



Cingulate Therapeutics

Developing next-generation therapeutics where standard-of-care treatments result in suboptimal outcomes

4Q - 2022



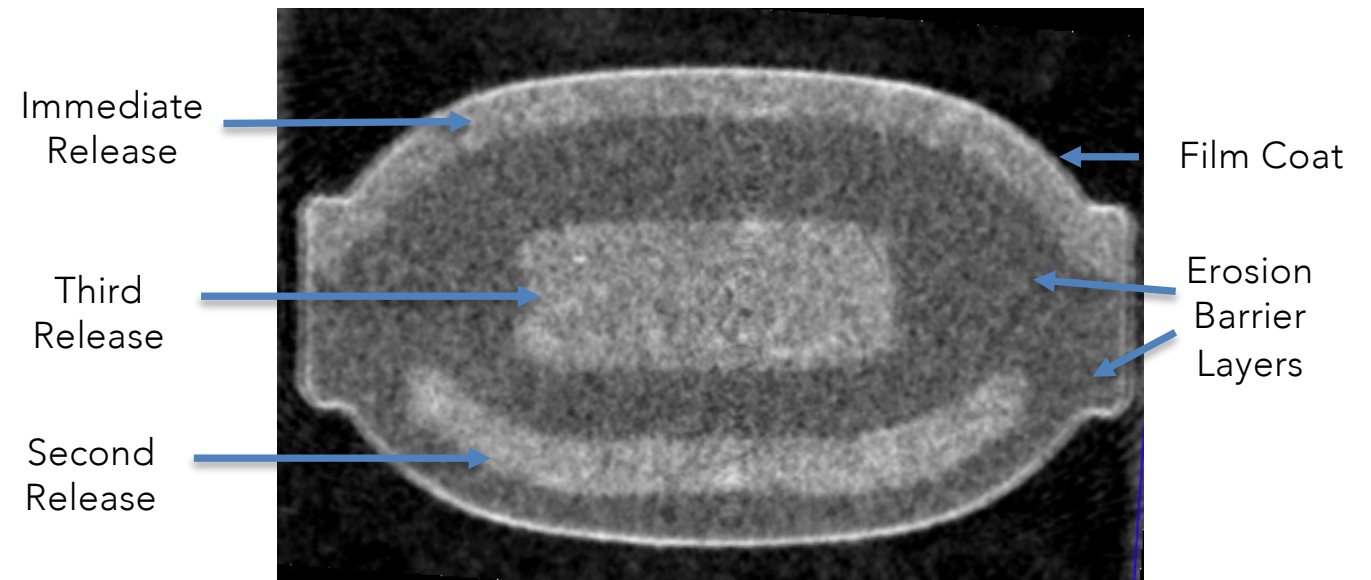
Forward-Looking Statements

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, 2021. 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.

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](#)

Pipeline of Next-Generation Medications in Billion-Dollar Markets

Identified PTR™ Platform Pipeline Opportunities



In Development

- ADHD
- Anxiety



Near-Term

- Insomnia
- Depression
- Bipolar Disorder
- Parkinson's Disease
- Cardiovascular Disorders
- Xerostomia (dry mouth)



Future Therapeutic Areas

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

Market Dynamics in ADHD & Anxiety

ADHD

- \$18Bn US market
- Stimulants dominate (90%+)
- Top 4 ADHD meds generic at CING launch
 - PBM rebates going away
 - Cingulate will dominate Share of Voice
- 100% of stimulants have been approved over last 50 years
- Streamlined FDA approval pathway
- IQVIA Survey: over 60% of providers unsatisfied with current options

Anxiety

- \$5Bn US market
- Buspirone is #1 non-benzodiazepine treatment
- Potential for breakthrough approval
 - PBM rebate offer to improve access
 - Improve patient outcomes
- Streamlined FDA approval pathway

Catalysts Into 2023

ADHD

CTx-1301

CTx-1302

4Q 2022

- Food Effect Clinical Study Report
- Initiate CTx-1301 Adult Onset / Duration Efficacy Trial

1H 2023

- Onset / Efficacy Trial Data
- Initiate Pivotal Phase 3 in Adolescents and Children

2H 2023

- Complete CTx-1301 Pivotal Phase 3
- CTx-1302 IND

Anxiety

CTx-2103

- CTx-2103 Formulation Study

- FDA Discussion regarding clinical development plan

- CTx-2103 IND

PTR™ Platform

- Expand Manufacturing Operations

- Out license opportunity for PTR™ Platform
 - Milestones
 - Royalty

- Potential OUS licensing of CTx-1301, CTx-1302, CTx-2103
- Expand CING – BDD Partnership
- Expand BD&L Activities w/ PTR™



Target dates; Actual time to achievement may vary

CING-US-117-1123

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**\$18
Billion***

**US ADHD
Market**
Dominated
by Stimulants

*Symphony Data.
12-months rolling
through Feb 2022

FIRST and ONLY ADHD Medication to Overcome All Unmet Needs

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



CINGULATE™

Targeting Treatment of ADHD - \$18Bn US Market Opportunity

Frequently diagnosed, chronic pattern interfering with functioning / development

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

Stimulants 91%
of US Market \$15.3Bn¹

70 Million Prescriptions per Year¹

Methylphenidates

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

Amphetamines

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

Non-Stimulants¹: 9%

- Atomoxetine
- Guanfacine
- Clonidine

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

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 ²
Vyvanse®	2007	2 hours	12 hours	✗	✗	Data Not Available	✗
Adderall® XR	2001	1 ½ hours	10 ½ hours	✗	✗	Data Not Available	✗
Concerta®	2000	2 hours	10 hours	✗	✗	Data Not Available	✗
Focalin® XR	2005	30 mins	11½ hours	✓	✗	Data Not Available	✗

60%

use short-acting 'booster' dose every day!

\$11.6B

76% Market Share (\$)²

* 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 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 Symphony Data. 12-months rolling through Jun 2022

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	✗	✗	✗	Potentially
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	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.



The Cingulate Solution for ADHD Patients & Providers



Nine Significant Points of Differentiation

NO ADHD product available today combines all unmet needs.

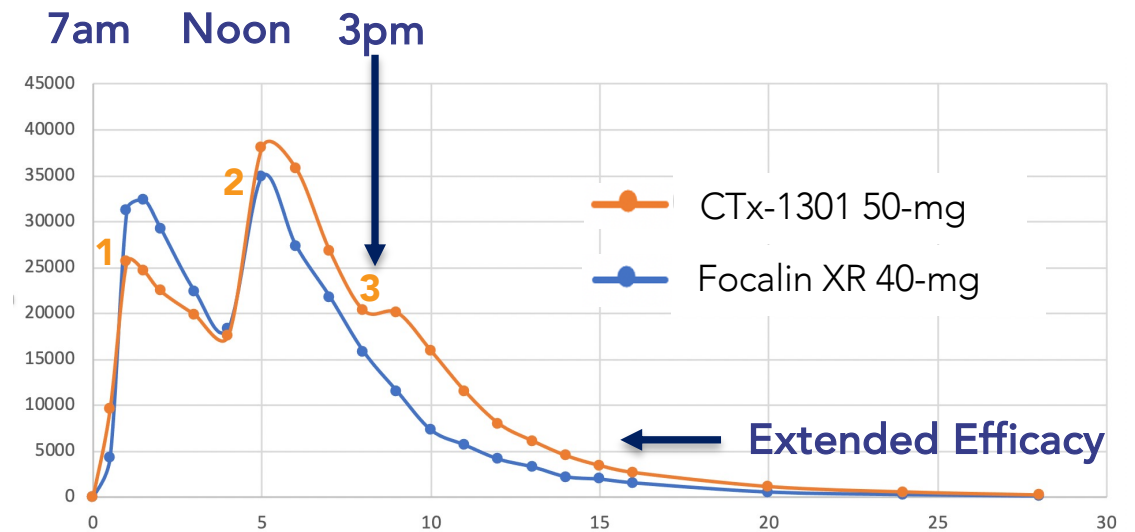
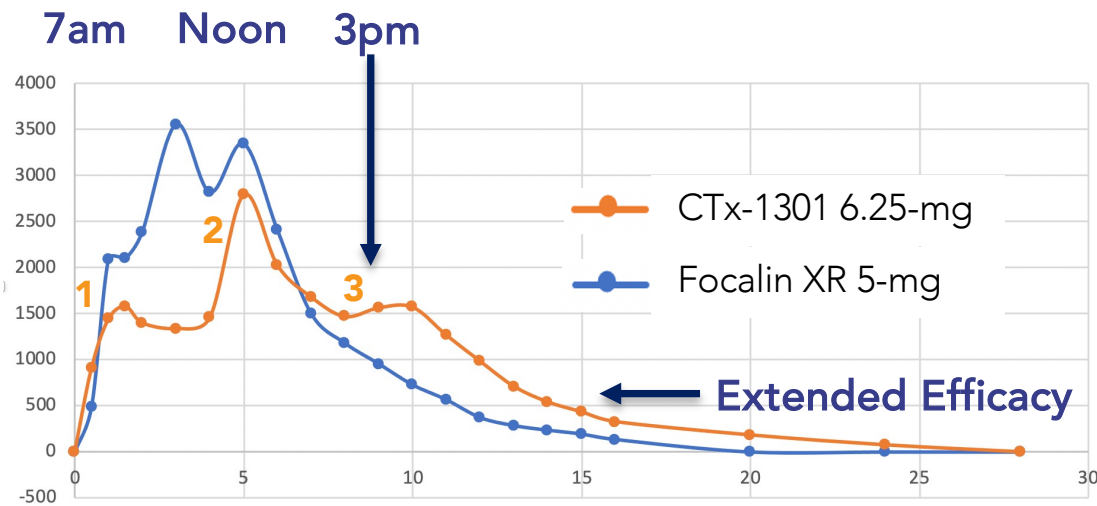
PTR™ technology affords our product candidates the following potential advantages over currently available ADHD treatments:




