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CTx-1301 Dexmethylphenidate: FDA Review & ADHD Clinical Data

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Executive Summary

CTx-1301 is a novel once-daily stimulant drug candidate for Attention-Deficit/Hyperactivity Disorder (ADHD) being developed by Cingulate Inc. (NASDAQ: CING). Chemically, it contains **dexmethylphenidate hydrochloride** (the active enantiomer of methylphenidate) in a multi-layer “Precision Timed Release” (PTR™) tablet designed to deliver three pulses of active drug at predefined times throughout the day. The U.S. Food and Drug Administration (FDA) accepted Cingulate's **505(b)(2) New Drug Application (NDA)** for CTx-1301 on September 29, 2025 and set a PDUFA (Prescription Drug User Fee Act) target action date of **May 31, 2026** (www.sec.gov). If approved, CTx-1301 would become a new **controlled-substance stimulant** option for ADHD that claims a rapid onset and full-day coverage with a smoother “descent” to minimize rebound symptoms (www.cingulate.com) (www.globenewswire.com).

CTx-1301's pivotal Phase 3 clinical trial in adults showed a strong treatment effect size (Cohen's d in ADHD rating scales) that **began 30 minutes post-dose and persisted to 16 hours** (www.globenewswire.com). Although the trial (N=21) *missed* statistical significance on its primary endpoint ($p=0.089$, trend-level) (www.cingulate.com) (www.globenewswire.com), patients on CTx-1301 had markedly better outcomes than placebo (e.g. a -1.2 vs 0.0 change in CGI-Severity score, $p<0.001$) and a notably large 16-hour effect size (≈ 0.98) (www.globenewswire.com). By comparison, a published meta-analysis of existing long-acting stimulants in adults found an average effect size of only ≈ 0.73 (range $\approx 0.5-0.9$) (www.globenewswire.com). Cingulate reports that CTx-1301 was well-tolerated with no serious adverse events and no insomnia during the randomized trial period (www.globenewswire.com) (www.cingulate.com). Investigators have observed that CTx-1301's fast onset and extended coverage "improve ADHD symptoms... over an entire active day" and could *eliminate the need for supplemental short-acting booster doses*, which over 60% of patients on current stimulants reportedly use today (www.cingulate.com).

The NDA for CTx-1301 was submitted under FDA's **505(b)(2) pathway** – a "hybrid" approval route that allows reliance on existing data for dexamethylphenidate (the active moiety in **Focalin® XR**, a reference listed drug) while adding Cingulate's own bridging studies to support the new formulation (www.fda.gov) (www.cingulate.com). Indeed, Cingulate conducted a 2020 Phase 1/2 bioavailability study confirming that its formulation has dose-proportional pharmacokinetics and comparable absorption to Focalin XR (www.cingulate.com), as well as fed/fasted (food effect) studies in 2022 and 2024 demonstrating that CTx-1301 can be taken with or without food (www.cingulate.com) (www.sec.gov). According to Cingulate SEC filings, FDA has been actively reviewing the NDA, issuing information requests (mainly on chemistry/manufacturing) and performing a pre-approval inspection of Cingulate's **contract manufacturer** (which resulted in three observations) (www.sec.gov). Cingulate has responded to all requests, but notes that **no assurance** can be made that FDA *will* approve CTx-1301 by the PDUFA date (or at all) (www.sec.gov).

This report provides a **comprehensive analysis** of CTx-1301's development, the 505(b)(2) regulatory pathway that enabled its expedited review, and the broader market for once-daily stimulant ADHD medications. We review the clinical data for CTx-1301 in detail (including statistical and effect-size outcomes), discuss the safety and pharmacologic rationale, and compare this candidate to existing therapies. We also examine the size and dynamics of the ADHD pharmaceutical market, including supply challenges, competition from current long-acting stimulants (and upcoming generics), and patient adherence issues. Finally, we discuss the implications of the impending **FDA decision** for patients, providers, and Cingulate, and outline potential future directions in ADHD treatment. All claims are supported by published sources and regulatory filings.

