)

Non-Stimulants: 10%

- Atomoxetine
- Guanfacine
- Clonidine
- Quelbree®

Societal Impact of ADHD

Estimated annual incremental costs of \$143 to \$266 billion in the United States

Earn ~ 30% less and 10% less likely to be employed

>40% higher rate of car accidents

2x greater divorce rate

2x greater incidence of accidental death

2x higher incarceration rate

¹Symphony Data. 12-months rolling through Sept 2023

References: <https://www.cdc.gov/ncbddd/adhd/data.html>
Doshi et al. J Am Acad Child Adolesc Psychiatr. 2012;51(10):990-1002.

ADHD Market Currently Dominated by 4 Stimulant Products

Major Unmet Medical Needs Persist

ADHD BRANDS	APPROVED	ATTRIBUTES ¹		UNMET NEEDS ¹			
		Onset	Duration (less onset)	Fast Onset of Action ≤ 30 min	Entire Active-Day Efficacy*	Minimize Crash/Rebound	Avoid Booster ¹
Vyvanse®	2007	1 ½ - 2 hours	8-9 hours	✗	✗	Data Not Available	✗
Adderall® XR	2001	1 ½ hours	7-8 hours	✗	✗	Data Not Available	✗
Concerta®	2000	2 hours	6-7 hours	✗	✗	Data Not Available	✗
Focalin® XR	2005	30 mins	7-8 hours	✓	✗	Data Not Available	✗

92%
of ALL
Extended
Release
Stimulant Rx's³

60%
use short-acting
'booster' dose
every day!²

* Entire-active day efficacy defined as less than or equal to a 30 min onset of action with true 12 hours of duration vs. baseline

¹ Information based upon product Package Inserts, and Summary Basis of Approvals for the approved products in chart and Ann C. Childress, Nathalie Beltran, Carl Supnet & Margaret D.

Weiss (2021) Reviewing the role of emerging therapies in the ADHD armamentarium, Expert Opinion on Emerging Drugs, 26:1, 1-16.

² Outside the Box: Rethinking ADD/ADHD in Children and Adults A Practical Guide; First Edition, p. 185 Thomas E. Brown, PhD

³ Symphony Data. 12-months rolling through Sept 2023

Why is Effect Size Important?

Statistical Significance (p value)^{1,2}

- Probability that both groups are equal
- Doesn't measure magnitude
- Not usable in comparisons

Clinical Effect ^{1,2}

'Clinical effect is used to determine if newer therapies are important enough to warrant clinical use and/or formulary decisions'²

- Independent of Sample Size
- Allows for Comparison Across Trials
- Examples: Effect Size, Number Needed to Treat...

¹ McGough, J. J., & Faraone, S. V. (2009). Estimating the size of treatment effects: moving beyond p values. *Psychiatry (Edgmont (Pa. : Township))*, 6(10), 21–29.

² Faraone S. V. (2008). Interpreting estimates of treatment effects: implications for managed care. *P & T : a peer-reviewed journal for formulary management*, 33(12), 700–711.

What Has CTx-1301 Clinical Data Shown Us?

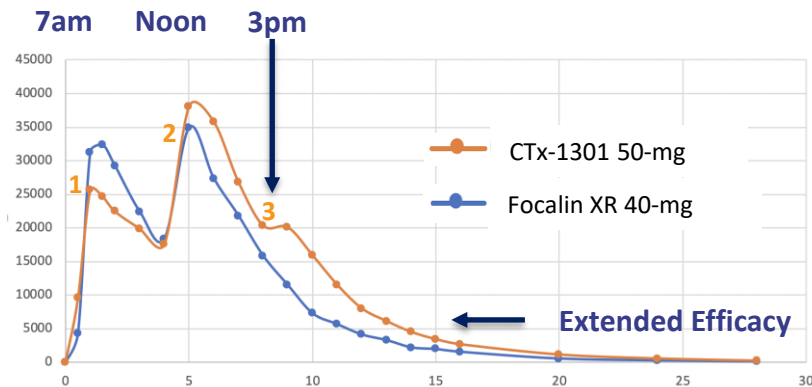
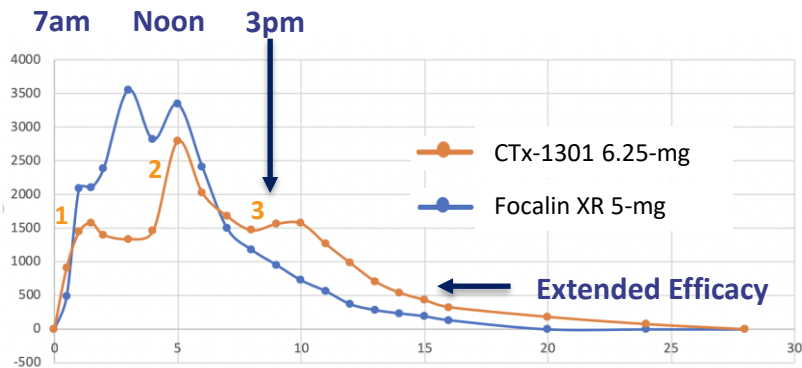
Impressive Effect Size in the Treatment of ADHD

- Ideal product profile with 3 precisely timed, ratioed, and styled releases of medication
- Phase 3 adult study
 - **Effect size 2 – 3 x greater*** than available ADHD treatments (**real-world impact**)
 - Entire Active-Day Efficacy with Fast onset of action
 - Psych Congress finalist at poster award reception
- Improved side effect profile
 - Phase 3 adult study: 1 Side effect (n=11) on CTx-1301, 3 side effects (n=10) on Placebo
 - Head-to-head vs Focalin XR: **28.6% reduction** in treatment emergent adverse events
 - All 6 trials completed consistently demonstrated this tolerability

* Effect Size data from published clinical trial results, calculations, and data on file Cingulate Inc. including PERMP, AISRS, ADHD-RS, WREMB-R scales.

One Product Designed to Overcome All Unmet Needs

Entire Active-Day Efficacy, Stop the Crash & Rebound, Eliminate the Booster Dose



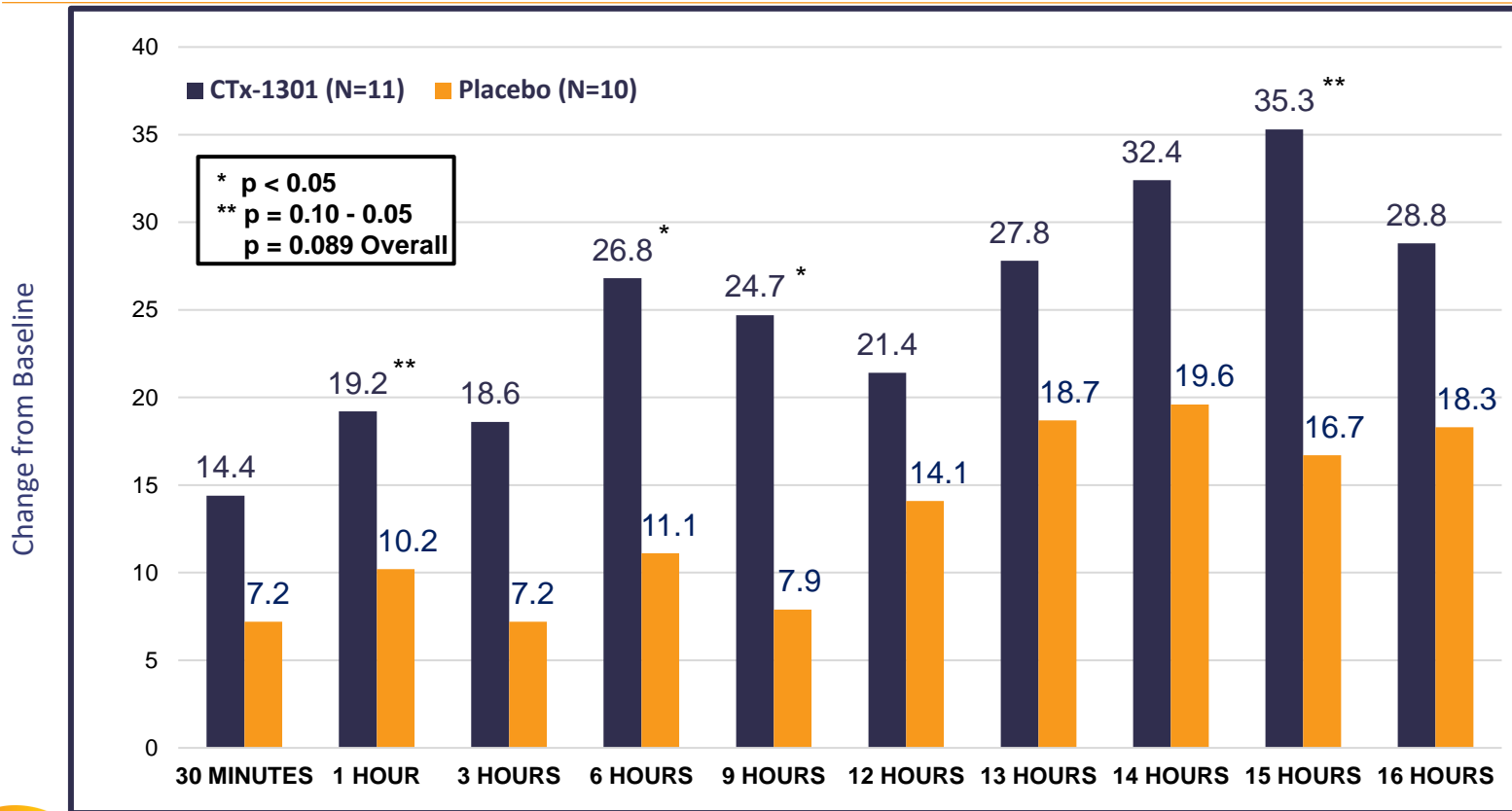
Subject ID: 01-510

CINGULATE [®]	TARGET ATTRIBUTES		UNMET NEEDS			
	Onset	Duration	Fast Acting (≤ 30 min)	Entire Active-Day Efficacy	Avoid Crash/Rebound	Avoid Booster
CTx-1301 (d-MPH)	30 mins	Up to 16 hours	✓	✓	✓	✓
CTx-1302 (d-AMP)	30 mins	Up to 16 hours	✓	✓	✓	✓

- 6.25-mg
- 12.5-mg
- 18.75-mg
- 25-mg
- 31.25-mg
- 37.5-mg
- 43.75-mg
- 50-mg

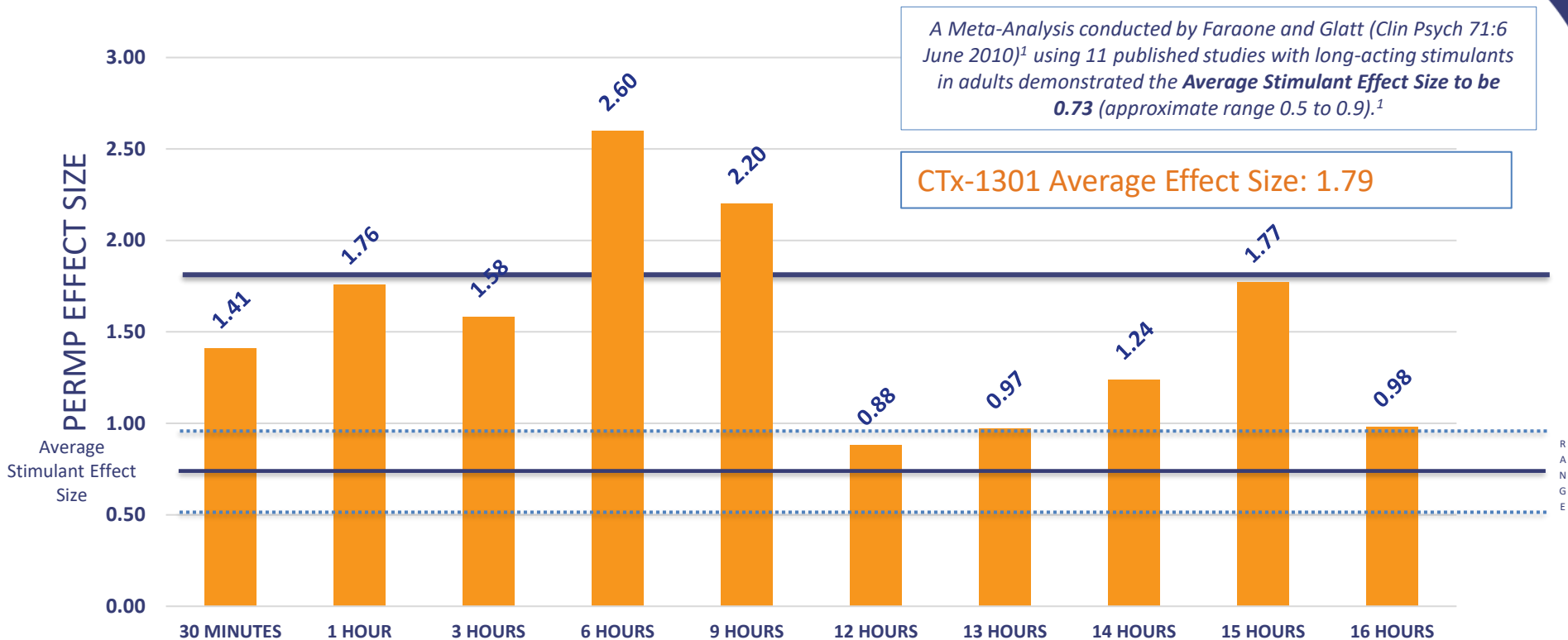


PERMP CTx-1301 & Placebo Adult Laboratory Classroom



Data on file, Cingulate Inc. 1301-022 NCT 05631626

CTx-1301 PERMP Effect Size over Entire Active Day



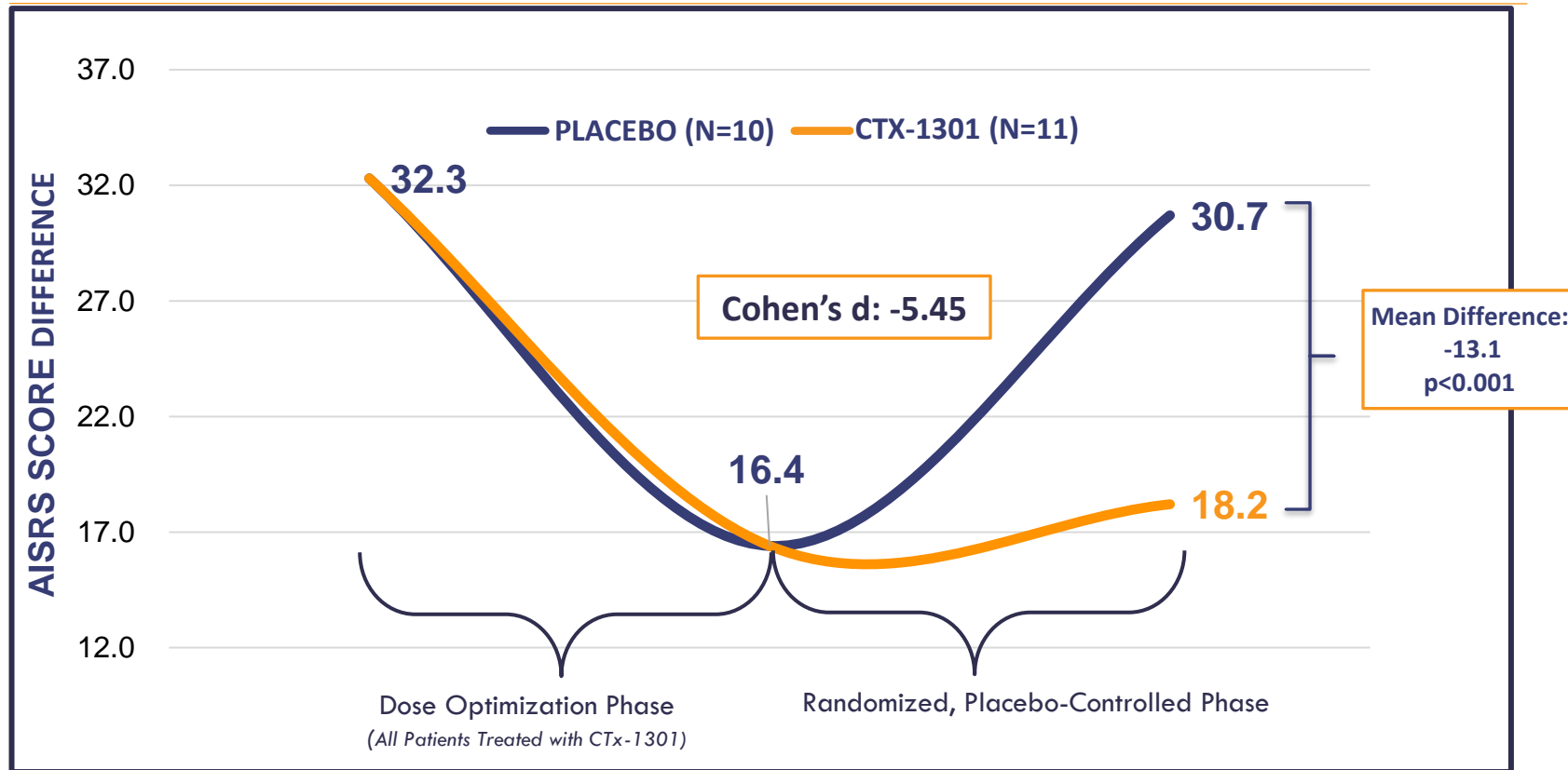
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p-value (30 min- 16 hour): 0.089

