CTx-1301 (Dexmethylphenidate HCl)

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BRANDED PRODUCTS:
Focalin XR: 505(b)(2) Reference Listed Drug CTx-1301(Brand Name TBD)

API NAME: Dexmethylphenidate HCl (CTx-1301)

DOSAGE FORM & CHARACTERISTICS:

- CTx-1301 (Dexmethylphenidate HCl; dMPH) is a film-coated trimodal modified-release tablet based on a tablet-in-tablet technology.
- dMPH to optimize patient treatment is released in a 35% pulse(t=0)/45% pulse (sustained release t=4hrs)/20% pulse (t=8hrs) ratio.
- Dosage strengths (8) of dMPH are 6.25mg; 12.5mg; 18.75mg; 25.0mg; 31.25mg; 37.5mg; 43.75mg; 50mg.
- The tablet is designed to provide an immediate release of dMPH (within 30 minutes), provide entire active day efficacy and based on the release ratio reduce and/or eliminate the need for an extra "booster" dose which is common in clinical practice.

INDICATION: Treatment of ADHD

MARKET DYNAMICS (US):

- Total ADHD Market:$22B; stimulants take 77% of the value. Long acting stimulants hold $15B of the prescriptions. (Symphony data Nov 2023)
- Adult ADHD is underdiagnosed and undertreated. Adult market is burgeoning, will continue with the introduction of APSARD adult guidelines in late 2024.

PAYOR RESEARCH:

- Conducted 10 in-depth telephone interviews with pharmacy directors recruited from traditional health insurers (n=6) and PBMs (n=4) managing **approx. 121.8 million total lives**:114.1 mil Commercial lives and 7.6 mil Medicaid lives.
- **CTx-1301 is likely to gain commercial coverage** as a Preferred brand without restrictions or as a Non-Preferred brand with 1-2 steps; dependent on rebate ranges; Medicaid coverage will require supplemental rebates.
- CTx-1301 was rated most valuable versus Vyvanse, Adderall XR, Concerta, Focalin XR, Azstarys, and Quelbree.
- Contracting and pricing estimates yielded a WAC & Rebate range that is favorable to Cingulate's current forecast models.

DRUG APPROVAL STATUS
Clinical Phase 3; NDA filing targeted July 2025
April 2025: targeted pre-NDA meeting with FDA to confirm submission
April 2024: alignment with the FDA on path forward to NDA submission
Phase 3 clinical studies: enrollment closed. Existing data will be analyzed and submitted with the NDA submission. (https://www.cingulate.com/news-releases/news-release-details/fda-clears-cingulate-file-marketing-approval-ctx-1301-treatment).

Twelve FDA-required Registration batches have been manufactured, representing all 8 doses to be commercialized (https://www.cingulate.com/news-releases/news-release-details/cingulate-achieves-key-manufacturing-milestone-development-its).

PATENT EXPIRY DATE:
- Focalin XR LOE: 2015;
- CTx-1301 patents: earliest 2035

Timelines for Partnership for CTx-1301:
- Definitive Agreement: **1H 2025**
- 505(b)(2) NDA filing: **Q3 2025**
- 505(b)(2) expected approval: **Q2 2026**

Terms for US Partner:

Remaining Development Costs: 50% Cingulate and 50% US Partner (listed below)

Licensing fees: $9.5M total
- On signing of the contract: $1.5M
- Conduct pre-NDA meeting: $1.5M
- 505(b)(2) NDA filing: $4M
- 505(b)(2) NDA approval: $2.5M

Post-Commercialization Milestone Payments: $7M total
- Upon $25M cumulative net sales: $1M
- Upon $50M cumulative net sales: $1M
- Upon $100M cumulative net sales: $5M

Commercialization Cost Split: 50% Cingulate and 50% US Partner

Clinical Manufacturing Cost of Goods:

Dosage	6.25mg	12.5mg	18.75mg	25mg	31.25mg	37.5mg	43.75mg	50mg
COGS	$ 2.28	$ 2.30	$ 2.32	$2.35	$ 2.37	$ 2.39	$ 2.41	$2.43

Net Profit Split: 50% Cingulate/50% US Partner

Sales Projections for US Partner (50/50 Profit Split):

2026 Net Sales 15MM
2027 Net Sales 100MM
2028 Net Sales 175M
2029 Net Sales 350M

Summary of Remaining Development Costs From January 2025 to Commercialization of CTx-1301		
Action Item	**Budget**	**Timing**
Manufacturing Analytics and Stability *	**$4,000,000**	**2025**
Regulatory Consulting fees* **	**$1,000,000**	**2025-2026**
Grand Total	**$5,000,000**	

*** Commercial supply agreement not in place; these costs are estimated. This includes process validation material which can be used for commercial product launch**

****As this is Cingulate's first NDA filing; PDUFA first filing fee expected to be waived**

This does not include any commercialization costs; new product marketing (commercial development) costs nor pre-market medical affairs costs

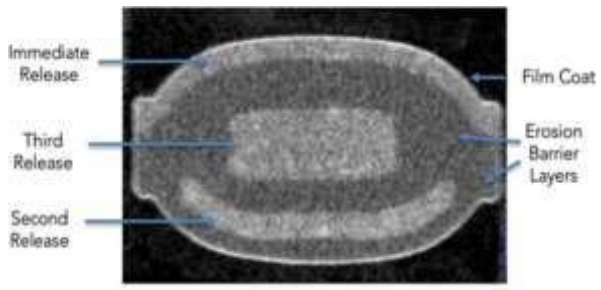
About Cingulate and CTx-1301

Cingulate® (CTx®) is a Phase 3 clinical-stage biopharmaceutical company utilizing its proprietary Precision Timed Release™ (PTR™) drug delivery platform to build and advance a pipeline of branded next-generation pharmaceutical products. These will be designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. With an initial focus on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD) and Generalized Anxiety Disorder (GAD), Cingulate is identifying and evaluating additional therapeutic areas where PTR™ technology may be employed to develop future product candidates. (www.Cingulate.com)

About CTx-1301

Cingulate's lead candidate, CTx-1301, utilizes Cingulate's proprietary PTR drug delivery platform to create a breakthrough, multi-core formulation of the active pharmaceutical ingredient dexmethylphenidate; stimulants are the gold standard of ADHD treatment due to their efficacy and safety; the long-standing challenge continues to be providing patients entire active-day duration of action. **CTx-1301 is designed to do the following:**

- **Deliver three releases of medication precisely at the predefined time, ratio, and style of release to optimize patient care in one tablet.**
- **the result is a rapid onset and entire active-day efficacy, with the third dose being released around the time when other extended-release stimulant products begin to wear off.**



ADHD market is dominated by 4 stimulate products: Focalin® XR, Concerta®, Vyvanse® and Adderall XR. None of these products satisfy all the patient needs of fast onset of action; entire active day efficacy, minimizing crash and rebound and the avoidance of a booster therapy. CTX-1301 has been designed to achieve all the patient needs.

CTx-1301 clinical data has demonstrated the following:

1. In an adult phase 3 study **the effect size of CTx-1301 was 2-5 times greater than currently available ADHD treatments**, demonstrating unprecedented real-world impact

2. **Head to head vs Focalin XR: 28.6% reduction in treatment-emergent adverse events**