- **Provide 'Entire Active-Day' Efficacy**
- Fast onset of action
- Eliminate need for booster / recovery dose
- Avoid crash and rebound effect
- Reduce abuse / diversion by eliminating booster
- Significantly improved tolerability
- Lower costs to patients, providers, and payers
- Ability to optimize with 8 dosage strengths
- Single-enantiomer API selection

One Product Overcomes All Unmet Needs

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



Subject ID: 01-510

	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-1301 (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

CTx-1301 Demonstrated Significantly Lower Adverse Events

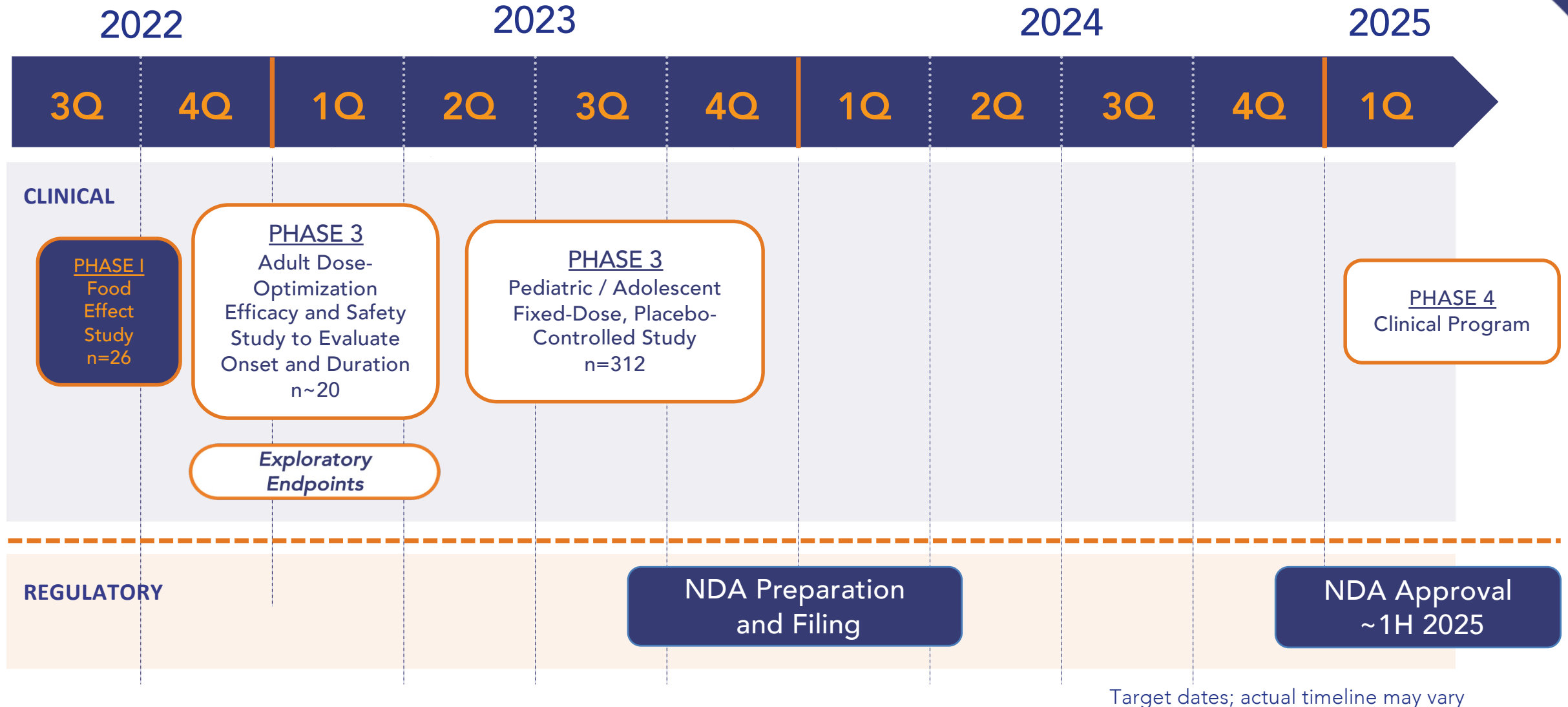
28.6% reduction in TEAE's related to CTx-1301 versus Focalin XR (14.3% difference)

	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

MASTERY[®] CTx-1301 Clinical and Regulatory Timeline



Commercialization to Drive Revenue

Changing dynamics in ADHD commercial landscape

- Ability to dominate share of voice
 - Concerta, Adderall XR, Focalin XR are all off-patent with no promotion
 - Vyvanse loss of exclusivity ~August 2023
- New entrants lack major promotional efforts, field forces, and revenue

Maximize Access for Patients and Providers

- Clinical, Practical, and Societal Story:
 - Efficacy and Tolerability
 - One versus Two Prescriptions
 - Abuse & Diversion
- *Rebates & Net to Plan Cost*
 - PBM's driven by rebate guarantees to payers; estimated >\$2B last year*
 - ADHD is a high brand utilization market with high-cost generics at 55-90% of branded drug cost*

Cingulate's Comprehensive Commercial Model

- **Branded product of choice ~ Patients, Providers, & Payers**
- **Strategic partnership to maximize market access, distribution, promotion across all channels**
 - Psychiatry / Neurology & Pediatrics / Family Practice encompass 84% of ADHD market*
 - Maximize and retain NPV to Cingulate