Cingulate.com

AISRS: CTx-1301 Delivered Ongoing Reduction in ADHD Severity



ADHD Effect Size Comparison in Adults*

ADHD Products & Candidate	Peak Effect Size** (Cohen's d)	p-value	Percentiles (Cohen's d)
CTx-1301***	1.79 @ 1 week	0.089	<u>96%</u>
Concerta®	0.42 @ 6 weeks	<0.001	~69%
Vyvanse®	0.94 @ 10 weeks	<0.001	~84%
Focalin XR®	0.5 @ 6 months	<0.001	~69%
Azstarys® +	0.49 @ 4 weeks	0.003	~69%
Adderall® XR	0.80 @ 4 weeks	<0.001	79%
Mydayis® XR	1.11 @ 4 weeks	<0.001	~85%
Strattera®	0.48 @ 6 months	≤0.012	~69%
Qelbree®	0.28; 0.312 @ 6 Weeks	0.004; N/A	~54%

* Data from published clinical trial results, calculations, and data on file Cingulate Inc. ** AISRS, ADHD-RS, WREMB-R, PERMP scales. *** CTx-1301 has completed Phase 3 of clinical development and not an approved product. + Study conducted in Children and Adolescents

CTx-1301 Demonstrated Significantly Lower Adverse Events

28.6% reduction in TEAE's related to CTx-1301 versus Focalin XR (14.3% difference)

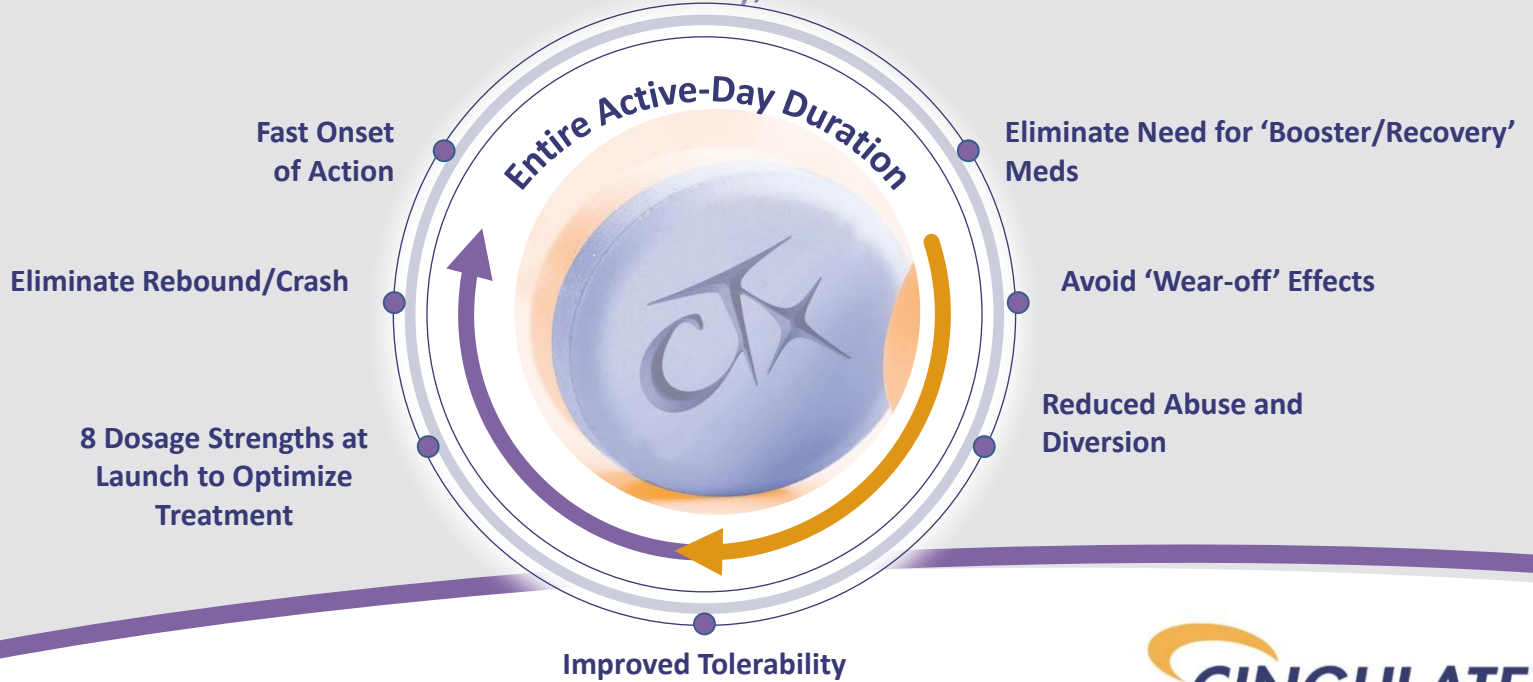
	Focalin XR 5 mg (n=41)	CTx-1301 6.25 mg (n=39)	Focalin XR 40 mg (n=43)	CTx-1301 50 mg (n=42)	All CTx-1301 (n=42)	All Focalin XR (n=44)
Patients with at least one						
Treatment Emergent Adverse Events	7 (17.1%)	4 (10.3%)	22 (51.2%)	14 (33.3%)	17 (40.5%)	25 (56.8%)
Mild	7 (17.1%)	4 (10.3%)	20 (46.5%)	14 (33%)	17 (40.5%)	23 (52.3%)
Moderate	0	0	2 (4.7%)	0	0	2 (4.5%)
Severe	0	0	0	0	0	0
TEAE Related to Study Drug	5 (12.2%)	3 (7.7%)	20 (46.5%)	13 (31.0%)	15 (35.7%)	22 (50.0%)
AE Leading to Study or Drug Withdrawal	1 (2.4%)	0	1 (2.3%)	0	0	2 (4.5%)

There were no serious adverse events.

Source: CSR CTx-1301-001 Listing 16.2.7.1

The ADHD Medication Providing Daily Durability

Precision Timed Release™ (PTR™) Platform Unlocks the Possibility for 'True' Once-daily, Multi-dose Tablets



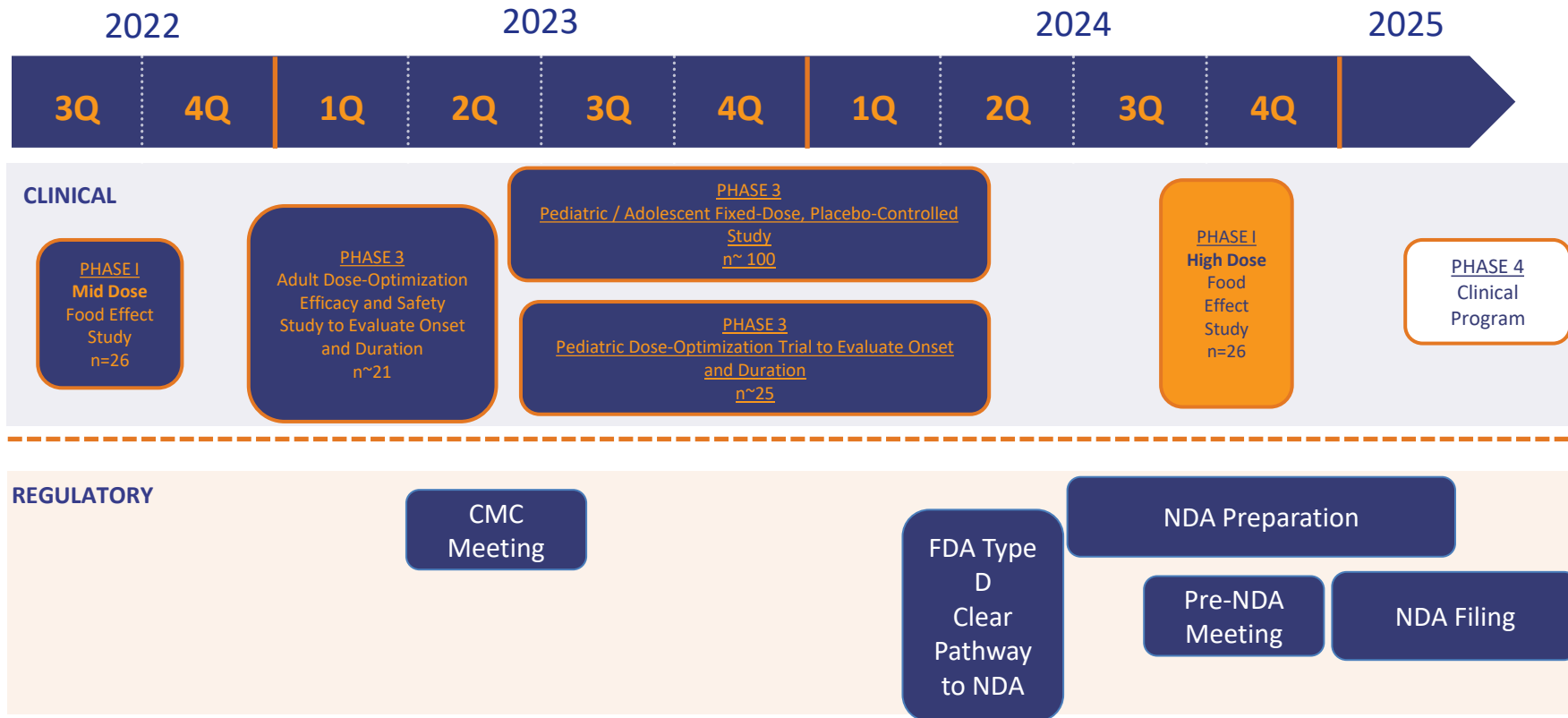
\$20+ Billion*

US ADHD Market
Dominated by Stimulants

*Symphony Data.
12-months rolling
through Sept 2022



MASTERY[®] CTx-1301 Clinical and Regulatory Timeline





The Cingulate Solution for Patients & Providers

Anxiety

CTx-2103 – Buspirone HCl for the Treatment of Anxiety

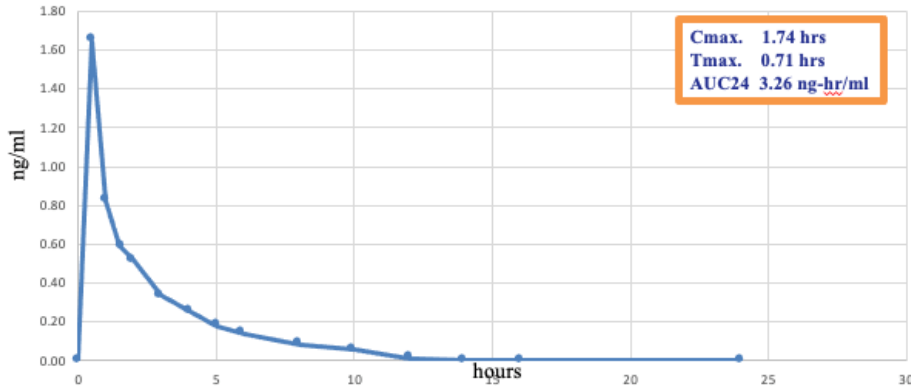
Next-Generation Buspirone designed to Improve Patient Outcomes

Three Times a Day

versus

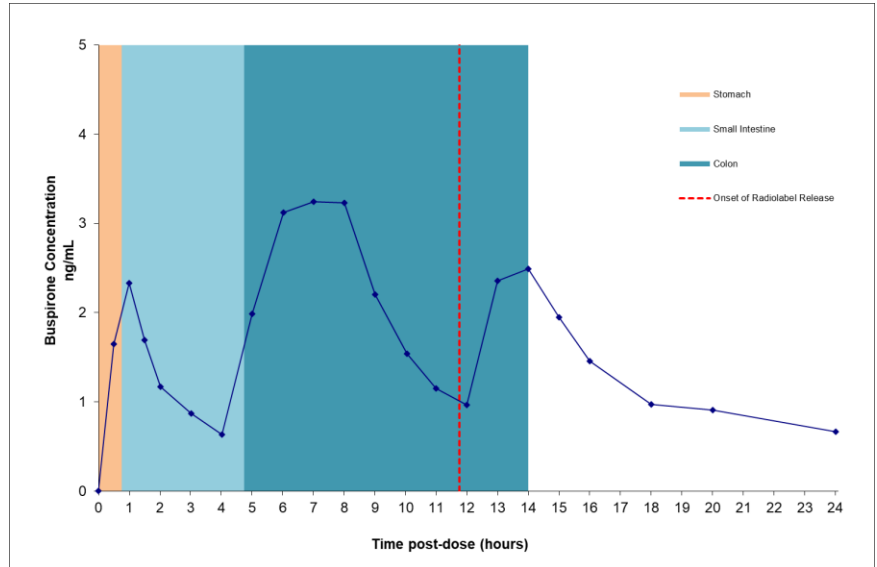
Once a Day

Single Dose Buspirone 10 mg- Immediate Release



Treatment D: A single tablet releasing 10 mg buspirone HCL (commercially available) immediately

**Cmax. 1.74 hrs
Tmax. 0.71 hrs
AUC24 3.26 ng-hr/ml**





Commercialization Strategy

Best in Class Market Preparation and Execution



Traditional Pharmaceutical Commercialization Is Increasingly Challenged

1 in 5

products reach peak U.S. sales of \$1B¹

62%

of products launched in the last 15 years have underperformed pre-launch forecasts¹

50%

of products fail to reach peak U.S. sales of \$250M¹

Furthermore, a recent McKinsey study² indicated that...

50%

of Providers never plan to see a sales rep again

50%

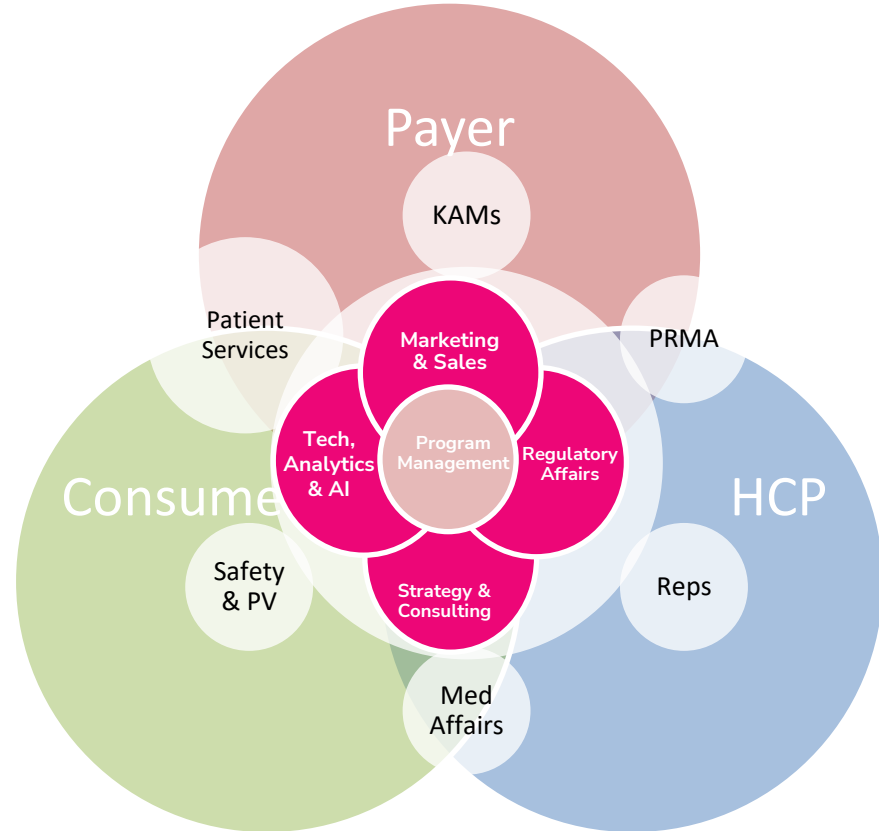
will see a sales rep once or twice a year, three times at most

¹ Data on File. Indegene Inc. 2021-2022.