Introduction and Background

ADHD Prevalence and Treatment Landscape

Attention-Deficit/Hyperactivity Disorder (ADHD) is a chronic neurodevelopmental condition characterized by inattention, hyperactivity, and impulsivity that often persists into adulthood. It affects millions of Americans: recent surveys estimate that roughly **11–12% of U.S. children** have ever been diagnosed with ADHD (www.cdc.gov) (www.cdc.gov). For example, a National Health Interview Survey (2020–2022) found **11.3%** of children ages 5–17 had a doctor's ADHD diagnosis (www.cdc.gov). By CDC estimates, approximately **7.0**

million U.S. children (3–17 years old) had an ADHD diagnosis by 2022 (www.cdc.gov). ADHD disproportionately affects boys (≈ 14 –15% of boys vs 8–9% of girls) (www.cdc.gov) (www.cdc.gov). Once diagnosed, many children continue to exhibit ADHD into adolescence and adulthood: studies suggest about **65–90%** of childhood ADHD cases persist in some form into later life (www.globenewswire.com) (www.cdc.gov).

Among U.S. adults, ADHD is also common but frequently underdiagnosed. The CDC's 2023 rapid survey estimated roughly **15.5 million U.S. adults** (about 6.0% of adults) currently have an ADHD diagnosis (www.cdc.gov). Notably, about half of these adults reported being diagnosed in adulthood (≥ 18 years of age) (www.cdc.gov). Epidemiological data worldwide indicate a 4–5% prevalence of ADHD in adult populations [and 2–5% globally] (www.cdc.gov) (www.cdc.gov). Despite this, only a minority of adults with ADHD actually take medication: CDC data show only about one-third of diagnosed adults had a stimulant prescription in the prior year (www.cdc.gov) (compared to about 70% of diagnosed children) (www.sec.gov).

Pharmacotherapy with stimulant medications remains the **first-line standard of care** for ADHD due to its robust efficacy. Both the methylphenidate class (e.g. Ritalin, Concerta, Focalin) and amphetamine class (e.g. Adderall, Dexedrine, Vyvanse) are approved for ADHD and substantially improve core symptoms. Approximately **90%** of all ADHD prescriptions in the U.S. are for stimulants (www.sec.gov), reflecting decades of trial evidence that these drugs outperform non-stimulants on average (pmc.ncbi.nlm.nih.gov). Practice guidelines in the U.S. and abroad uniformly recommend stimulants (long-acting versions) as first-line pharmacotherapy for both children and adults (pmc.ncbi.nlm.nih.gov).

Stimulant medications are highly effective, but their pharmacokinetics and duration of action present clinical challenges. Most immediate-release (IR) stimulants wear off in 3–4 hours, requiring multiple daily doses. Long-acting (extended-release, or XR) formulations were developed to allow **once-daily dosing**, but many patients still experience end-of-day rebound or need supplemental “booster” doses. For instance, surveys show that *over 60%* of patients taking an ER stimulant end up using an extra IR dose later in the day (www.cingulate.com). This is partly because even XR stimulants often have only a single or bimodal release profile that cannot maintain adequate plasma levels throughout a 12–14 hour active day. As Cingulate's investigators note, the pharmacological “crash” or rebound effect from falling blood levels can cause symptom recurrence or exacerbation in late afternoon/evening (www.cingulate.com). Moreover, conventional stimulants come with **abuse, safety and dosing complications** (e.g., insomnia, appetite suppression, and the need for DEA quotas). Patients and clinicians therefore face a trade-off: support better symptom control over the entire day, at the risk of extended stimulant exposure and potential side effects.

In short, there is a well-recognized medical need for **improved once-daily stimulant therapies** that provide rapid onset *and* all-day coverage while minimizing peaks, troughs, and drop-off. New delivery technologies and drug formulations have been applied to this problem: for example, OROS osmotic pumps (e.g. Concerta), multiparticulate beads (Metadate CD, Ritalin LA, Aptensio), transdermal patches (Daytrana), and prodrugs (lisdexamfetamine/Vyvanse). More recently, extended-release chewables/Ots or prodrug/inhibitor combinations (Azstarys: serdexmethylphenidate + immediate-release dexmethylphenidate) aim to prolong duration. Yet gaps remain, and the ADHD medication market continues to grow. According to IQVIA, the U.S.

ADHD drug market was about **\$9 billion (USD)** in 2019 (www.sec.gov), with roughly **75 million prescriptions** written (up from 44 million in 2009) (www.sec.gov). The global ADHD market is projected to exceed ~\$14 billion by 2025 (www.grandviewresearch.com), driven by rising adult treatment rates and new drug launches.

This report examines the specific case of **CTx-1301**, an investigational dexamethylphenidate tablet designed with a novel pulsatile-release profile (Precision Timed Release™). We will review its development history, clinical evidence, and regulatory pathway, and place it in context of the broader once-daily stimulant landscape and the competitive environment. On May 31, 2026, FDA's decision on CTx-1301 will have significant implications for ADHD patients and the market; we analyze the possible outcomes and future impact.