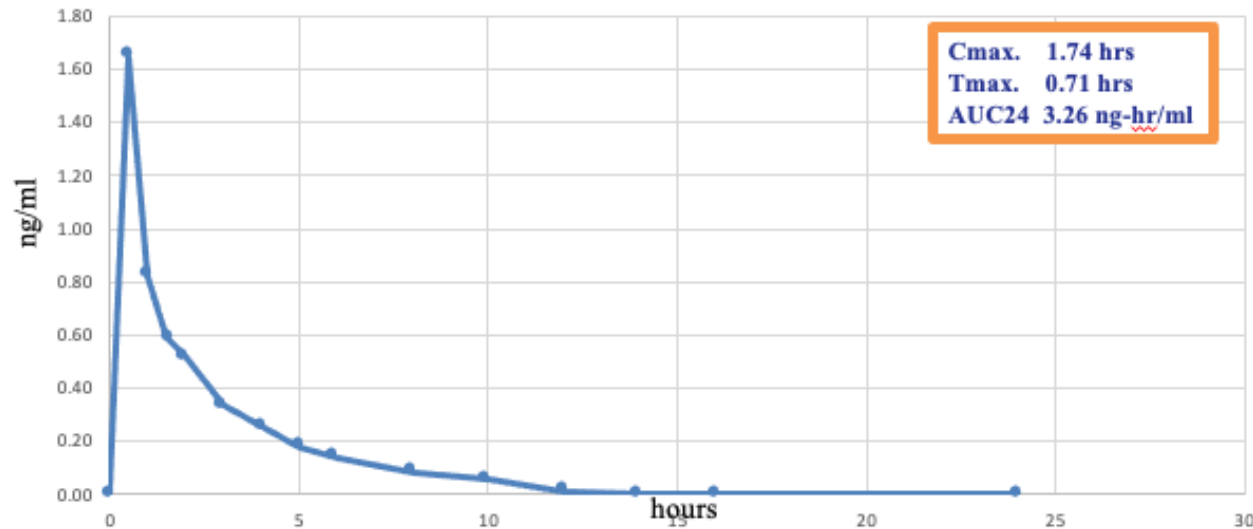


The Cingulate Solution for Anxiety Patients & Providers

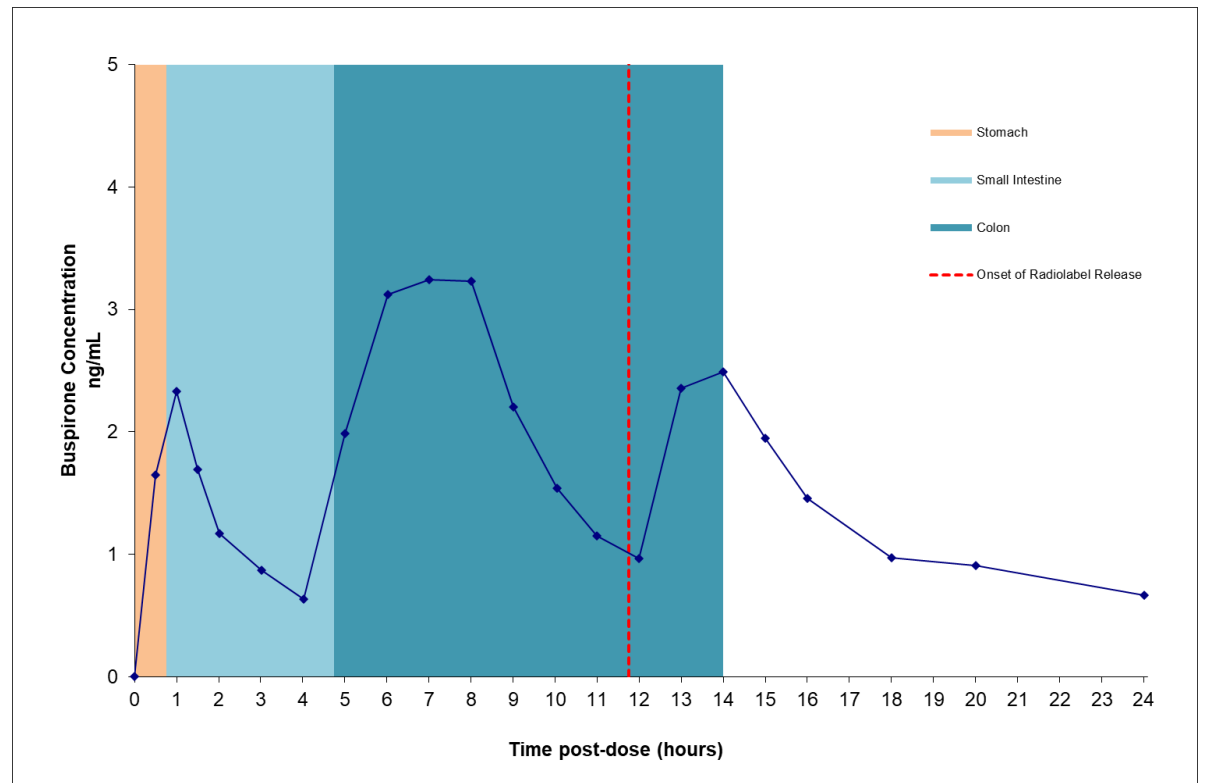
CTx-2103 – Buspirone HCl for the Treatment of Anxiety

Next-Generation Buspirone designed to Improve Patient Outcomes
CTx-2103 Trimodal Tablet

Single Dose Buspirone 10 mg- Immediate Release



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



Exclusivity: IP, Agreements, and Trade Secrets

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

- OralogiK™ Erosion Barrier Layer
 - Five (5) patents granted (US & Global) expiry dates ranging from 2031 to 2035,
 - One (1) OralogiK™ patent pending (US, Europe)
- Three (3) Cingulate product specific patents under prosecution with USPTO and global entities
 - Pharmacokinetics
 - Pharmacodynamics
 - Trimodal release of API
 - Formulation, Precise Timing, Ratio of API

Exclusivity agreements

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

Trade Secrets

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



Cingulate Mission

- ✓ Develop...
- ✓ Shape market acceptance, and...
- ✓ Prepare to commercialize next-generation drug candidates...
Where currently prescribed standard-of-care treatments result in suboptimal outcomes for all stakeholders

➡ ***Achievement Drives Shareholder and Team Member Value***



Thank You



ADHD Market Leaders Do Not Provide “Built-In Booster”


Market Leaders Stop Delivery of Medication 4-5 Hours After Administration


ADHD BRANDS	ATTRIBUTES ¹		RELEASE PROFILES ¹		
	Onset	Duration (less onset)	DOSE 1 / STYLE / TIME	DOSE 2 / STYLE / TIME	DOSE 3 / STYLE /TIME
Vyvanse®	2 hours	12 hours	100% PRODRUG SUSTAINED RELEASE OVER 2 – 3 HOURS	0	0
Adderall® XR (and generics)	1 ½ hours	10 ½ hours	50% IMMEDIATE RELEASE	50% IMMEDIATE RELEASE AT HOUR 4	0
Concerta® (and generics)	2 hours	10 hours	22% IMMEDIATE RELEASE	78% SUSTAINED RELEASE OVER 4-5 HOURS	0
Focalin® XR (and generics)	30 mins	11½ hours	50% IMMEDIATE RELEASE	50% IMMEDIATE RELEASE AT HOUR 4	0

¹ Information based upon product Package Inserts, and Summary Basis of Approvals

CTx-1301 (d-MPH) and CTx-1302 (d-AMP)

Ideal Design Provides Exclusive Ability to Overcome Unmet Needs

 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-1301 (d-AMP)	30 mins	Up to 16 hours	✓	✓	✓	✓

 CINGULATE®	TARGET ATTRIBUTES		RELEASE PROFILES		
	Onset	Duration	DOSE 1 / STYLE / TIME	DOSE 2 / STYLE / TIME	DOSE 3 / STYLE / TIME
CTx-1301 (d-MPH)	30 mins	Up to 16 hours	35% IMMEDIATE RELEASE	45% SUSTAINED RELEASE OVER 90 MINUTES AT HOUR 3	20% IMMEDIATE RELEASE AT HOUR 7
CTx-1302 (d-AMP)	30 mins	Up to 16 hours	45% IMMEDIATE RELEASE	35% SUSTAINED RELEASE OVER 90 MINUTES AT HOUR 3	20% IMMEDIATE RELEASE AT HOUR 7