² McKinsey & Company, The future of HCP engagement. Supporting information from U.S. HCP research. October 2021.

Cingulate & Indegene Integrated GTM Solution

Customer focused, integrated solutions model allows for more effective commercialization and higher revenue generation than traditional commercial options



CTx-1301 Reimbursement Potential

Executive Summary of Qualitative Findings (July 2, 2024)

- Respondents manage approximately 121.8 million total lives, of which they personally manage 114.1 million Commercial lives, and 7.6 million Medicaid lives
- CTx-1301 is likely to gain commercial coverage as a Non-Preferred brand with 1-2 steps or a Preferred brand without restrictions all dependent on rebate ranges; Medicaid coverage, as you know, requires supplemental rebates.
- CTx-1301 was rated most valuable versus Vyvanse, Adderall XR, Concerta, Focalin XR, Azstarys, and Qelbree.
- Contracting and pricing estimates yielded a WAC & Rebate range that is favorable to Cingulate's current forecast models.

Value Maximizing Commercial Model

Leverage AI and ML to build a commercial model based on the best mix to drive revenue



Traditional Model

- Hundreds of reps target inaccessible HCPs (60-75%)
- Expensive, inefficient and ineffective
- Reps and individual channels are not integrated



Cingulate & Indegene Model

- Proprietary AI & ML identify best mix of channels with highest probability of driving return
- Positioned to maximize revenue and ROI
- Sales reps and AI **drive** traditional and nontraditional channels with integration
- Market Access (PRMA) Strategy
- Optimize capital with scalability

Why Cingulate (Nasdaq: CING)

29

- ✔ **Near and Long-Term Future Revenue Streams**
- ✔ **CING is Building Multiple Assets that Solve Real Problems**
- ✔ **Commercialization is Built and Ready for Scale**

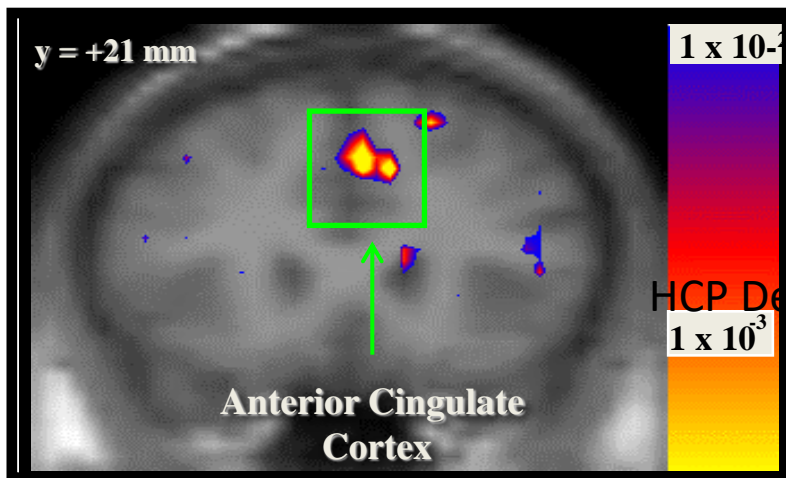


Thank You

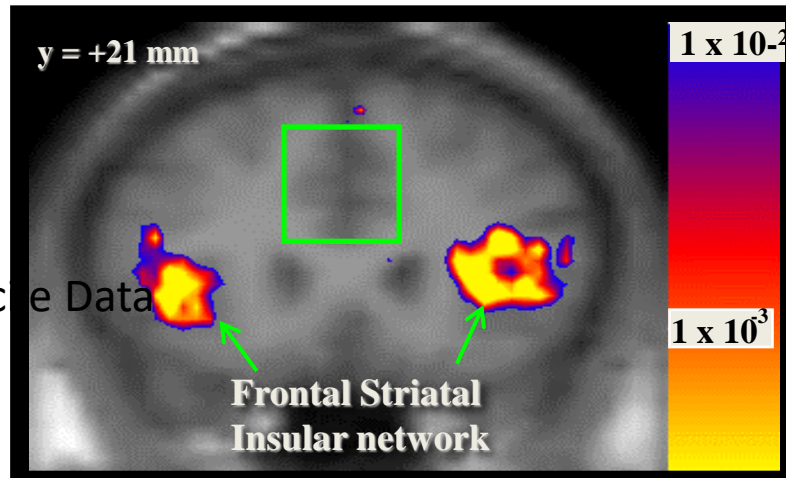


Neurobiological relationship to ADHD

Normal control



ADHD



fMRI shows decreased blood flow to the anterior cingulate and increased flow in the frontal striatum

MGH-NMR Center & Harvard-MIT CITP. Bush, et al. *Biol Psychiatry*. 1999;45:1542-1552.

Recent Launches Lack Meaningful Clinical Innovation

Niche Delivery Platforms – Designed to Fail in ADHD

ADHD BRANDS	ATTRIBUTES ¹		UNMET NEEDS			
Product	Onset	Duration	Fast Acting (≤ 30 min)	Entire Active- Day Efficacy*	Avoid Crash/Rebound	Avoid Booster
Quillivant / Chew [®] XR	60 mins	8 hours	✗	✗	✗	✗
Mydayis [®]	2 or 4 hrs	16+ hours	✗	✗	✗	✗
Adzenys [®] ER/ODT	60 mins	8-9 hours	✗	✗	✗	✗
Cotempla [®] XR/ODT	60 mins	10-12 hours	✗	✗	✗	✗
Aptensio [®] XR	60 mins	9 hours	✗	✗	✗	✗
Evekeo [®] / ODT	60 mins	10 hours	✗	✗	✗	✗
Dynavel [®] XR Oral Susp.	60 min	13 hours	✗	✗	✗	✗
Zenzedi [®]	60 mins	4-5 hours	✗	✗	✗	✗
Jornay [®] PM (at night)	2-hour window	10-11 hours	✗	✗	✗	✗
Adhansia [®] XR – Discontinued	60 mins	12-13 hours	✗	✗	✗	✗
Azstarys [®] (summer 2021)	Failed Endpoint	Failed Endpoint	✗	✗	✗	✗

* Entire-active day efficacy defined as less than or equal to a 30 min onset of action with 14-16 hours of duration vs. placebo

¹ Information based upon product Package Inserts and Summary Basis of Approvals and Ann C. Childress, Nathalie Beltran, Carl Supnet & Margaret D. Weiss (2021) Reviewing the role of emerging therapies in the ADHD armamentarium, Expert Opinion on Emerging Drugs, 26:1, 1-16.

CTx-1301 Adult ADHD – Completed Onset and Duration Trial

Outcome:

- CING identified effect size of CTx-1301 formulation to confirm upcoming Phase 3 Pivotal Study Designs

Objectives:

- Primary: Efficacy of CTx-1301 compared to placebo in treating adults with ADHD in a laboratory classroom study
- Secondary:
 - Onset and duration of CTx-1301 in treating adults with ADHD in a laboratory classroom study
 - Safety and tolerability of CTx-1301 compared to placebo in a laboratory classroom study

Study Subjects: 21 (11 CTx-1301 Treatment ; 10 Placebo)

PERMP: Math tests that assess and quantify an ADHD patient's ability to focus and complete tasks

Effect Size: Statistic to assess and quantify the medication efficacy performance versus placebo; larger is better

AISRS: Double-blinded Clinician rated ADHD scale to assess and quantify level of ADHD severity

CGI-S: Clinician ADHD scale used to assess and quantify overall ADHD severity and improvement or worsening of patient's clinical presentation

Adult ADHD Investigator Symptom Rating Scale

CTx-1301 AISRS Effect Size (Cohen's d)

All subjects treated with CTx-1301

	Mean Starting Baseline	Mean Baseline Visit 7 (pre-dose)	Mean Visit 8	LS Mean CFB (Visit 7 to Visit 8)	p-value	Effect Size (Cohen's d)
CTx-1301-022	32.7 (5.06)	16.4 (4.86)	18.2 (7.59)	1.9 ±1.66	<0.001	5.45
Placebo	31.9 (3.45)	15.6 (3.17)	30.7 (4.37)	15.0 ±1.74	--	--

CFB: Change From Baseline; LS: Least Squares, Standard Deviation: (SD), ±: Standard Error

Effect Size Inattentive: 5.03, p-value <0.001

Effect Size Hyperactive-Impulsive: 3.14, p-value 0.006

Cohen's d	Percentiles*
0.0	50
0.2	54
0.5	69
0.8	79
1.0	84
2.0	98
3.0	99.9

*Percentage of active medication subjects who would have a score above the average subject in the experimental group

Exclusivity: IP, Agreements, and Trade Secrets

Intellectual property rights expected to provide exclusivity through 2035 at a minimum

- OralogiK™ Erosion Barrier Layer: 38 Total Patents Granted
 - Six (6) patents granted (US & Major Markets) expiry dates ranging from 2031 to 2035, specific to CING claims currently
- Three (3) Cingulate product specific patents under prosecution with USPTO and global entities
 - 4 OUS Granted (Australia, Israel, EU & Canada)
 - 2 CING patent applications given “*Positive Written Report*” by US Search Authority



Exclusivity agreements

- Compression technology exclusivity for branded Cingulate products
- Significant modifications and exclusive process technologies incorporated



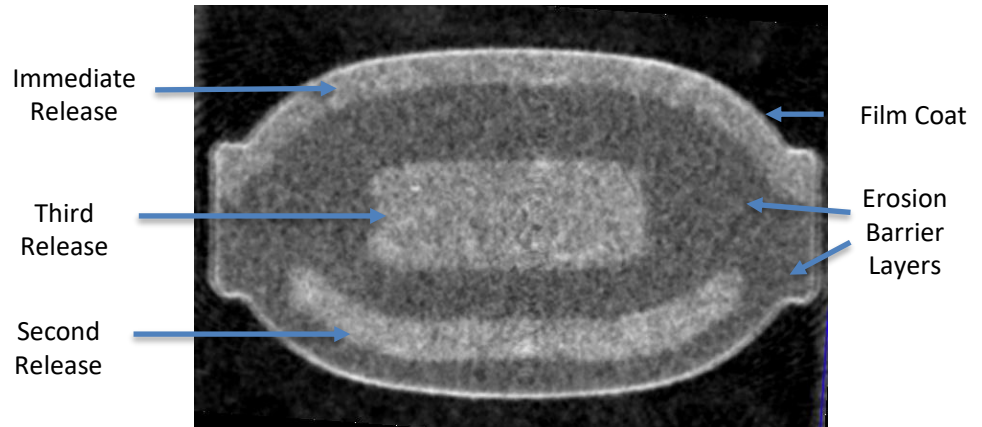
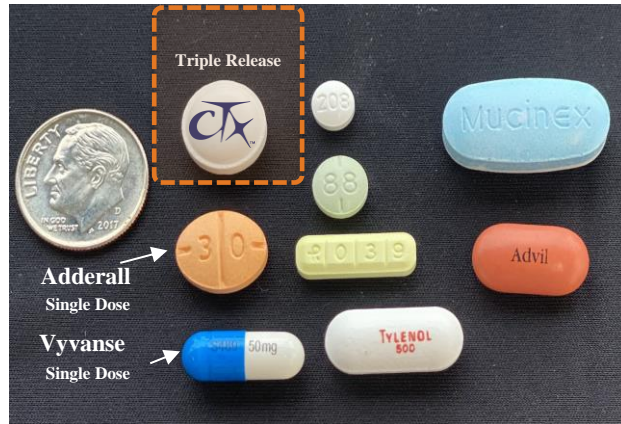
Proprietary Know-How

- Methods, tools, processes, designs, and equipment trade secrets



Next-Generation Medications in Billion-Dollar Markets

Precision Timed Release™ (PTR™) Platform Unlocks the Possibility for 'True' Once-daily, Multi-dose Tablets



[See the PTR™ Platform in Action](#)

- ADD Slide re SKAMP and Baseline to educate



Cingulate Therapeutics

CTx-1301 Study Summaries



CTx-1301-POC (BDD – Proof of Concept)

Primary Objective:

- To confirm the time and site of radiolabel release of the second and third dose layers of the CTx-1301 triple dose product in vivo

Secondary Objectives:

- To compare the pharmacokinetic profiles of the marketed product Focalin XR to the CTx-1301 triple dose product
- To determine gastrointestinal transit parameters of the CTx-1301 triple dose product

First subject enrolled: 25 Apr 2017

Last subject, last visit: 19 Jun 2017

N=14

Results: Mean initial C_{max} and T_{max} values were comparable between the three treatment arms. Second and third delayed-release layers of CTx-1301 were delivered as designed, maintaining blood levels of d-MPH longer than Focalin XR resulting in a slower descent of d-MPH. No serious adverse events were reported following any treatment.

CTx-1301-000 (Formulation Study)

Primary Objective:

- To confirm the pharmacokinetic profile of plasma concentration of CTx-1301 in vivo

Secondary Objective:

- To evaluate the occurrence of treatment-emergent adverse events (TEAEs) throughout the study

First subject enrolled: 20 May 2019

Last subject, last visit: 01 Jun 2019

N=12

Results: This exploratory formulation study was designed to evaluate and confirm the PK concentration profile of CTx-1301. Consistent with the expected trimodal release characteristics of the CTx-1301 exploratory formulation, all subjects demonstrated the desirable extended concentration and smooth, controlled descent of d-MPH levels at the end of the concentration-time curve with the single oral 25mg dose of CTx-1301.

The drug tested was safe and well tolerated by the subjects included in the study. No TEAEs were reported in the study.

CTx-1301-001 (Pivotal BA Study)

Primary Objective:

- To compare the bioavailability of Focalin XR to CTx-1301 in a fasted state
- Demonstrate bioavailability of the highest dose of CTx-1301 (50mg) to Focalin XR (40mg) dose
- Demonstrate bioavailability of the lowest dose of CTx-1301 (6.25mg) to Focalin XR (5mg) dose
- Demonstrate proportionality of CTx-1301 by evaluating the 6.25mg dose to the 50mg dose

Secondary Objectives:

- To provide PK data on blood plasma levels of d-MPH
- To evaluate the safety of CTx-1301 6.25mg and 50mg dose

First subject enrolled: 22 Nov 2019

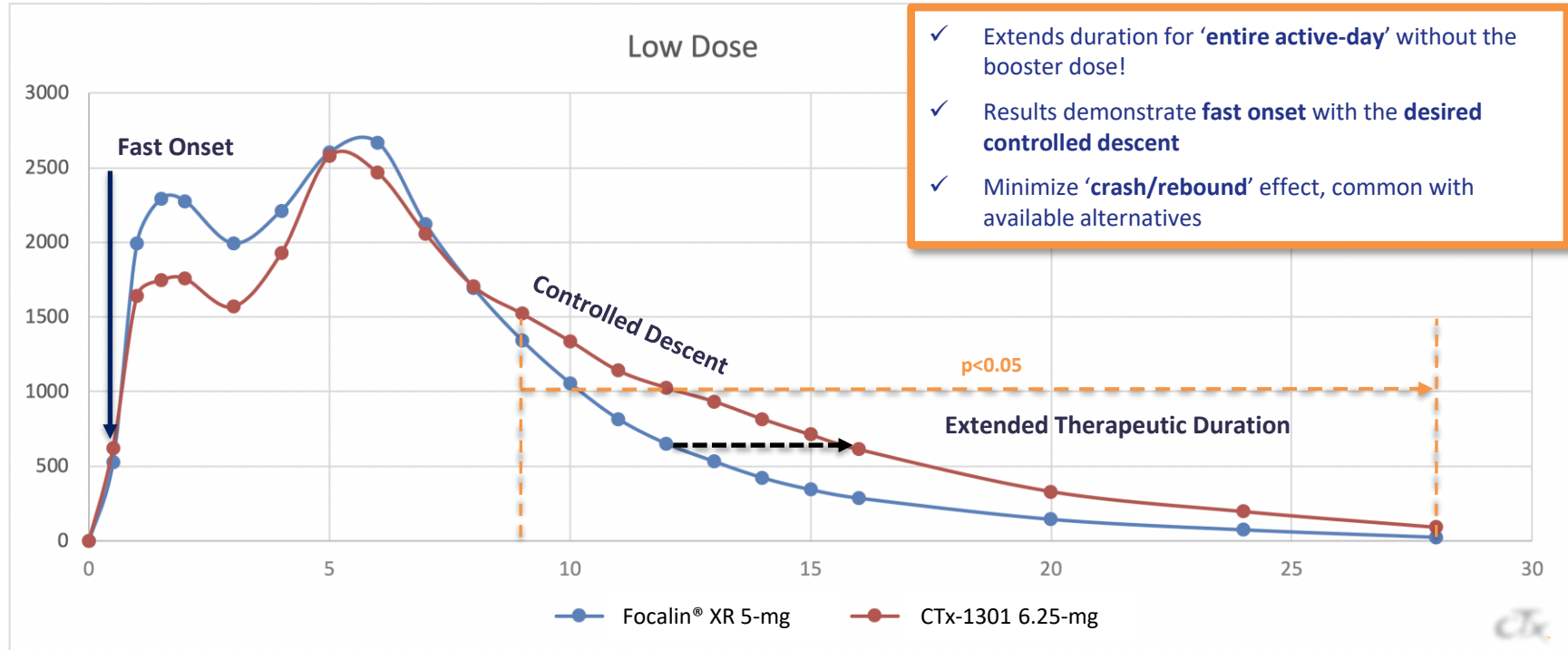
Last subject, last visit: 06 Mar 2020

N=45

Results: Primary measures of exposure exhibited similar bioavailability between Focalin XR and CTX-1301, with the adjusted geometric mean ratios remaining within the 80% to 125% range. Good dose proportionality was observed between the two doses of CTx-1301. The CTx-1301-to-Focalin XR dose-normalized partial AUC ratios increased over time, reflecting the differences in the formulation design. No deaths, and no serious, severe, or clinically meaningful TEAEs occurred during the study.