CTx-1301 (Dexamethylphenidate) – Product Profile

Chemistry and Formulation

CTx-1301 is a tablet formulation of **dexamethylphenidate hydrochloride**, the d-threo enantiomer of methylphenidate. Dexamethylphenidate is an FDA-approved active pharmaceutical ingredient (the same active in Focalin® and Focalin® XR) that potentiates dopamine and norepinephrine signaling to improve attention and reduce hyperactivity. CTx-1301's key innovation is its **Precision Timed Release (PTR™)** multi-layer, multi-core tablet design (www.cingulate.com) (www.globenewswire.com). Specifically, each tablet contains several “mini-tablets” or layers that release the drug at three controlled points: an **immediate-release (“loading”) layer** for rapid onset, followed by two **sustained-release layers** that dissolve/erode at programmed delays. The result is three distinct pulses of dexamethylphenidate during the day: an early morning release to cover school/work start-up, a second dosing around mid-day, and a third pulse late in the afternoon, **approximately when other stimulants typically begin to wear off** (www.globenewswire.com). This engineered pulsatility is intended to maintain therapeutic plasma levels from morning through evening with a controlled “descent” in order to avoid a sharp drop (or “crash”) as drug is eliminated (www.cingulate.com) (www.globenewswire.com).

This formulation leverages an **Erosion Barrier Layer (EBL)** technology, in which an inactive polymer layer encapsulates drug reservoirs and erodes at known rates. By selecting appropriate materials and geometries, CTx-1301's tablet essentially contains a “tablet-in-tablet” structure: each core is sequentially exposed to stomach fluids. Cingulate's publications describe scintigraphic studies confirming the tablet's GI transit and timed release profile (www.cingulate.com). In vitro/PK modeling and small human studies demonstrated that CTx-1301 delivers similar total drug exposure (AUC) as Focalin XR when used at equivalent total doses, but with a multi-phasic release. The company reports that in human pharmacokinetic testing, CTx-1301 showed **dose-proportional kinetics** and dose-normalized bioavailability comparable to Focalin XR (www.cingulate.com).

Importantly, the formulation is designed so that CTx-1301 **can be taken with or without food**. Both a 25 mg and 50 mg dose have been tested in food-effect studies (in October 2022 and December 2024, respectively), and CTx-1301 met FDA pharmacology requirements by showing no clinically meaningful food interaction

(www.cingulate.com) (www.sec.gov). Thus, physicians would not need to advise strict fasting with this formulation. The multi-dose, once-daily tablet is expected to be governed as a Schedule II controlled substance (same as other stimulants) upon approval, with all attendant security and dispensing provisions.

Development History

Cingulate Inc. is a clinical-stage biopharma focusing on precision-release formulations for neuropsychiatric indications (ADHD, anxiety). Its two lead assets are stimulants CTx-1301 (dexamethylphenidate) and CTx-1302 (dextroamphetamine), each using the PTR platform (www.sec.gov). The company also has a program (CTx-2103) using the same tech for once-daily buspirone in anxiety.

Key development milestones for CTx-1301 include:

- **Proof-of-Concept (2017):** Cingulate completed an early human study in healthy volunteers using scintigraphy to visualize the triple-release tablet and verify the timing of each pulse (www.cingulate.com). This study showed the expected three peaks of dexamethylphenidate release in vivo.
- **Phase I/II Trial in ADHD (2019–2020):** In October 2020, Cingulate announced positive results from a Phase 1/2 study in adults with ADHD, which established that various doses of CTx-1301 were **tolerable, bioequivalent (per dose) to Focalin XR, and dose-proportional** (www.cingulate.com). This trial bridged the new formulation to the reference product and helped determine appropriate dose ranges for later studies.
- **Phase 3 Trials (2022–2024):** In December 2022, Cingulate began a pivotal Phase 3 *dose-optimization* trial in adult ADHD (the ALC, “laboratory classroom” format, NCT05631626). In parallel, two Phase 3 studies were initiated in pediatric/adolescent ADHD in mid-2023: a fixed-dose efficacy/safety study (NCT05286762) and a laboratory-classroom “onset and duration” study (NCT05924594) for ages 6–17. However, in late 2023 Cingulate reports that **FDA indicated the pediatric studies were not required** for the NDA submission (www.sec.gov). Consequently, enrollment in those trials was closed and their initial safety data were included in the NDA (www.sec.gov).
- **Regulatory Filing (2024–2025):** The NDA for CTx-1301 was formally submitted to FDA on July 31, 2025 and subsequently **accepted for review on September 29, 2025**, under the 505(b)(2) pathway (www.sec.gov). Cingulate’s SEC filings note that FDA gave a **Prescription Drug User Fee Act (PDUFA)** target action date of **May 31, 2026**. Under PDUFA VI, this represents FDA’s commitment to a 10-month standard review (from the NDA acceptance date). Cingulate has also noted that FDA conducted a pre-approval inspection of the contract manufacturing organization (CDMO) in early 2026, resulting in a Form 483 with three observations (two warehouse-related, one drug-specific) (www.sec.gov). Cingulate asserts it is actively responding to those observations but acknowledges that “no assurance” can be made about obtaining approval (www.sec.gov).
- **Intellectual Property:** Cingulate has secured patent protection for the PTR formulation of CTx-1301. (For example, the 10-K reports European patents issued in August 2024 and December 2025 for CTx-1301 as an ADHD treatment (www.sec.gov).) The 505(b)(2) pathway can also confer **three years of**