6.25-mg



12.5-mg



18.75-mg



25-mg



31.25-mg



37.5-mg



43.75-mg

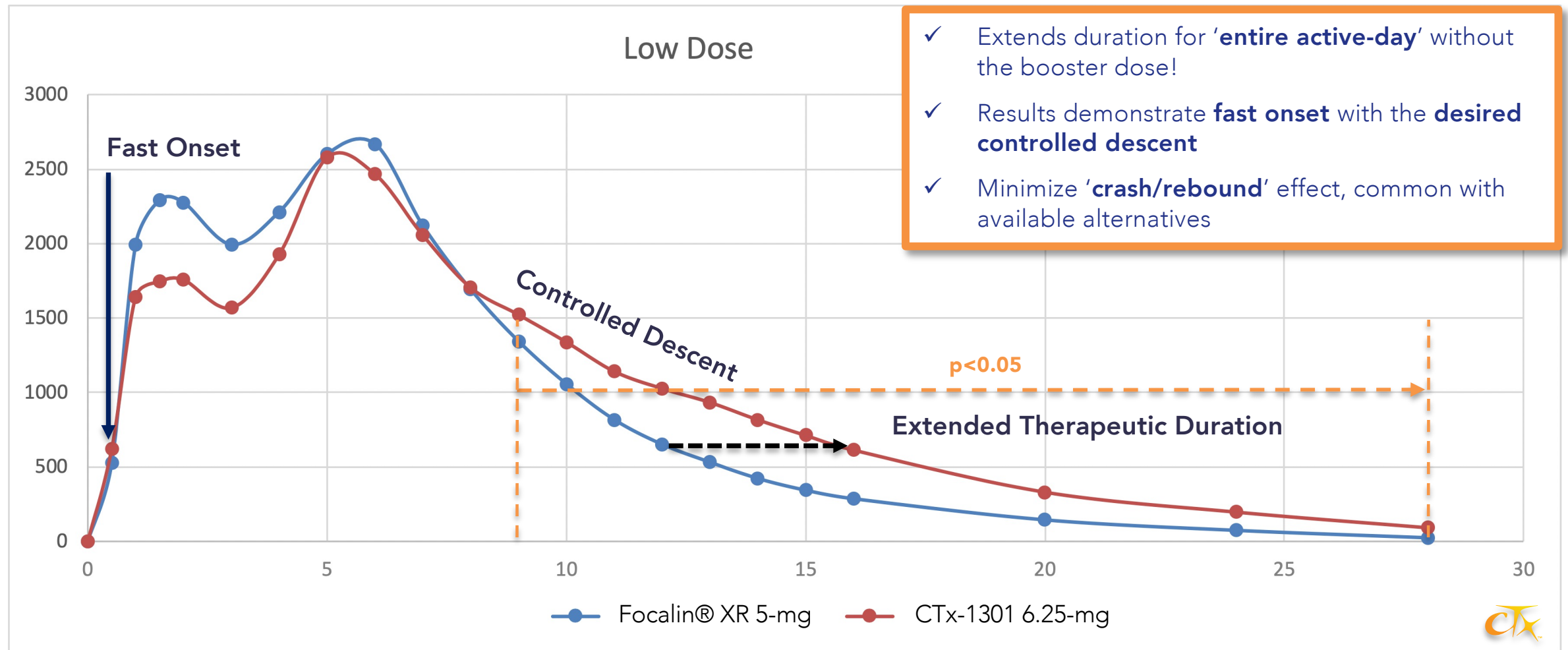


50-mg



CTx-1301 Clinical Phase 2 Study Results

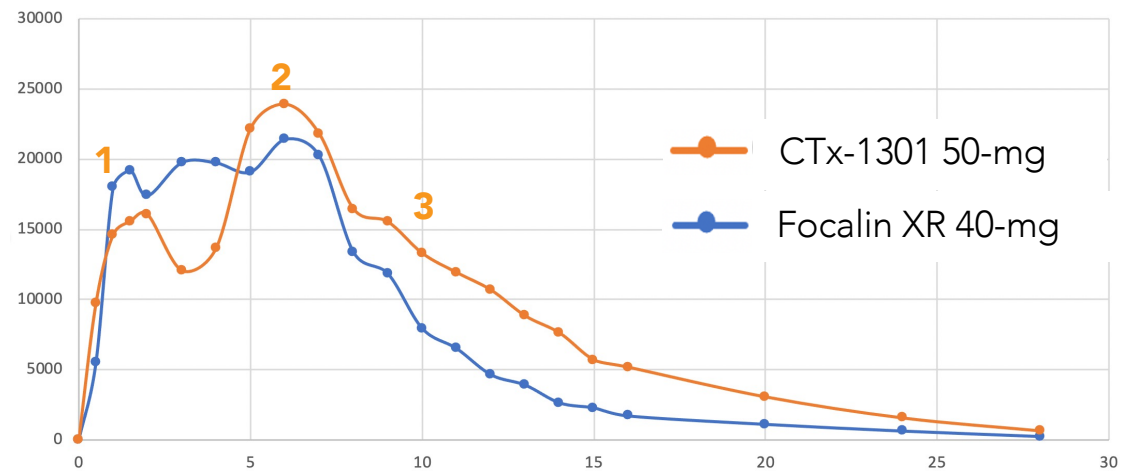
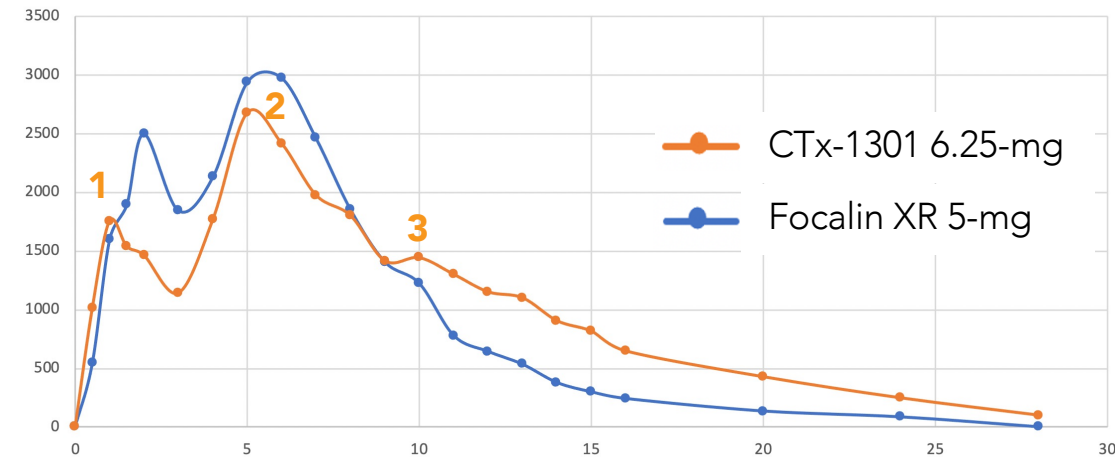
Plasma dexamethylphenidate (dMPH) Concentration vs Time



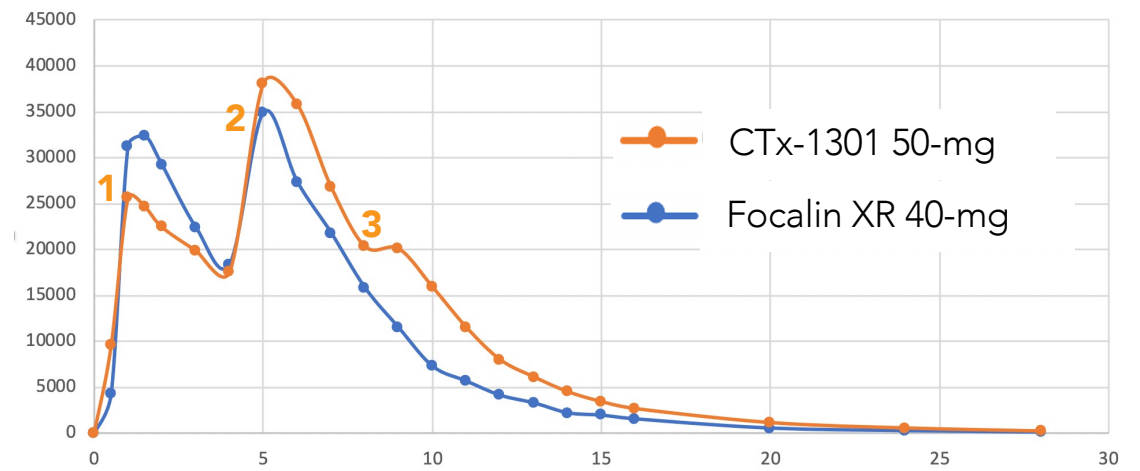
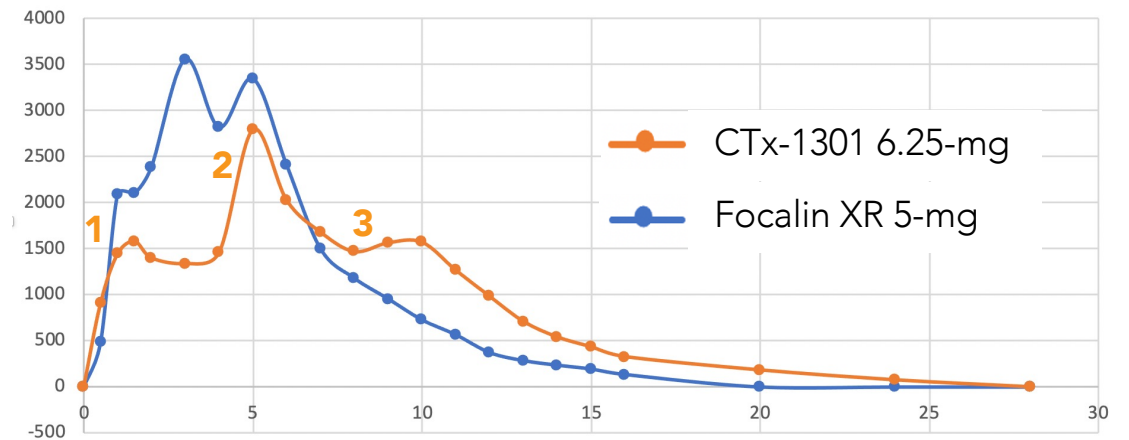
One Product Overcomes All Unmet Needs