CTx-1301 Clinical Phase 2 Study Results

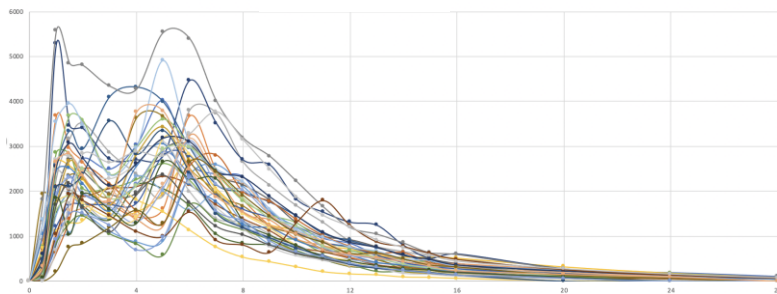
Plasma dexamethylphenidate (dMPH) Concentration vs Time



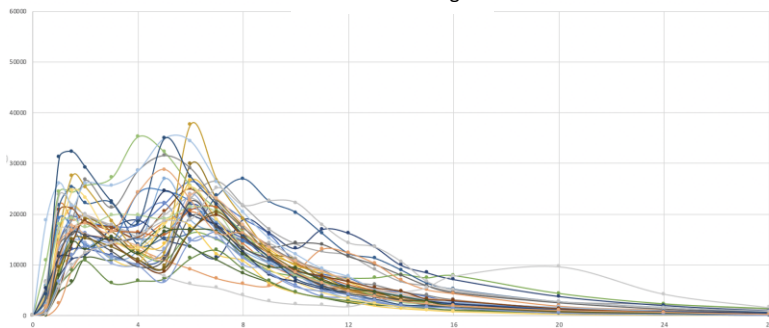
CTx-1301 Clinical Phase 2 Study Results

CTx-1301 and Focalin® XR Complete PK Data Sets in ADHD Subjects Perform as Expected
Cingulate's 8 Available Dosage Strengths Uniquely Provides Ability to Optimize Patient Treatment

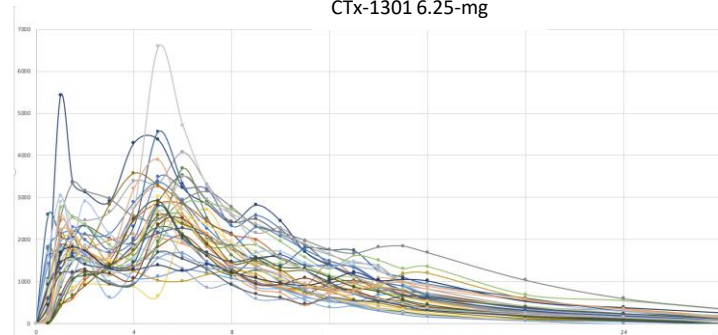
Focalin XR 5-mg



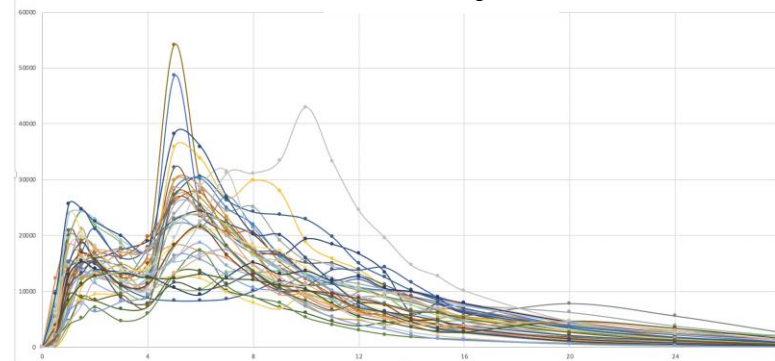
Focalin XR 40-mg



CTx-1301 6.25-mg

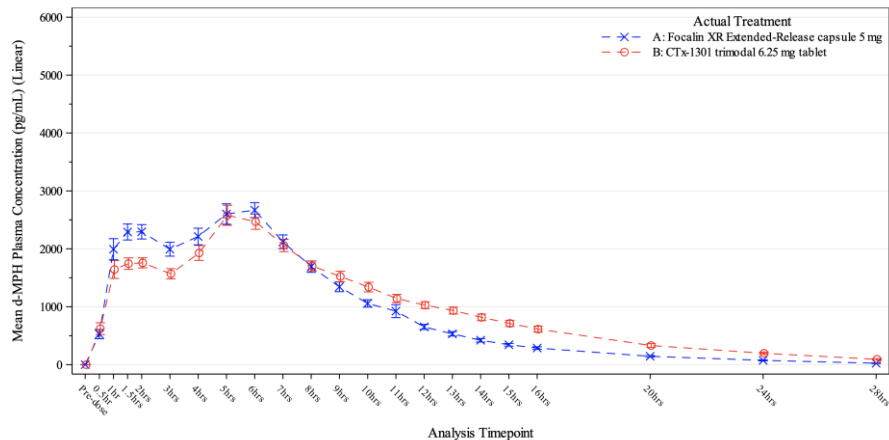


CTx-1301 50-mg

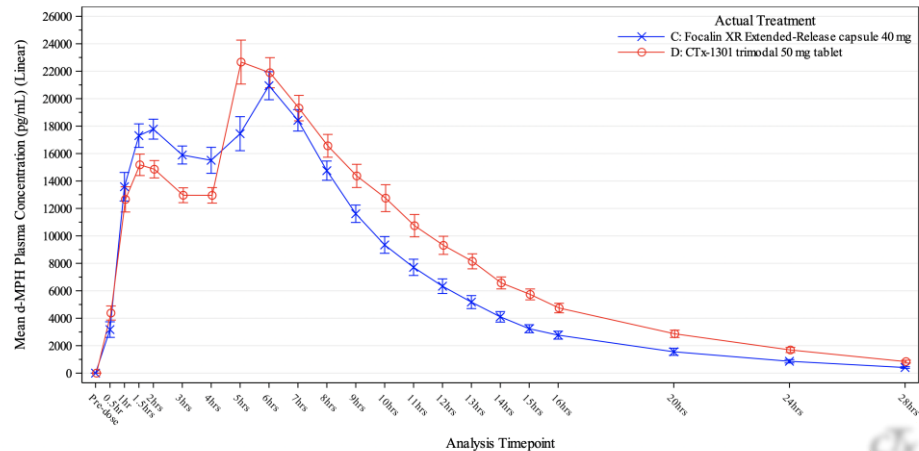


CTx-1301 Clinical Phase 2 Study Results

PTR™ Technology Delivers Minimal Intersubject Variability



- ✓ Despite expected intersubject variability with all methylphenidates, illustrated by the error bars, **all the benefits of PTR™ are maintained**
- ✓ **39 ADHD Subjects**, very tight standard error especially in late day
- ✓ Provides **ideal entire active day concentration** with ability to minimize “crash”



CTx-1301-003 (Fed/Fast Study)

Primary Objective:

- To assess the effect of food on the rate and extent of absorption, and the overall bioavailability of a single dose of CTx-1301

Secondary Objectives:

- To provide PK data on blood plasma levels of d-MPH both in fed and fasted state to examine potential differences between treatments (CTx-1301 25mg fed vs CTx-1301 25mg fasted) within the selected time intervals
- To evaluate the safety of CTx-1301 25mg tablet

First subject enrolled: 03 Oct 2022

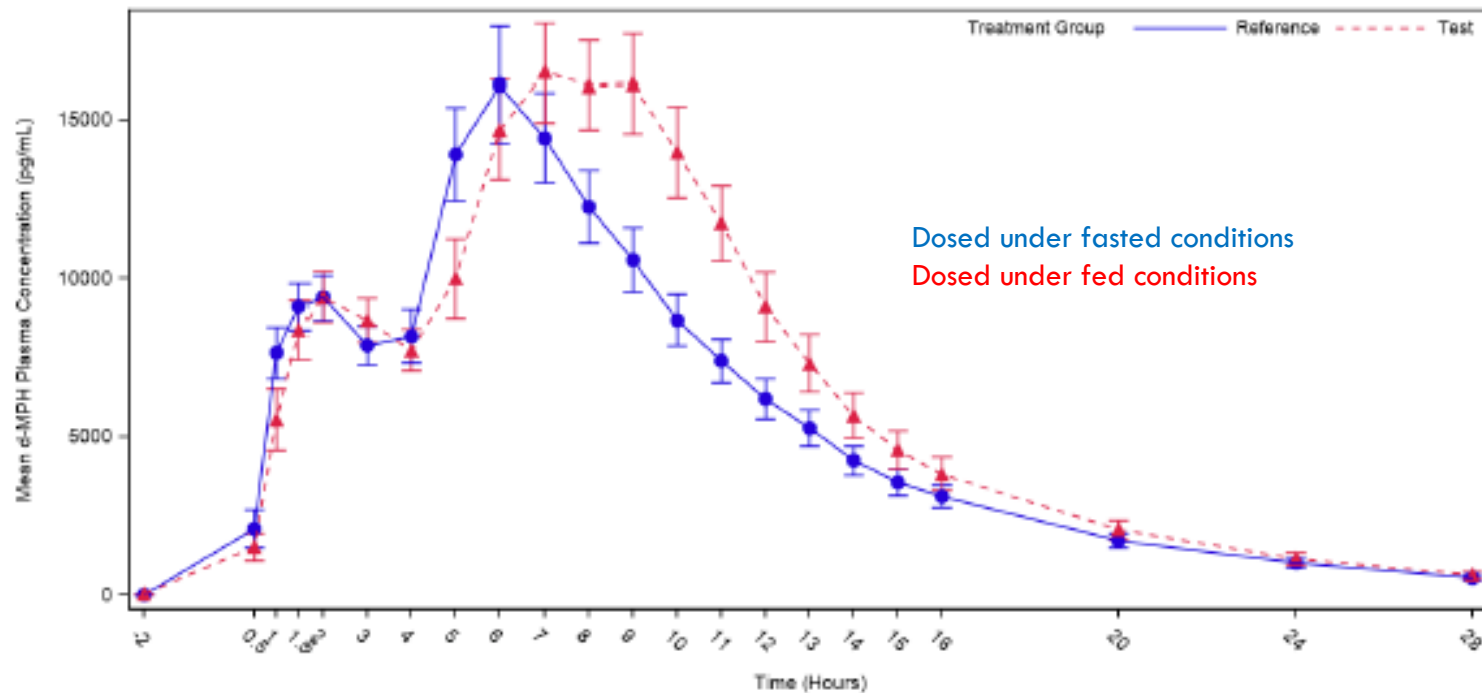
Last subject, last visit: 14 Oct 2022

N=23

Results: Single oral doses of 25mg CTx-1301 administered under both fed and fasted conditions seemed well tolerated. Intake of a high-fat, high-calorie meal before administration of CTx-1301 resulted in increases in peak and total exposure of d-MPH. Administration of CTx-1301 with food did not delay absorption and thus, should not affect onset of action. CTx-1301 can be administered orally with or without food. Most TEAEs reported during the study were mild. No subject experienced a severe TEAE, serious TEAE, TEAE leading to study or drug withdrawal, or TEAE leading to death.

CTx-1301-003 (Fed/Fast Study)

Plot of Mean (SE) Plasma d-MPH Concentrations vs Time (linear scale) by Treatment
Population: Pharmacokinetic Population



CTx-1301-004 (Pediatric Classroom Study)

Primary Objective:

- To evaluate the efficacy of CTx-1301 compared to placebo in treating children 6-12 years old with ADHD in a laboratory classroom

Secondary Objectives:

- To determine the onset and duration of clinical effect of CTx-1301 in treating ADHD in children 6-12 years old in the laboratory classroom study
- To determine safety and tolerability of CTx-1301 compared to placebo in a laboratory classroom study

Exploratory:

- Evaluate overall treatment experience of subjects who are stable on ADHD stimulant medications within the 30 days prior to Screening compared to CTx-1301 at the end of dose optimization phase

First subject enrolled: 02 Aug 2023

Last subject, last visit: 05 Feb 2024

N=80

Topline results: 23 Apr 2024

CTx-1301-005 (Pivotal PIII – Pediatric Fixed Dose)

Primary Objective:

- To evaluate the efficacy of a fixed dose of CTx-1301 compared to placebo in treating pediatrics with ADHD using the ADHD-RS-5 total score

Secondary Objectives:

- To evaluate the efficacy of a fixed dose of CTx-1301 compared to placebo in treating pediatrics with ADHD using the CGI-S
- To determine the safety and tolerability of a fixed dose of CTx-1301 compared to placebo in a fixed-dose study design
- To evaluate the pk levels of d-MPH after a single dose
- To evaluate the pk levels of d-MPH at steady state
- To evaluate the pk/pd correlation of d-MPH at steady state

First subject enrolled: *25 July 2023*

Last subject, last visit: *08 Jan 2024*

Topline results: *01 Apr 2024*

N=385

CTx-1301-022 (Adult ADHD – Onset and Duration)

Primary Objective:

- Efficacy of CTx-1301 compared to placebo in treating adults with ADHD in a laboratory classroom study

Secondary Objectives:

- Onset and duration of CTx-1301 in treating adults with ADHD in a laboratory classroom study
- Safety and tolerability of CTx-1301 compared to placebo in a laboratory classroom study

Exploratory Objectives:

- Evaluate overall treatment experience of subjects who are stable on ADHD stimulant medications within the 30 days prior to Screening compared to CTx-1301 at the end of dose optimization phase

Additional Benefit:

- Identify effect size of CTx-1301 formulation for future study design

First subject enrolled: 29 Dec 2022

Last subject, last visit: 27 May 2023

Topline results: 30 Jun 2023

N=21

CTx-1301 Phase 3 Adult Trial Top-Line Results

1. Study found large effect sizes at the key time points of 30 minutes (1.41) and 16 hours (0.98) ; average effect size for available long-acting stimulants is 0.73*
2. The onset and duration data are the most significant as this is where ADHD products are primarily differentiated in the context of the numerous approved products
3. CTx-1301 demonstrated positive effects on PERMP (Permanent Product Measure of Performance), AISRS (Adult ADHD Investigator Symptom Rating Scale) and was found to reduce the severity of illness on CGI (Clinical Global Impression), which the study was not powered to do nor evaluate
4. CTx-1301 was well-tolerated
5. Further validates the Precision Timed Release (PTR) technology

Farone et al. Meta Analysis of Effect size Adult ADHD

Table 5. Mean Effect Sizes and Number of Studies, Stratified by Outcome Scores and Type of Medication

Score Used to Assess Efficacy	Nonstimulant		Stimulant	
	Mean Effect Size	No. of Studies	Mean Effect Size	No. of Studies
ADHD-RS				
Total	0.51	5	0.89	9
Inattentive symptoms	1.26	1	0.95	5
Hyperactive symptoms	0.74	1	0.94	6
AISRS	0.53	1
DSM-IV hyperactive/impulsive symptoms	0.23	1
CAARS-Investigator Rating				
Total	0.39	3	0.76	2
Inattentive symptoms	0.36	2
Hyperactive/impulsive symptoms	0.31	2
CAARS-Self Rating				
Total	0.38	4
Inattentive symptoms	0.41	2
Hyperactive/impulsive symptoms	0.31	2
WURS	0.35	3	0.83	1
CGI-Improvement	0.62	1
CGI-ADHD	0.46	5	0.79	3
Global rating of ADHD	0.28	1

Abbreviations: ADHD = attention-deficit/hyperactivity disorder, ADHD-RS = Attention-Deficit/Hyperactivity Disorder Rating Scale, AISRS = Adult Attention-Deficit/Hyperactivity Disorder Investigator Symptom Rating Scale, CAARS = Conners' Adult ADHD Rating Scale, CGI = Clinical Global Impressions scale, WURS = Wender-Reimherr Utah Rating Scale.

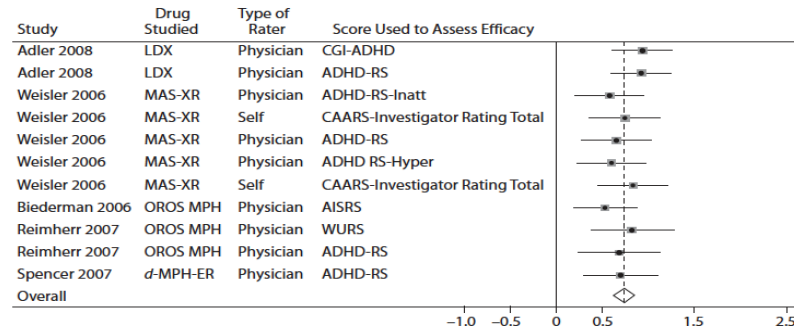
Faraone et al. Meta Analysis of Effect size Adult ADHD

Figure 1 shows the results for long-acting stimulants. The mean effect size of 0.73 for long-acting stimulants is statistically significant ($z = 13.0, P < .001$). There was no significant heterogeneity among effect sizes ($\chi^2_{10} = 6.2, P = .8$). Figure

lants. The mean effect size of 0.39 is statistically significant ($z = 13.9, P < .001$). There was no significant heterogeneity among effect sizes ($\chi^2_{30} = 25, P = .8$). Because Figure 3 suggests that our failure to find heterogeneity for nonstimulants

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Figure 1. Standardized Mean Differences (SMDs) and 95% Confidence Intervals (CIs) for Long-Acting Stimulants^a



^aThe dark box indicates the effect size with the size of the box proportional to the power of the study. The horizontal line through each box gives the 95% confidence interval. At the bottom of the plot, the center of the diamond gives the mean SMD, and the width gives its 95% confidence interval. For Weisler 2006, there are 2 entries for the ADHD-RS; the first gives results based on morning ratings, and the second gives results based on afternoon ratings.

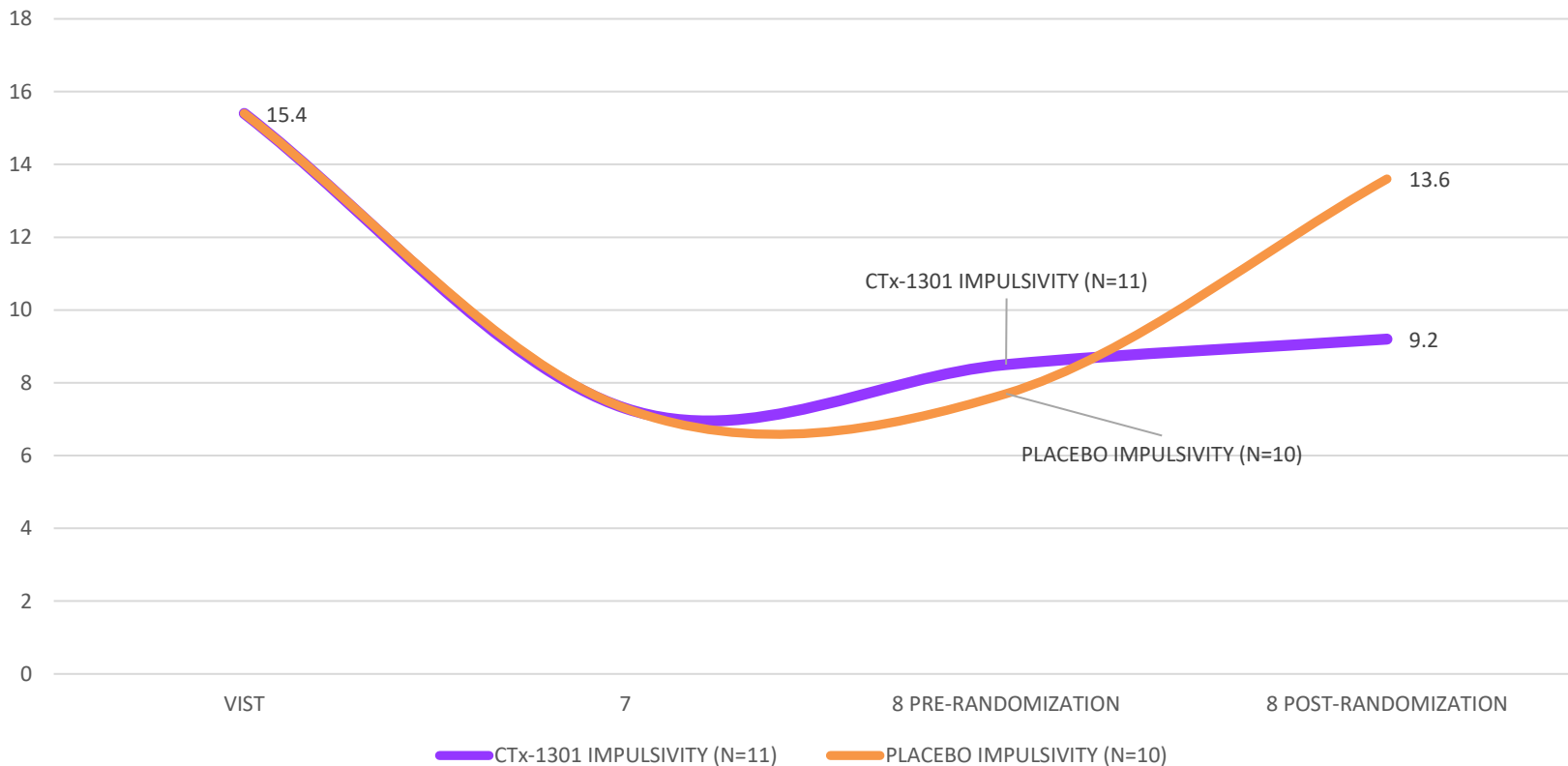
Abbreviations: ADHD-RS = Attention-Deficit/Hyperactivity Disorder Rating Scale, AISRS = Adult Attention-Deficit/Hyperactivity Disorder Investigator Symptom Rating Scale, CAARS = Conners' Adult ADHD Rating Scale, CGI = Clinical Global Impressions scale, d-MPH-ER = dexamfetamine extended release, Hyper = hyperactive symptoms, Inatt = inattentive symptoms, LDX = lisdexamfetamine dimesylate, MAS-XR = mixed amphetamine salts extended release, OROS MPH = osmotic-release oral system methylphenidate, WURS = Wender-Reimherr Utah Rating Scale.

AISRS TOTAL Score change (visit 7 to visit 8)

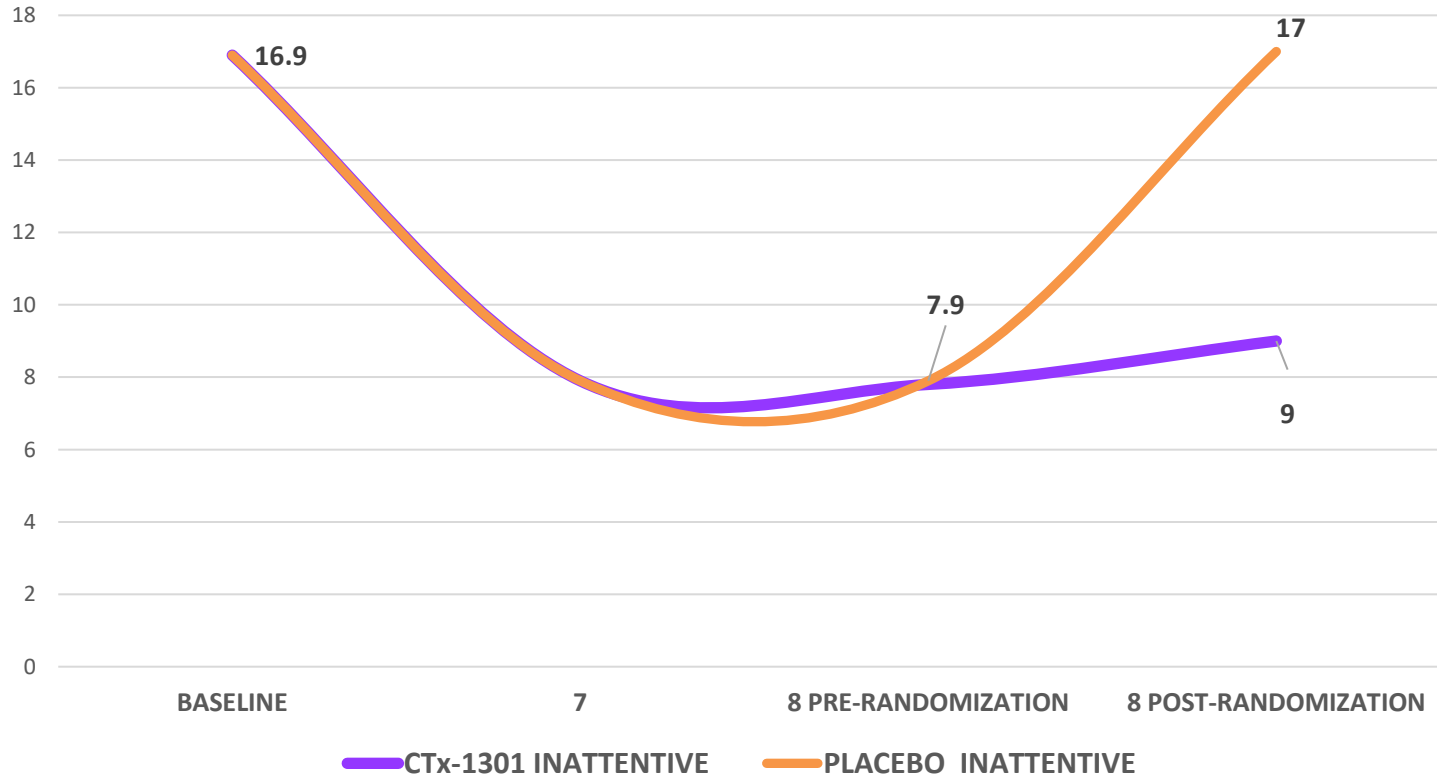
AISRS scores changed when randomized to CTx-1301 or Placebo

- All patients (n=21) at baseline demonstrated AISRS score indicating severe ADHD symptoms
- All patients (n=21) demonstrated clinical improvement in AISRS rating during the dose-optimization phase from baseline to Visit 7
- Patients randomized to CTx-1301 (n=11) or Placebo (n=10) at Visit 7
- Visit 8 assessed AISRS after one week on CTx-1301 or Placebo
- CTx-1301 patients maintained the reduction in ADHD severity
- Placebo patients returned to baseline severity