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

Subject ID: 01-504



Subject ID: 01-510



De-Risked Development

100% of Stimulants Have Been Approved

26

30+ stimulant product approvals in ADHD over last 50+ years

Methylphenidates	Status	Approval Date
Azstarys*	APPROVED	March 2021
Adhansia XR*	APPROVED	February 2019
Jornay PM*	APPROVED	August 2018
Cotempla XR ODT*	APPROVED	June 2017
Quillichew ER*	APPROVED	December 2015
Quillivant XR*	APPROVED	September 2012
Aptensio XR*	APPROVED	April 2015
Daytrana*	APPROVED	April 2006
Focalin XR	APPROVED	May 2005
Methylin Chewable Tablets*	APPROVED	April 2003
Ritalin LA	APPROVED	June 2002
Focalin	APPROVED	November 2001
Metadate CD*	APPROVED	April 2001
Concerta	APPROVED	August 2000
Metadate ER*	APPROVED	June 1988
Desoxyn	APPROVED	Pre-1984
Ritalin	APPROVED	Pre-1984

Amphetamines	Status	Approval Date
Evekeo ODT*	APPROVED	January 2019
Evekeo	APPROVED	August 2018
Adzenys ER*	APPROVED	September 2017
Mydayis	APPROVED	June 2017
Adzenys XR/ODT*	APPROVED	January 2016
Dyanavel XR	APPROVED	October 2015
Zenzedi	APPROVED	May 2013
Procentra	APPROVED	January 2008
Vyvanse	APPROVED	February 2007
Adderall XR	APPROVED	October 2001
Adderall	APPROVED	February 1996
Dextrostat	APPROVED	Pre-1984
Dexedrine Spansule	APPROVED	Pre-1984
TRN-110 (Tris Pharma)	Phase 3 (Oct. 2019)	Projected 2021
Amphetamine Transdermal System (Noven)	Phase 2 (March 2013)	Projected 2022
ADAIR (Abuse Deterrent Amphetamine IR - Vallon)*	Phase 2 (June 2017)	Projected 2023

References: ClinicalTrials.gov, FDA Summary of Approvals, Noven Pharmaceuticals, Tris Pharma, and Vallon Pharmaceuticals

Note: Asterisks indicate stimulants used / plan to use the 505(b)2 regulatory pathway for approval

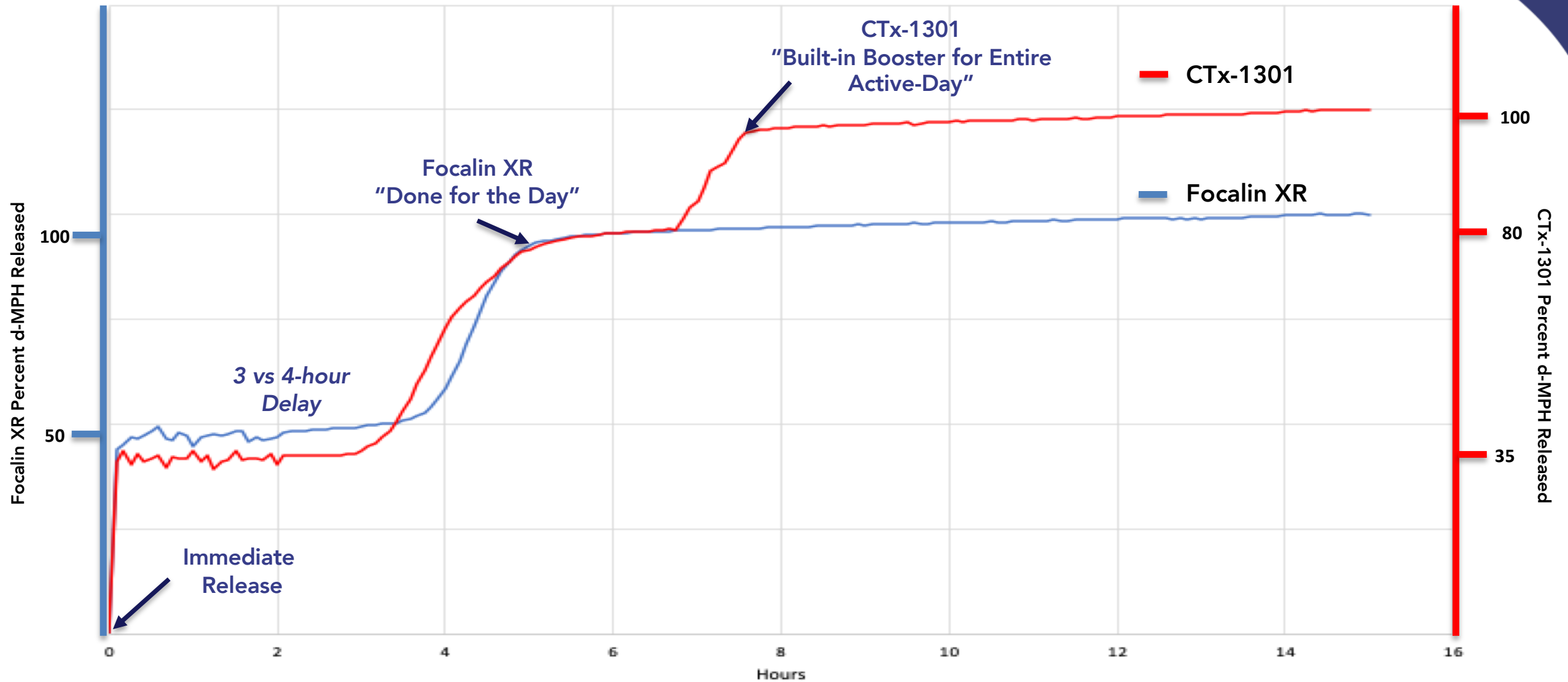


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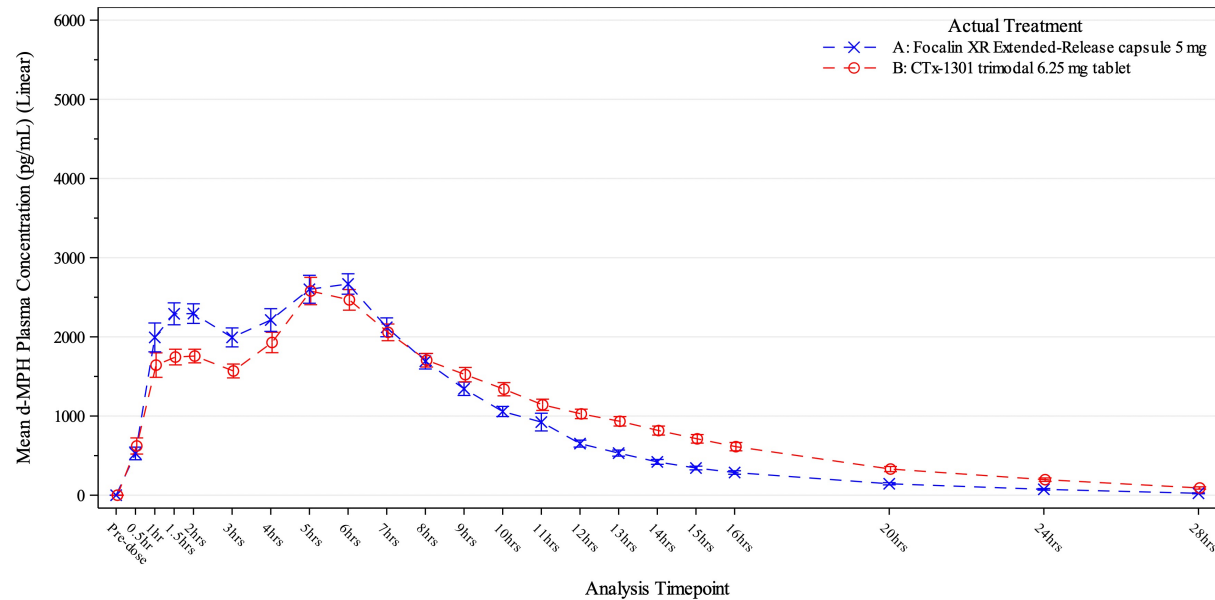
Cingulate.com