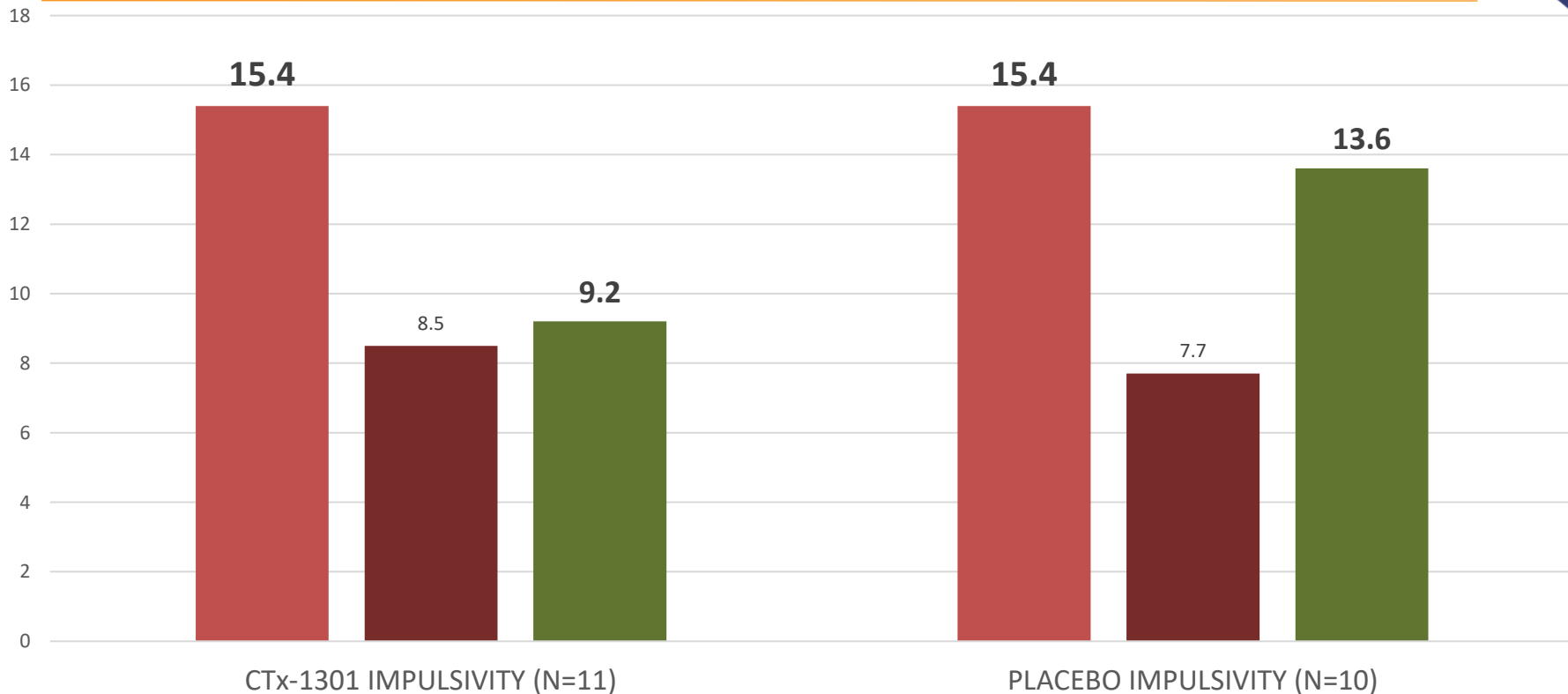
AISRS Impulsivity subscale score



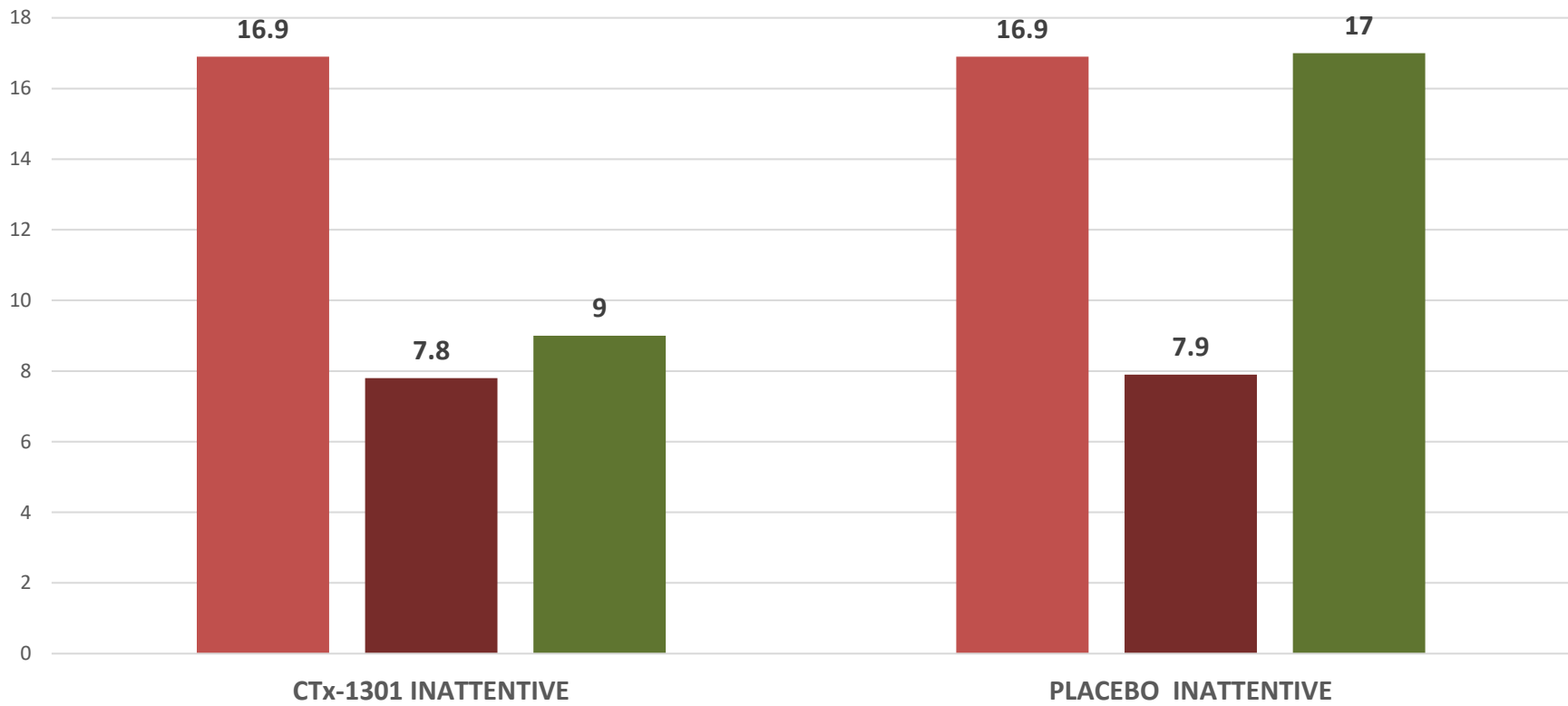
AISRS Inattentive subscale score



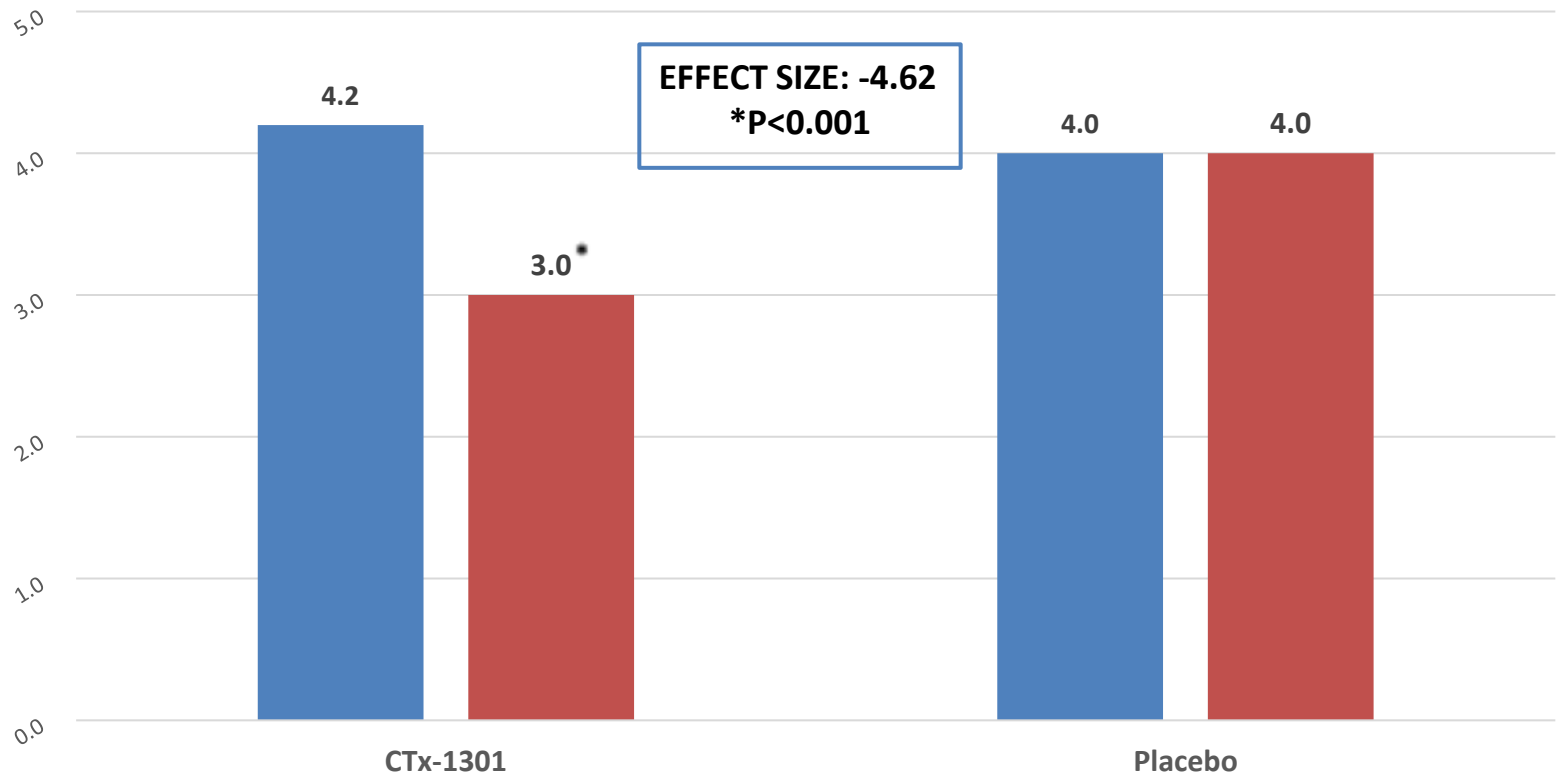
AISRS Impulsivity subscore change



AISRS Inattentive subscore change

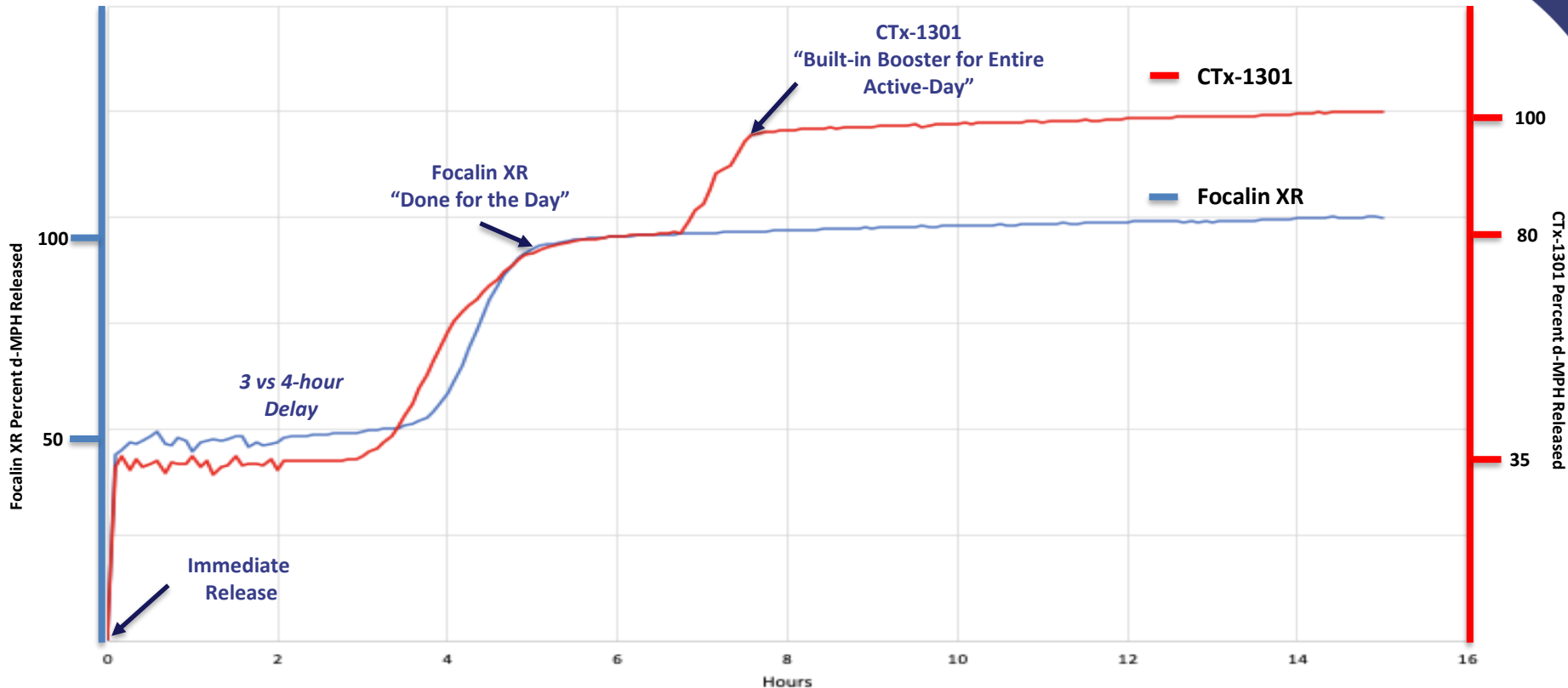


Clinical Global Impression-Severity (CGI-S)



■ BASELINE (PRE-DOSE) ■ RESULT (POST-DOSE)

In-Vitro Comparison: CTx-1301 (25-mg) and Focalin XR (20-mg)



2023 Milestones Achieved

1H 2023

3Q 2023

4Q 23 / 1H 24

ADHD

CTx-1301
CTx-1302

- ✓ CTx-1301 Phase 1 Food Effect Clinical Data
- ✓ CTx-1301 Adult Onset / Duration Efficacy Trial
- ✓ Adult Onset / Efficacy Trial Data
- ✓ Initiate Both Phase 3 Trials in Children and Adolescents
- ✓ FDA CMC Meeting
- Child / Adolescent CTx-1301 Pivotal Phase 3 Trial Completion & Data
- Child Onset/Duration Trial Completion & Data
- Prepare CTx-1302 IND

Anxiety

CTx-2103

- ✓ CTx-2103 Formulation Study Report
- ✓ Formulation Study Presentation
- Prepare & File CTx-2103 IND
- ✓ ➤ FDA Pre-IND Meeting

PTR™ Platform

- ✓ Expand Manufacturing Operations
- Pursue out license opportunity for PTR™ Platform
 - Potential Milestone Payments
 - Potential Royalty Payments
- Potential licensing of CTx-1301, CTx-1302, CTx-2103 outside of the United States
- Expand CING – BDD Partnership
- Expand BD&L Activities w/ PTR™

Agenda

- Capital Update
- IR/PR
- Manufacturing
- Comp Committee Meeting Timing?

Capital Update

- 2Q24 estimated \$2M raise required (including Nasdaq minimum equity)
 - May 5 Standstill Termination
 - ~\$600,000 via ELOC and ATM to date
 - Through June 30 (projected)
 - ELOC: \$600k
 - ATM: \$120k
 - Other \$700k
- HCW
 - PIPE / Follow On Offer in discussion
 - \$1- 1.5M PIPE
 - Up to \$6M follow on
 - Warrant Inducement (5.6M shares) in August potentially least dilutive vs \$6M raise
- Retail, HNW, Indegene Discussion
- Nasdaq compliance discussion

Cingulate Inflection Points and Cash Requirements

	2024				2025*					2026
	Q2	Q3	Q4	TOTAL	Q1	Q2	Q3	Q4	TOTAL	Launch
Clinical [°]	\$1.0	\$2.2	\$1.4	\$4.6	\$0.0	\$0.3	\$0.0	\$0.0	\$0.3	\$0.0
Manufacturing ^ˆ	\$0.3	\$0.8	\$0.3	\$1.4	\$0.2	\$0.1	\$0.1	\$4.0	\$4.4	\$4.7
Regulatory	\$0.1	\$0.0	\$0.7	\$0.8	\$0.8	\$0.3	\$0.0	\$0.0	\$1.1	\$0.0
General & Administrative	\$0.6	\$1.4	\$1.4	\$3.4	\$1.5	\$1.5	\$1.5	\$1.5	\$6.0	\$6.0
Commercialization (Indegene)	\$0.0	\$0.0	\$0.0	\$0.0	\$2.5	\$2.5	\$2.5	\$2.5	\$10.0	\$20.0
TOTAL (\$M)	\$2.0	\$4.4	\$3.8	\$10.2	\$5.0	\$4.7	\$4.1	\$8.0	\$21.8	\$30.7

Inflection Points:

FDA Clears Submission Pathway
 KOL Webcast
 NDA Manufacturing Success
 Pre-NDA Meeting
 High Dose F/F Data

NDA Filing Window

CTx-1301 Approval Window

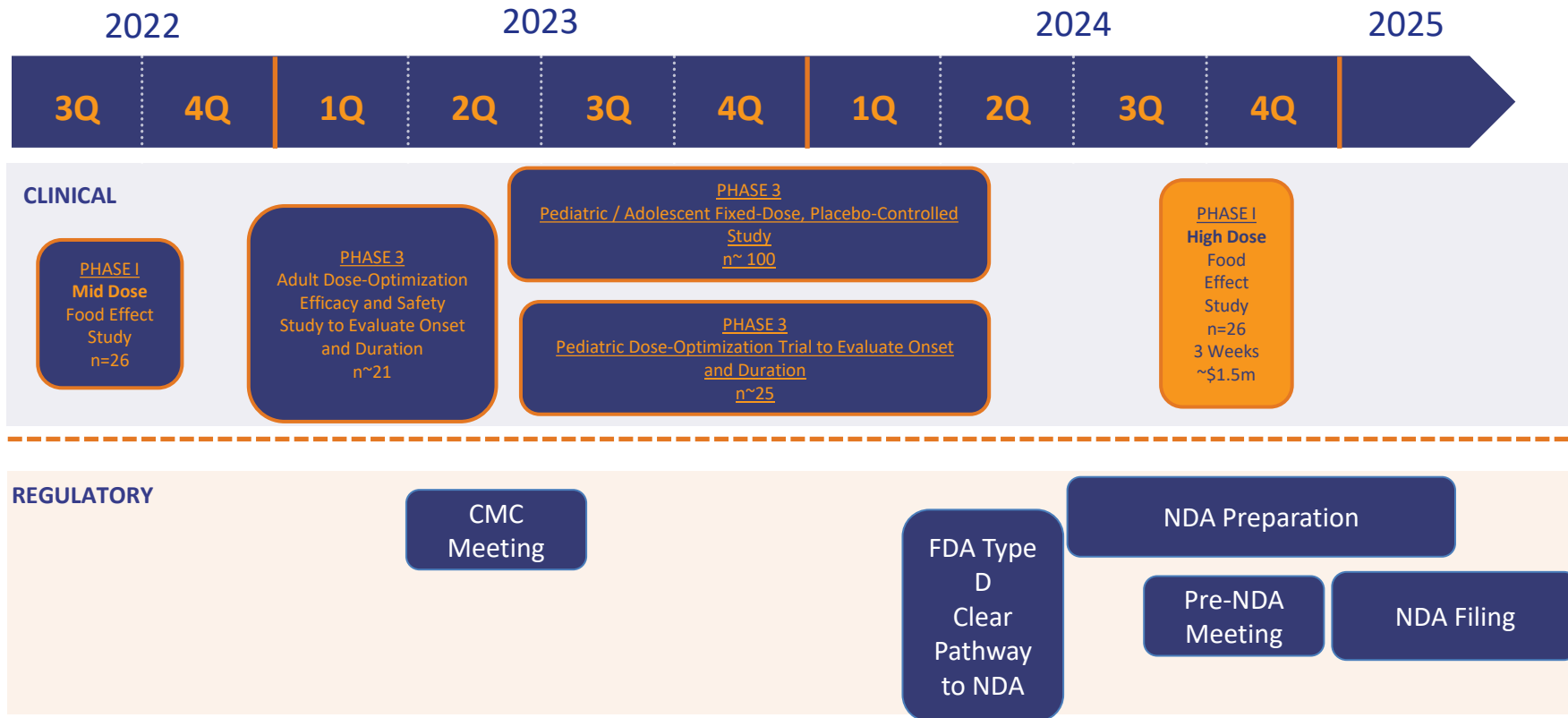
CTx-1301 Launch Window

*- NDA submission expected January- June 2025

[°]. 50mg Fast Fed Study, Close-out of Fixed Dose Study

^ˆ. Stability on registration batches (2024), process validation batches (2025), pre-launch inventory (2026)

MASTERY[®] CTx-1301 Clinical and Regulatory Timeline

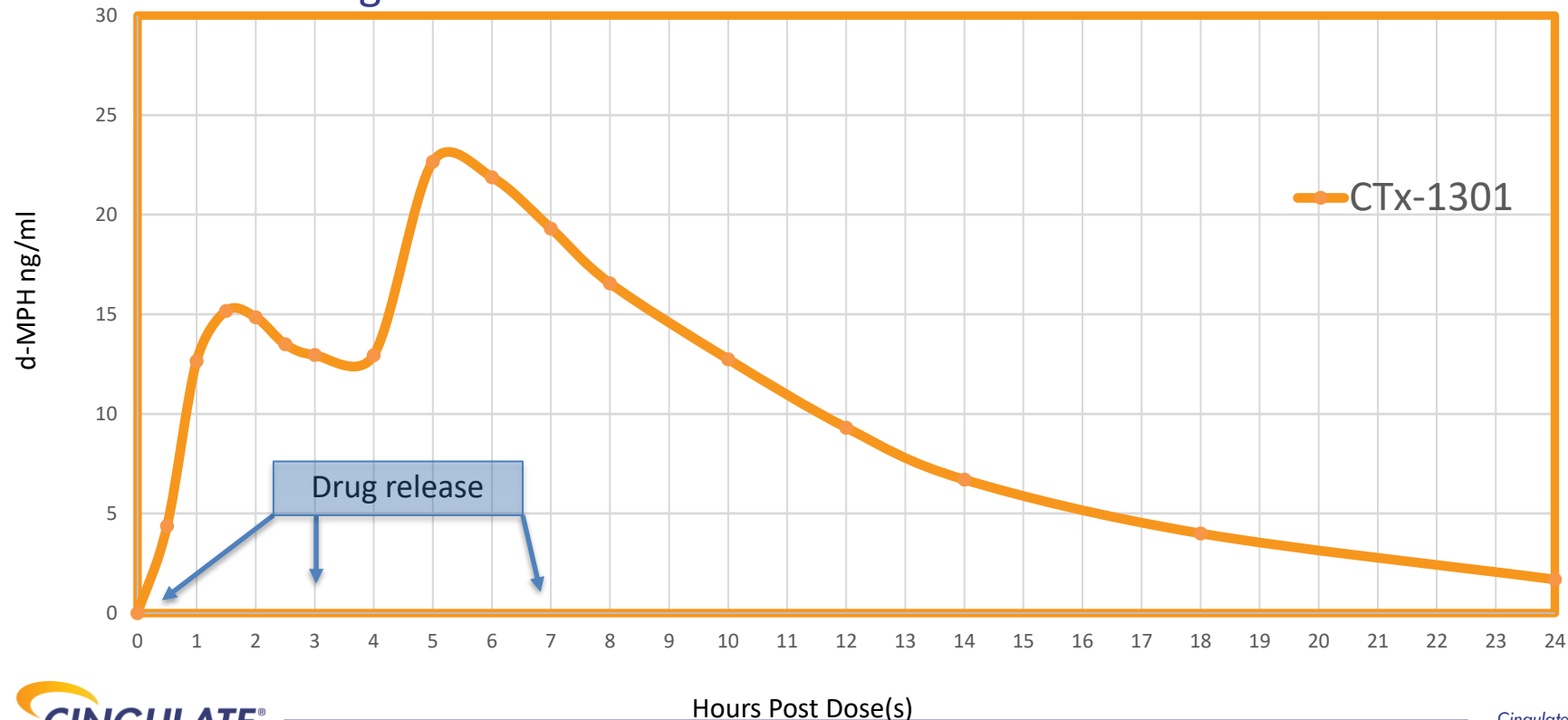


Mean Plasma Concentration Time-profile of CTx-1301 and Competitors

- Comparison of maximum daily doses per FDA approved label for competitor products are compared to CTx-1301 50-mg (intended maximum dose)
- Data for competitor products abstracted from product labeling
- Competition PK
 - Concerta 72-mg (36-mg maximum commercially available, 2 x 36-mg)
 - Focalin XR 40-mg
 - Azstarys 52.3-mg/10.4-mg
 - Adhansia XR 100-mg (85-mg maximum commercially available)
 - Quillivant XR 60-mg
 - Cotempla XR ODT 51.8-mg (25.9-mg maximum commercially available, 2 x 25.9-mg)
 - Ritalin LA 40-mg
 - Metadate CD 60-mg

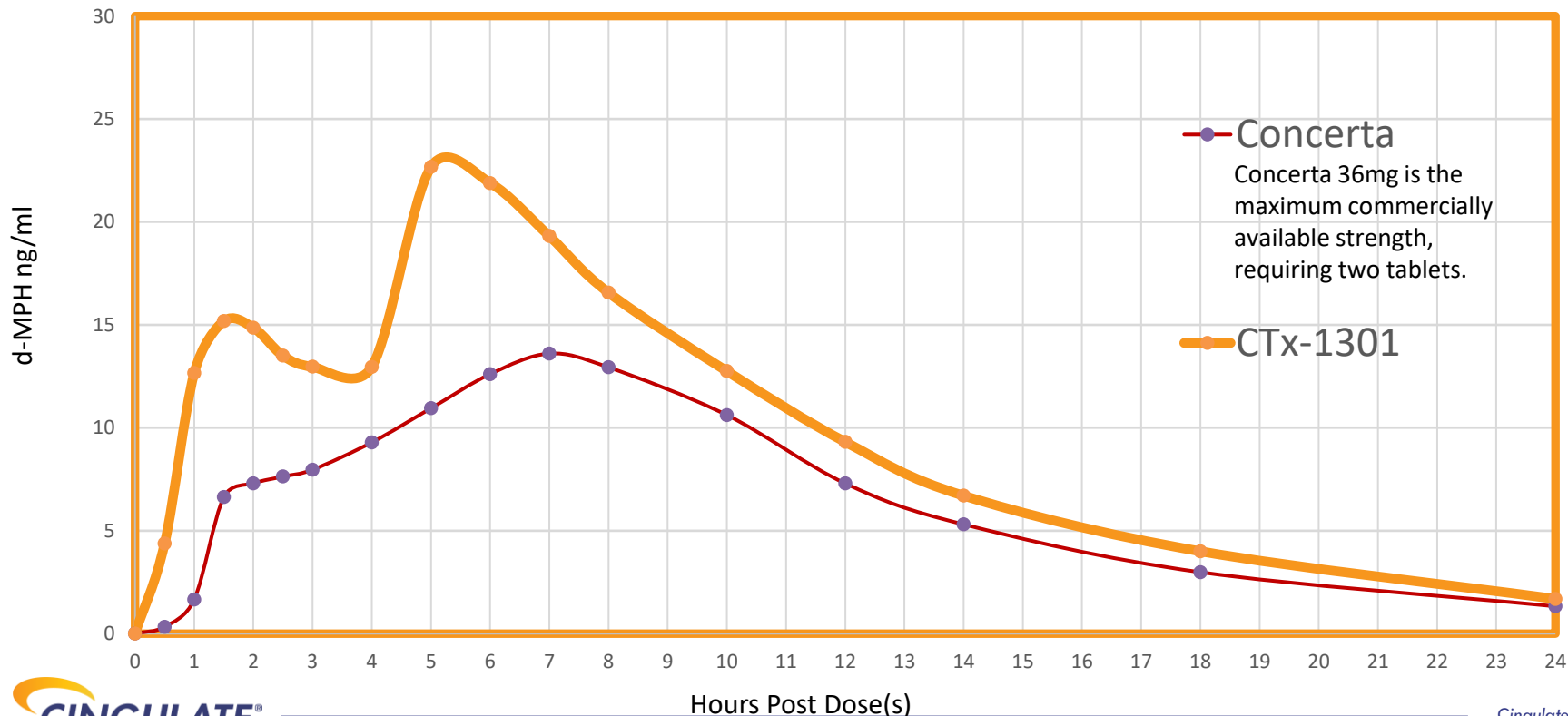
CTx-1301 (dMPH) 50-mg Bioavailability Study

Mean Plasma Drug Concentration



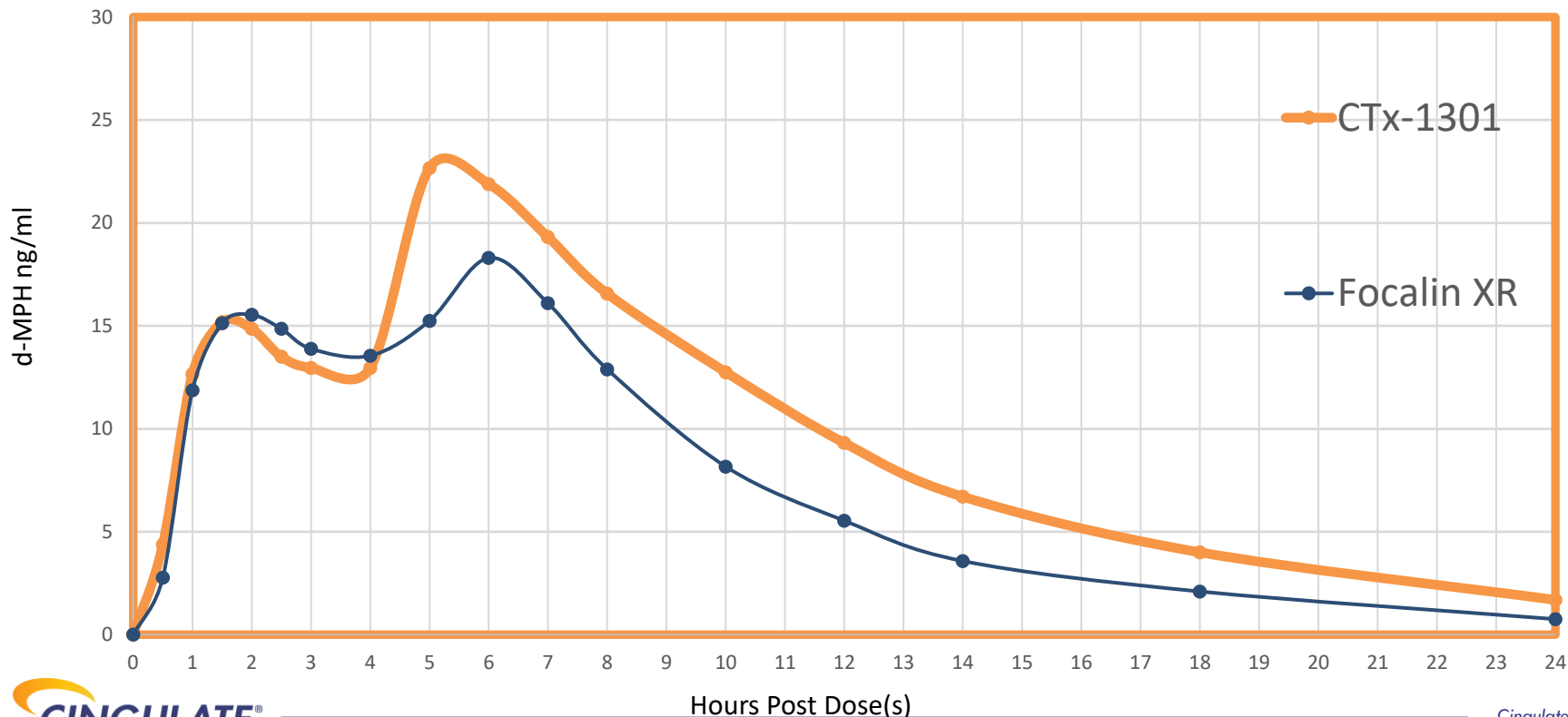
CTx-1301 50-mg & Concerta 72-mg (36-mg dMPH)

Mean Plasma Concentration Time-profile – NORMALIZED TO dMPH



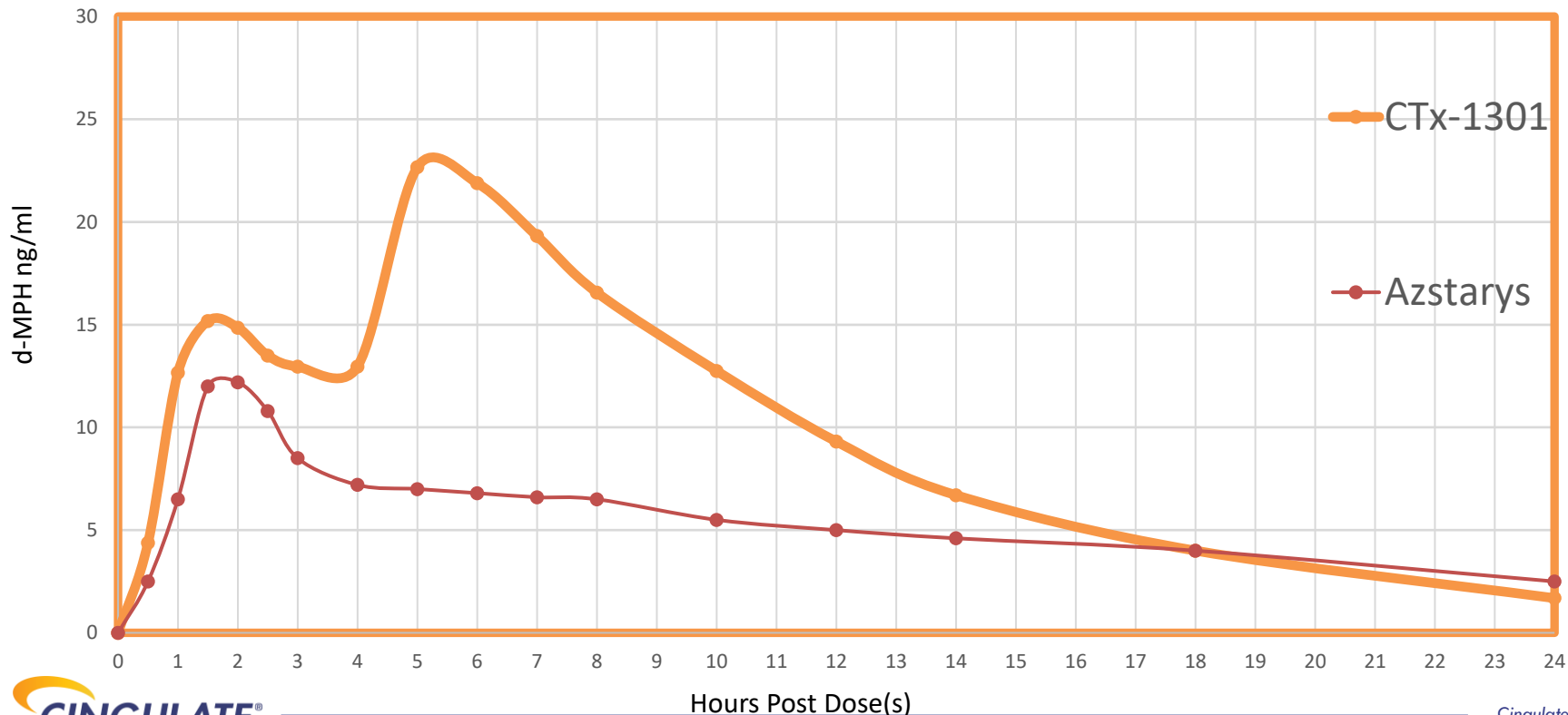
CTx-1301 50-mg vs Focalin XR 40-mg

Mean Plasma Concentration Time-profile – NORMALIZED TO dMPH



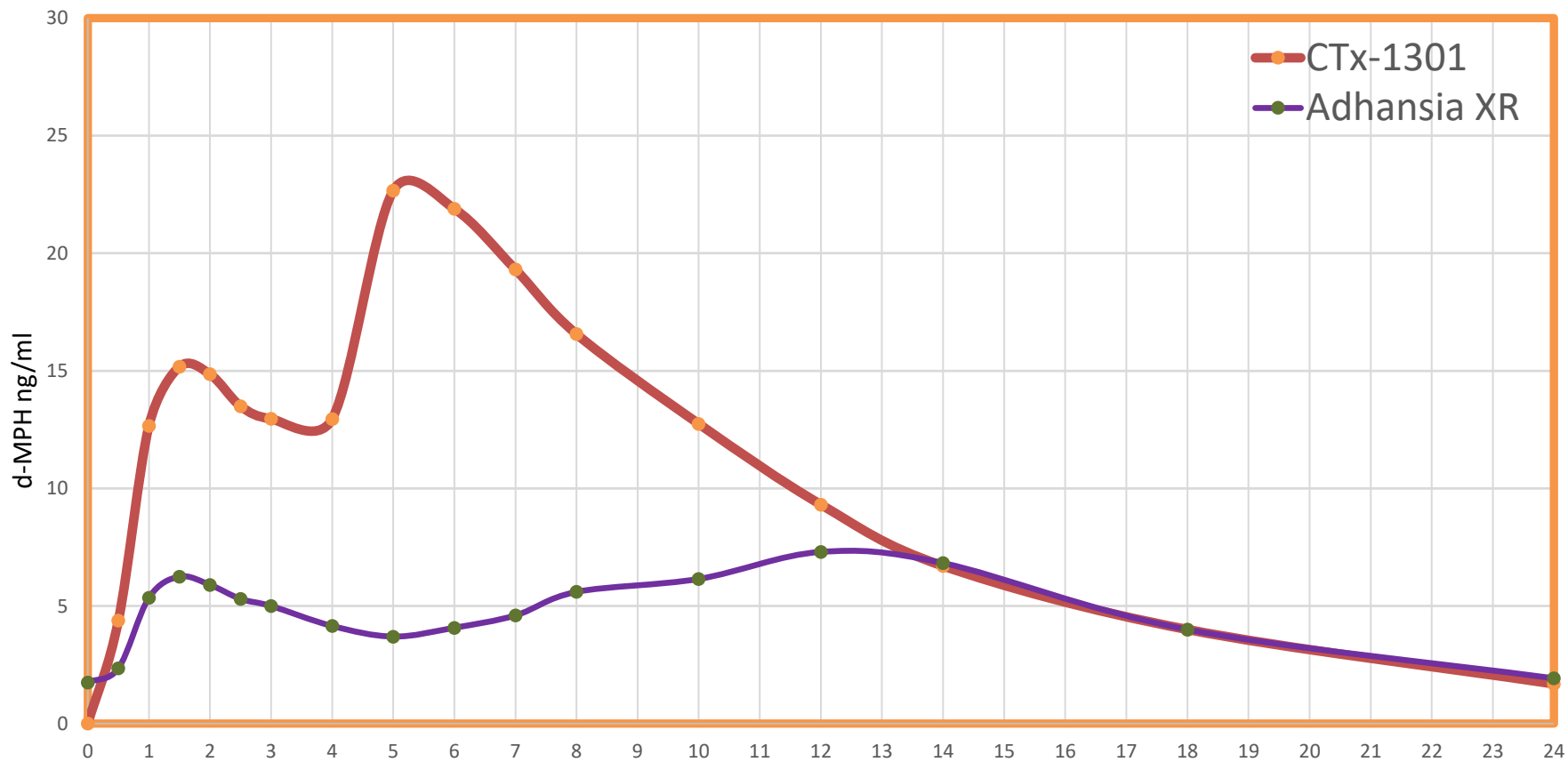
CTx-1301 50-mg vs Azstarys 52.3-mg/10.4-mg