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

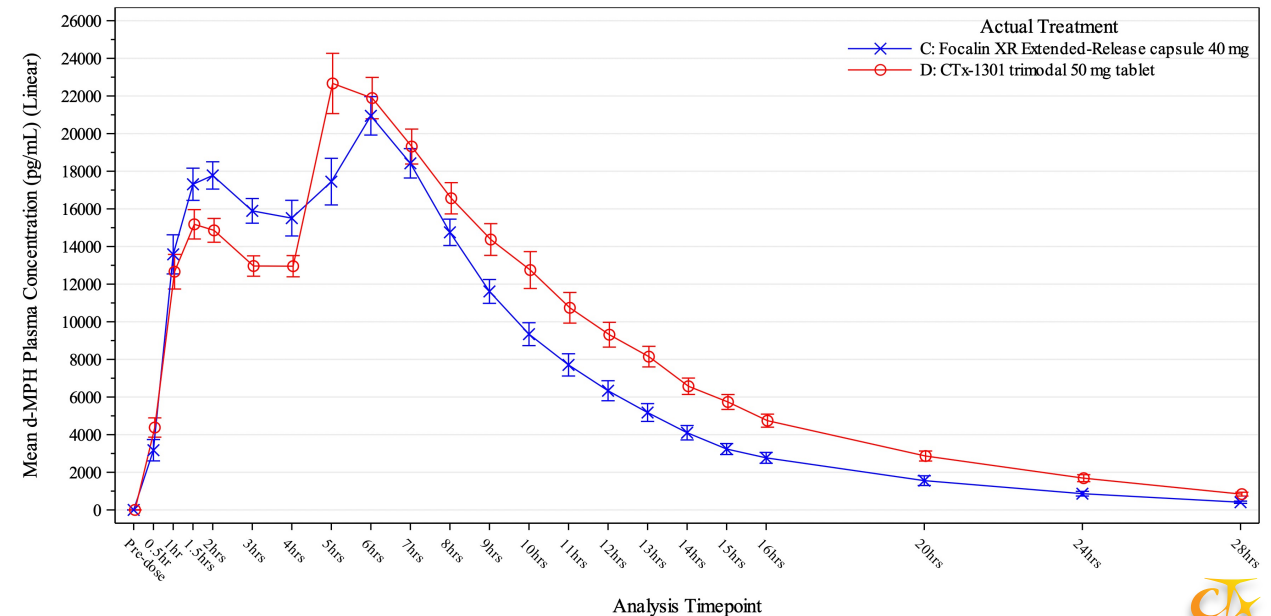


CTx-1301 Clinical Phase 2 Study Results

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"**



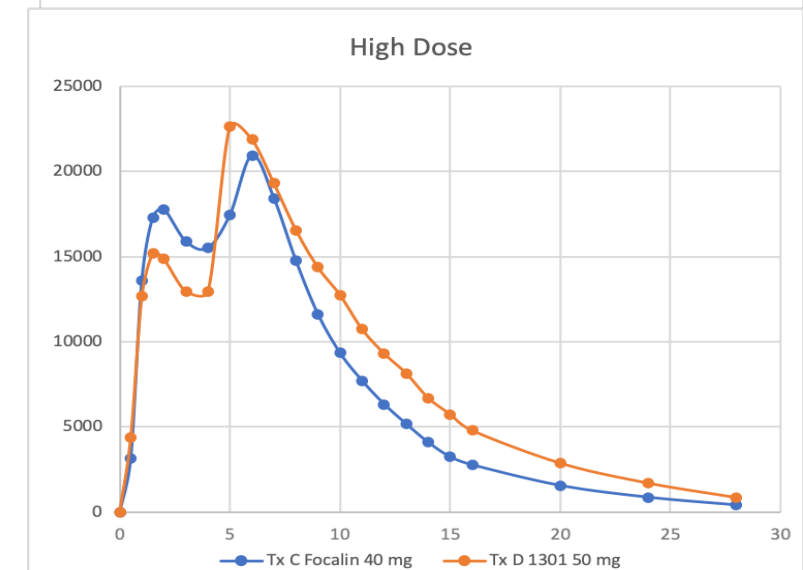
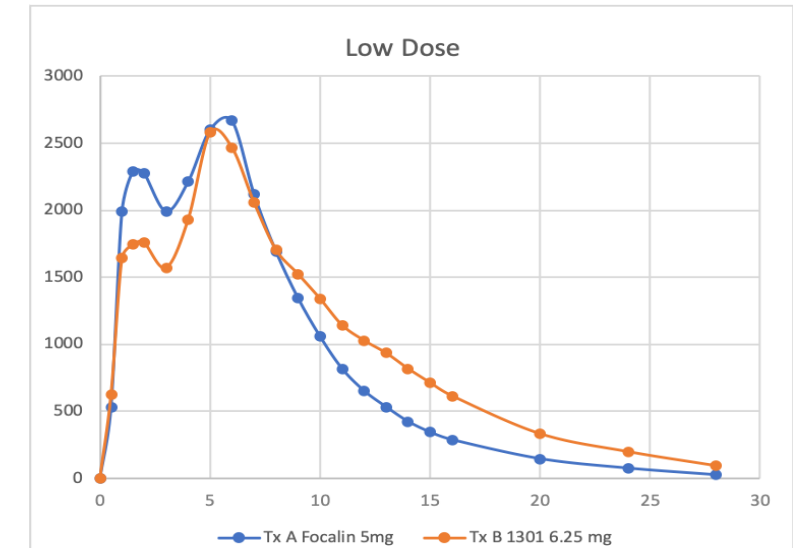
CTx-1301 Bridges to Focalin® XR

The primary trial objective is to compare the bioavailability of the marketed product (Focalin XR) to CTx-1301 trimodal investigational product under fasted conditions and demonstrate dose proportionality of CTx-1301.

			Test/Reference
Geometric Mean	Focalin 5mg (Tx A)	1301 6.25 mg (Tx B)	Ratio B/A
C_{MAX}	3069	2820	0.92
t_{max} Median	5	5	1.00
$AUC_{(0-28)}$	23193	25918	1.12

In the context of a bioavailability analysis, similarity will be concluded if the 90% confidence interval (CI) of the geometric mean ratios for C_{max} , AUC_{inf} , AUC_{last} fall near or within the 90% CI of [0.80—1.25]. The TOST procedure will identify two treatments *as equivalent* when the lower bound of a 90% confidence interval falls near or below 1.25 or the upper bound of a confidence interval falls near or above 0.80 (or both).

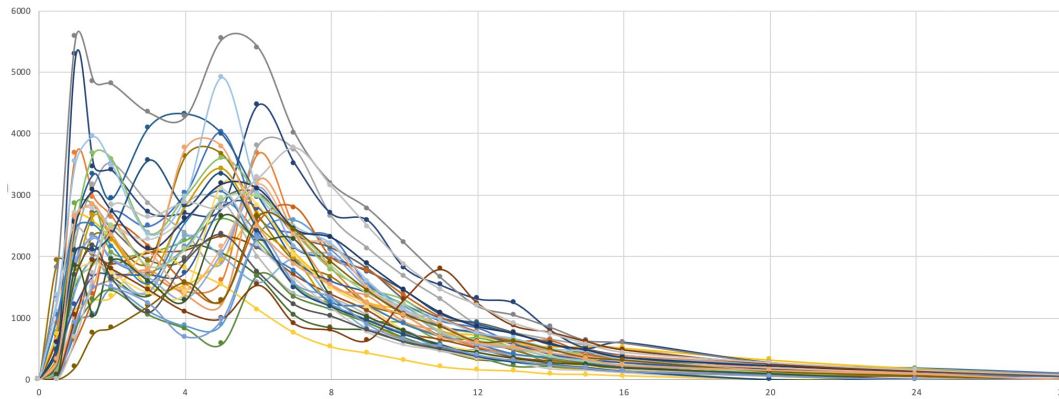
			Test/Reference
Geometric Mean	Focalin 40 mg (Tx C)	1301 50 mg (Tx D)	Ratio D/C
C_{MAX}	23099	24299	1.05
t_{max} Median	6	5	0.83
$AUC_{(0-28)}$	192860	225279	1.17