Mean Plasma Concentration Time-profile – NORMALIZED TO dMPH



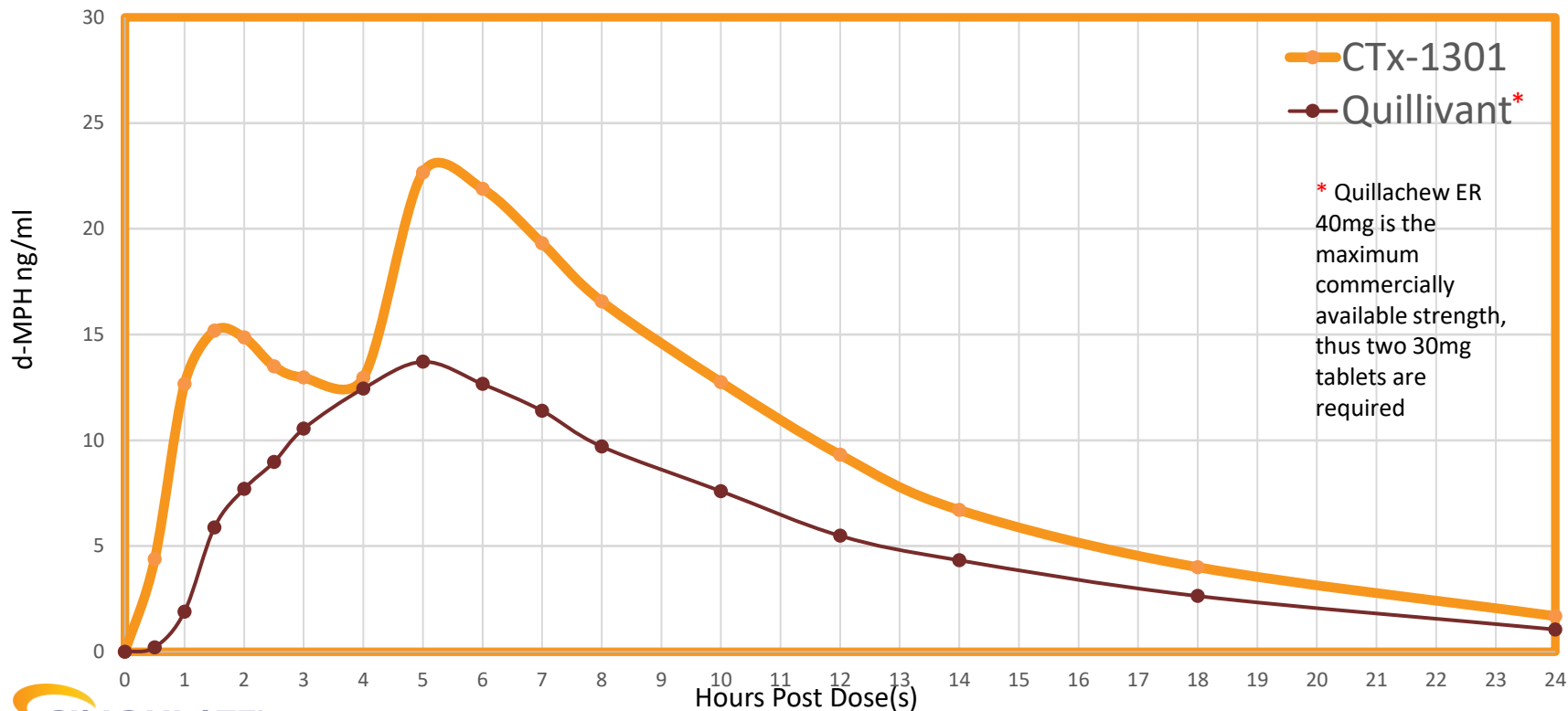
CTx-1301 50-mg & Adhansia XR 100-mg

Mean Plasma Concentration Time-profile – NORMALIZED TO dMPH



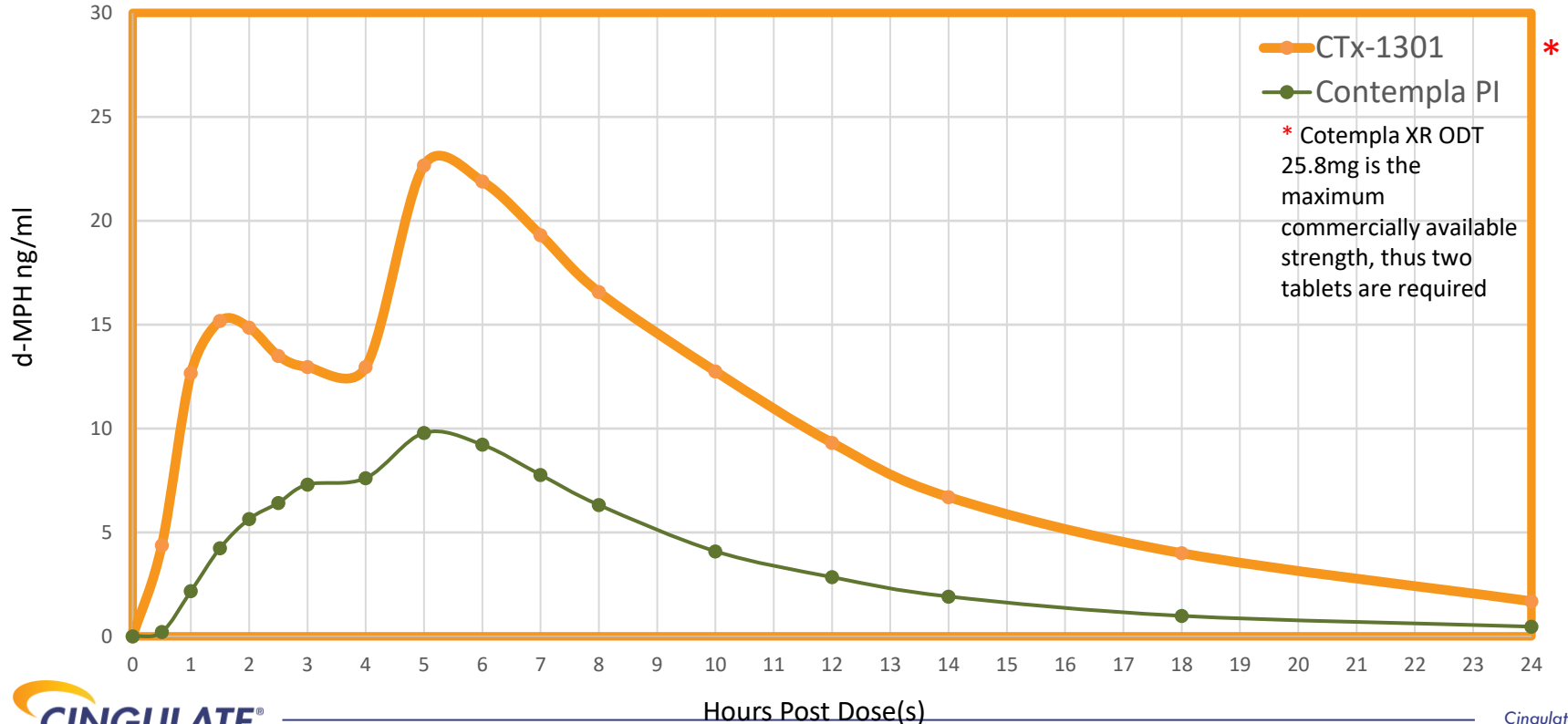
CTx-1301 50-mg vs Quillivant XR 60-mg

Mean Plasma Concentration Time-profile – NORMALIZED TO dMPH



CTx-1301 50-mg & Cotelma XR-ODT 51.8-mg (25.9mgx2)

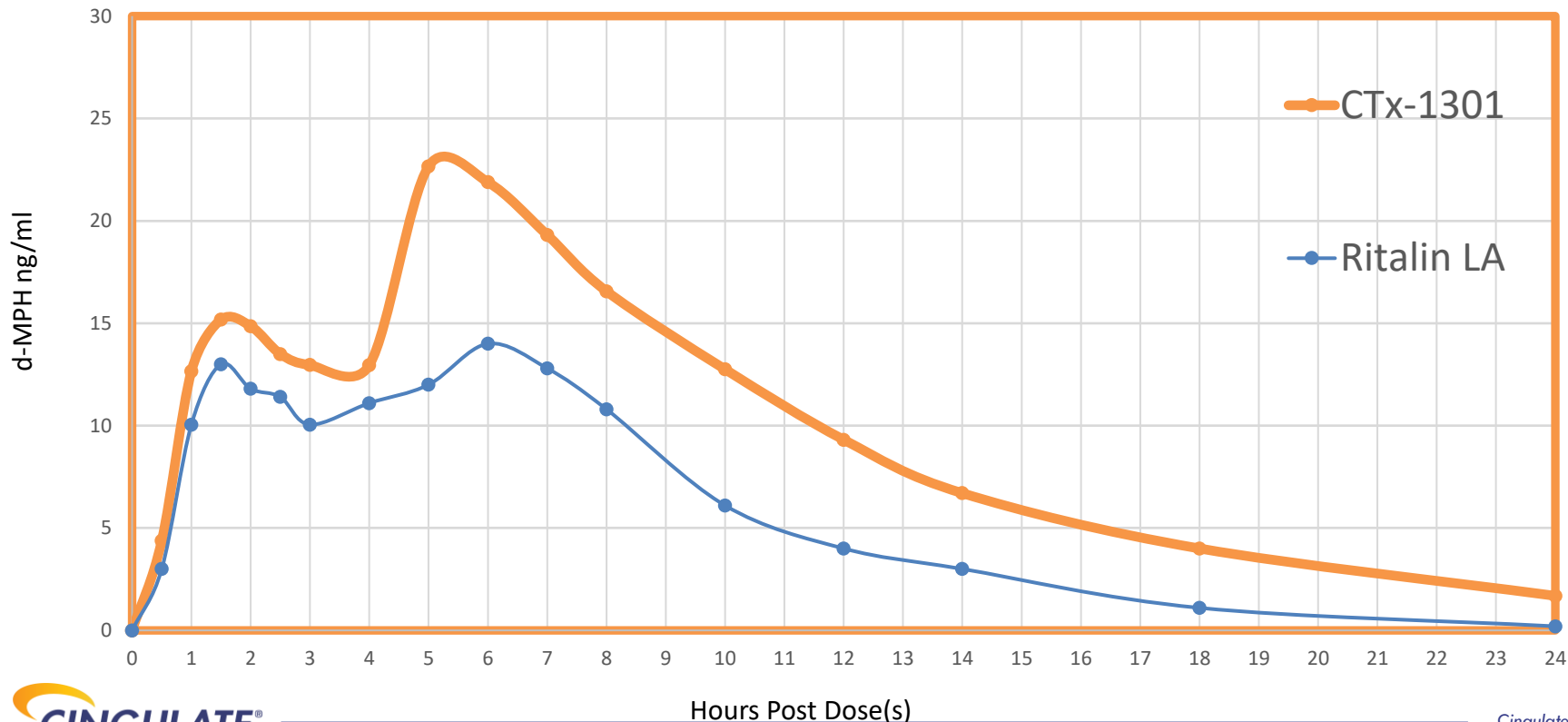
Mean Plasma Concentration Time-profile – NORMALIZED TO dMPH



CTx-1301
Cotelma PI
* Cotelma XR ODT 25.8mg is the maximum commercially available strength, thus two tablets are required

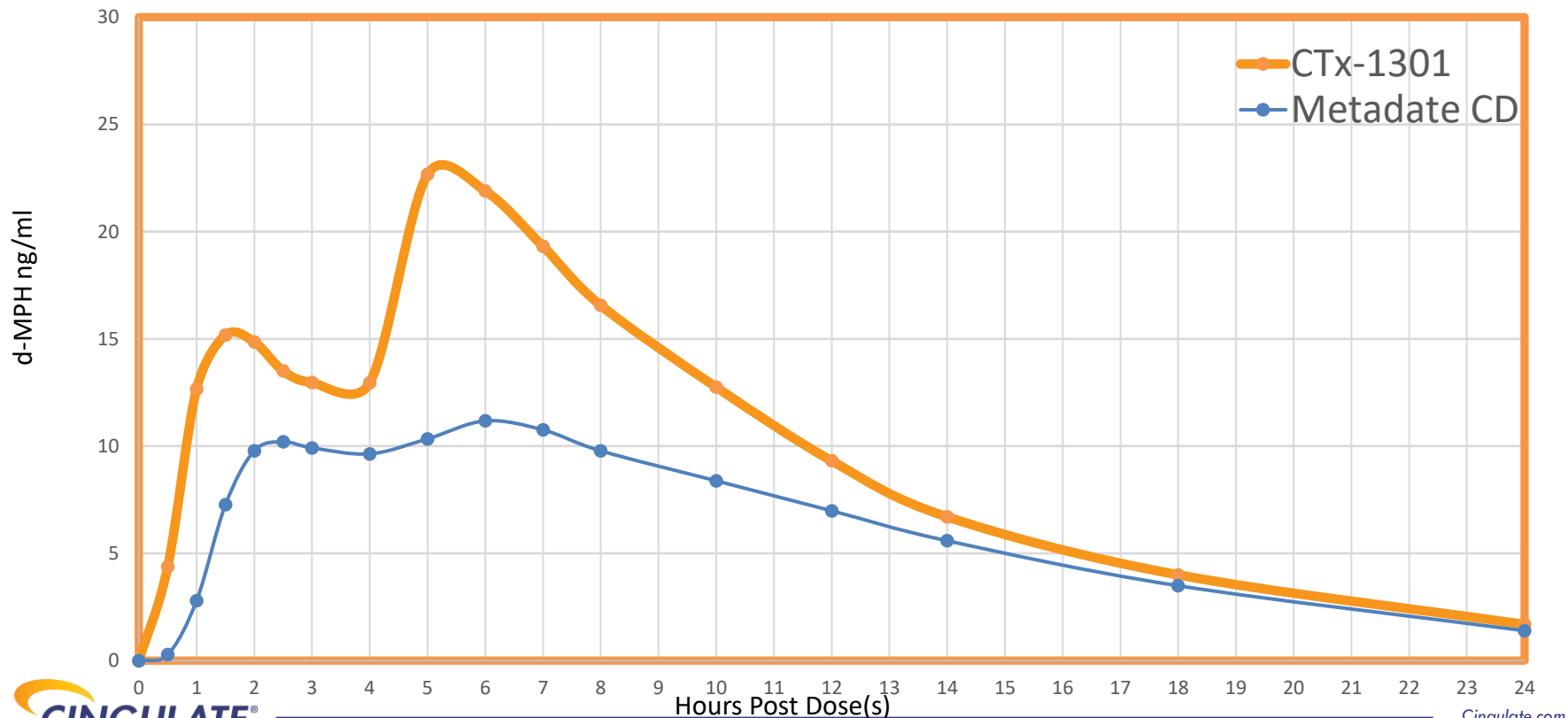
CTx-1301 50-mg vs Ritalin LA 60-mg

Mean Plasma Concentration Time-profile – NORMALIZED TO dMPH



CTx-1301 50-mg & Metadate CD 60-mg

Mean Plasma Concentration Time-profile – NORMALIZED TO dMPH



Summary Mean Plasma Concentration Time-profile

CTx-1301 and Other MPH Products – *NORMALIZED TO dMPH*