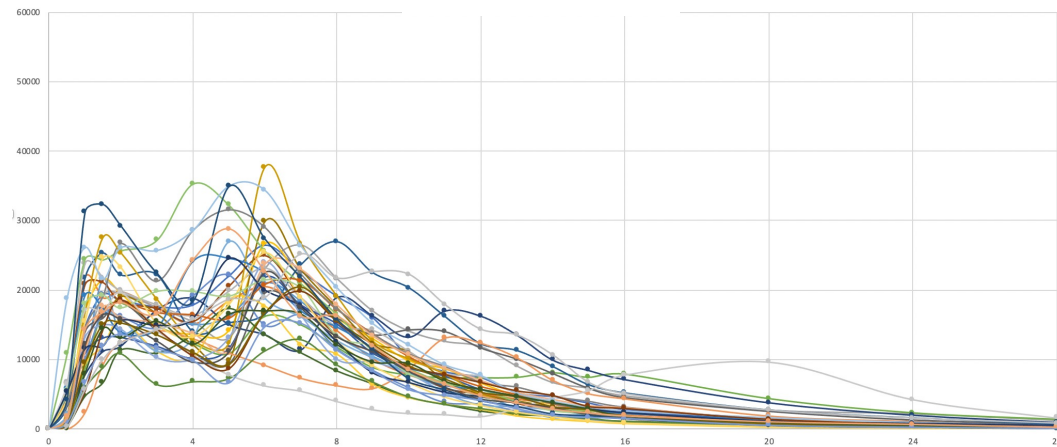
CTx-1301 Clinical Phase 2 Study Results

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

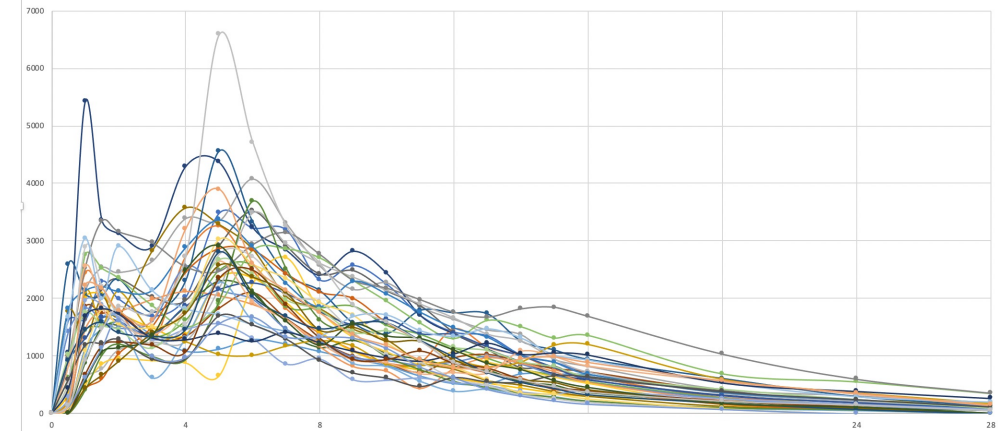
Focalin XR 5-mg



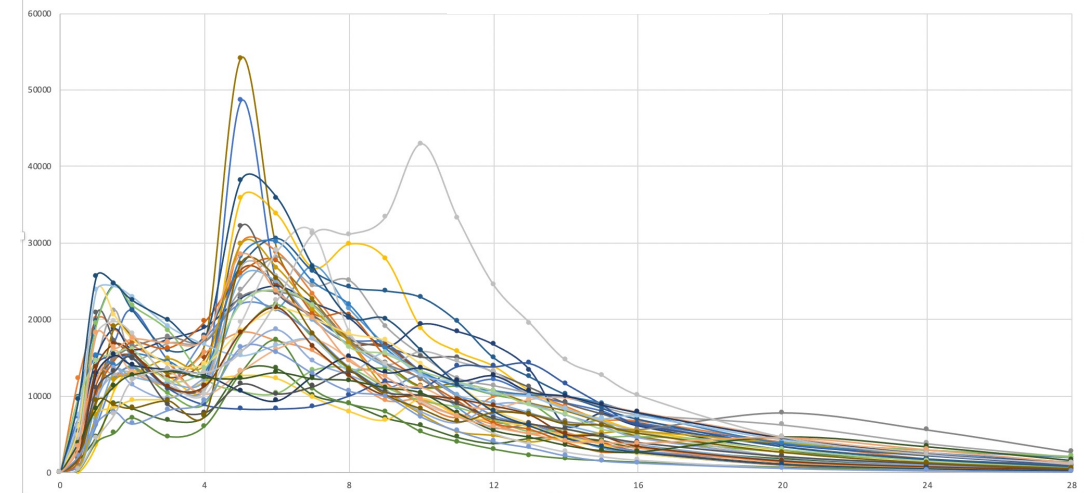
Focalin XR 40-mg



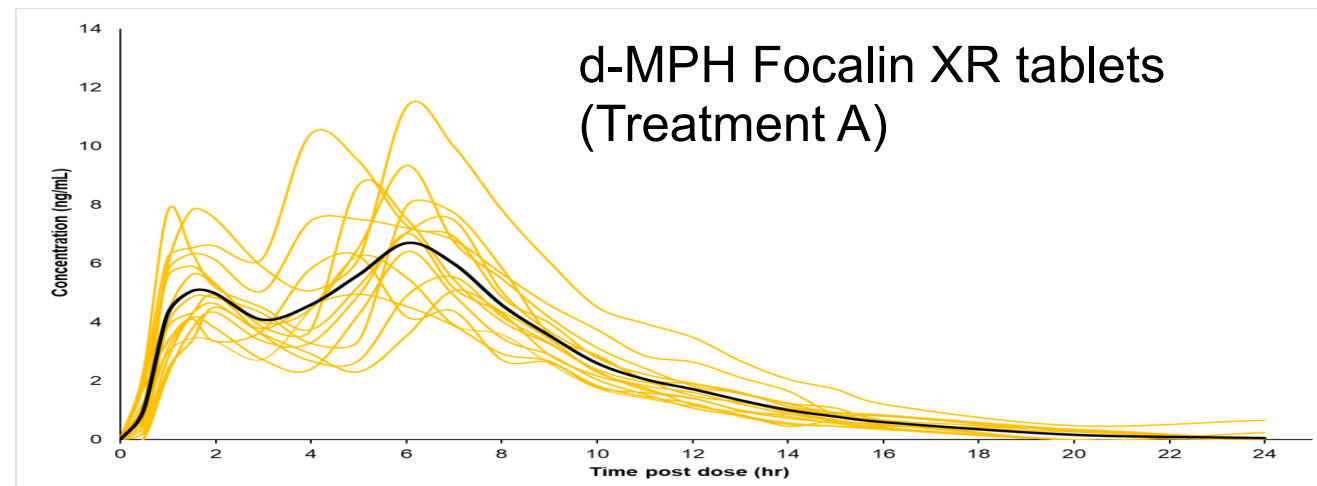
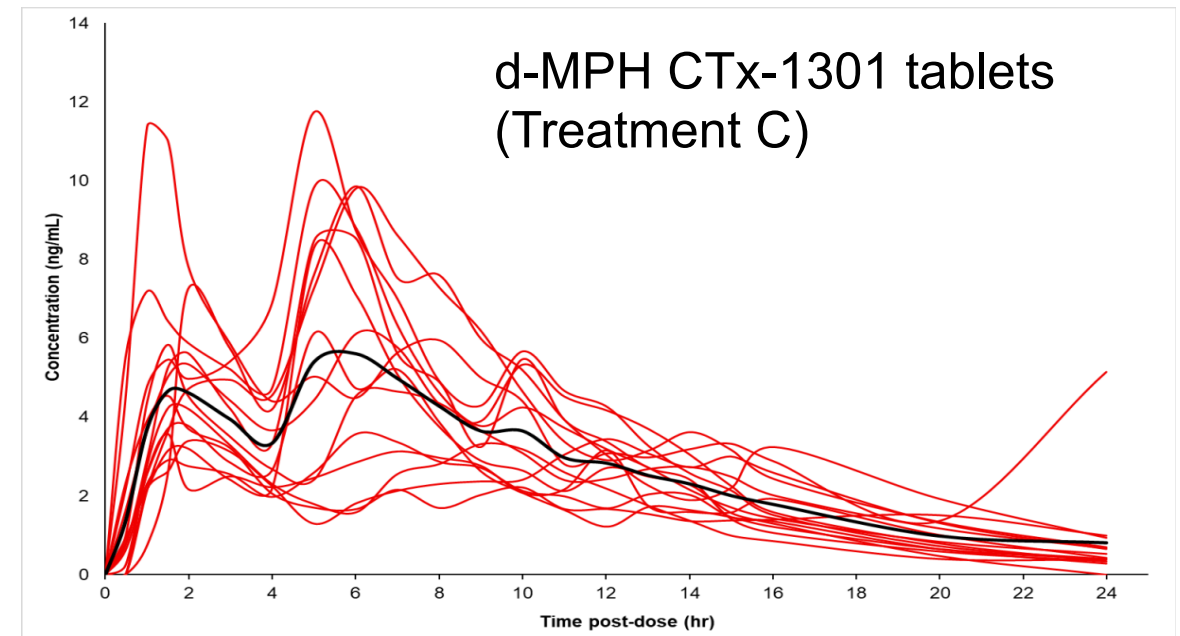
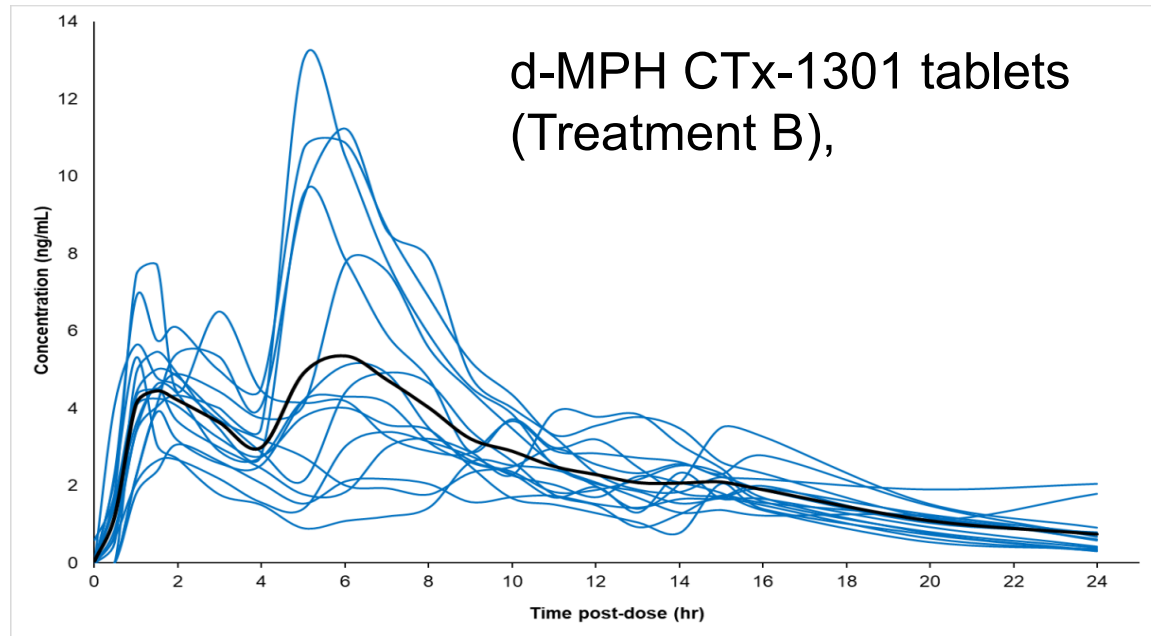
CTx-1301 6.25-mg



CTx-1301 50-mg

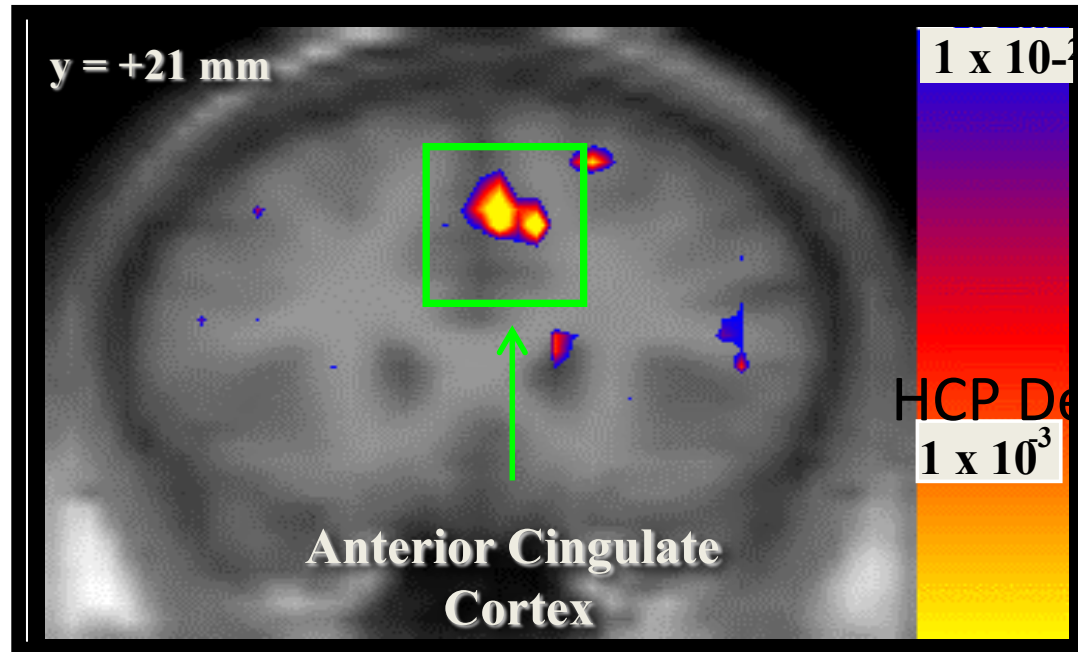


CTx-1301 Results PK Comparison

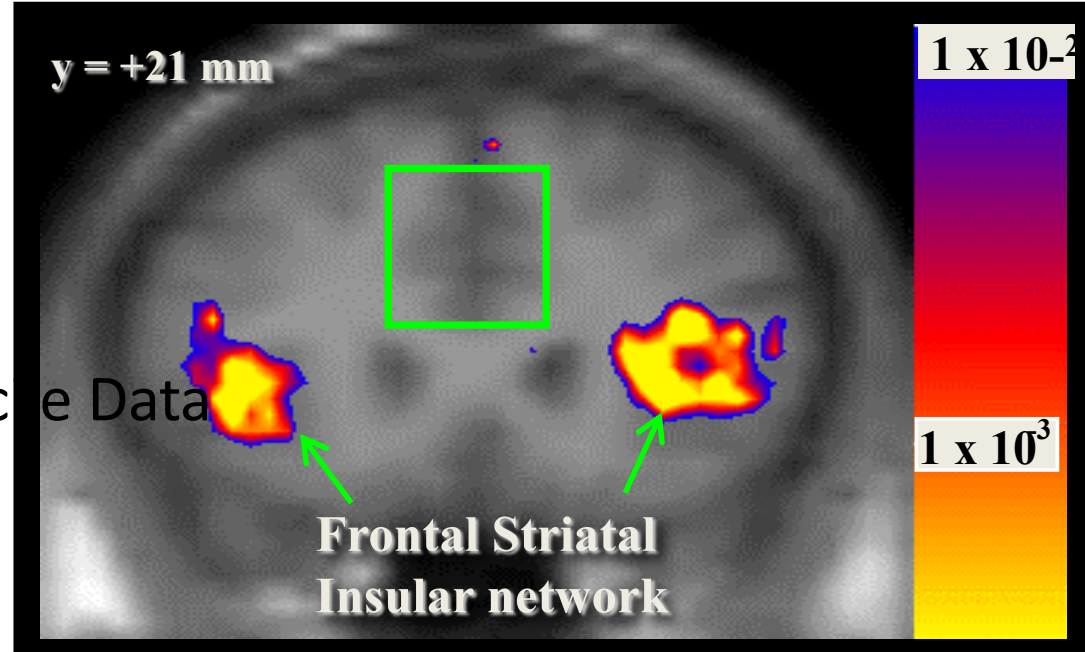


Neurobiological relationship to ADHD

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.