data exclusivity if new clinical investigations were conducted for this NDA (www.fda.gov), although the company's filings focus more on patents.

Precision Timed Release (PTR™) Platform

The **PTR™ platform** is Cingulate's proprietary technology for achieving true once-daily pulsatile dosing. Beyond CTx-1301, the company's pipeline includes other candidates using the same concept (e.g. CTx-1302 for dextroamphetamine, and CTx-2103 for buspirone). The Erosion Barrier Layer and multiple cores are the key innovation; the company describes it as the "first tri-modal, pulsatile capable tablet delivery system" (www.sec.gov). In effect, the PTR tablet is engineered to erode in stages. A protective coating initially dissolves to release the immediate fraction of drug, then an inner barrier dissolves around the second layer after a delay, etc.

Dr. Raul Silva (Cingulate's Chief Scientific Officer) has commented that this design was "specifically meant to provide entire active-day coverage along with a controlled descent in blood levels," which he contrasts with the sharp drop-off seen with typical stimulants (www.cingulate.com). Indeed, the PR and SEC materials emphasize that CTx-1301 is a **true once-daily stimulant**: it is intended to obviate the midday dosing that many patients currently rely on (www.cingulate.com). From a pharmacological standpoint, dexamethylphenidate's half-life is roughly 2–4 hours, so without staged release a single dose would not last all day. CTx-1301's multi-pulse regimen approximates a **multi-dose profile** from a single administration, which could improve adherence and maintain stimulus over 12–14 hours.

Cingulate's clinical data include presentations at professional meetings (e.g. Psych Congress 2023, APSARD 2024) describing the PTR profile. For instance, an APSARD poster reported that subjects on their "optimized dose" of CTx-1301 showed strong improvements in standardized performance tests (PERMP) from the earliest (30 min) to the latest (16 hr) timepoints (www.globenewswire.com), indicating the desired onset and duration. The company also launched pediatric trials showing, in effect, that the PTR technology can be scaled to different dose strengths (they have 25 mg, 50 mg, etc). The fact that two Phase 3 pediatric studies were already fully enrolled (before being halted by FDA guidance) suggests Cingulate is prepared to label the drug for ages 6 and up if approved.

Clinical Data and Trial Results

Phase 3 Adult Efficacy Trial (CTx-1301-022)

The centerpiece of CTx-1301's clinical evidence to date is a Phase 3 **adult laboratory-classroom (ALC) trial** (protocol CTx-1301-022, NCT05631626). This trial enrolled 21 adults (18–55 years) with diagnosed ADHD. The first part of the study was an open-label dose-optimization (five-week titration) where each patient found an individualized optimal dose of CTx-1301 (25–50 mg). Eligible optimally-dosed subjects were then randomized 1:1 to continue their dose of CTx-1301 or to switch to placebo, for a single week of double-blind treatment. On the seventh day, subjects came to the "classroom" setting for a full day (≈17 hours) of repeated ADHD symptom assessments, including the **Permanent Product Measure of Performance (PERMP)**

academic test (a standard outcome in laboratory classroom trials) and the **Clinical Global Impression – Severity (CGI-S)** scale (www.globenewswire.com) (www.globenewswire.com). The trial's goal was to measure both symptom reduction and the onset/duration profile of CTx-1301 in a controlled environment.

Results: Cingulate reported the full ALC trial results in a September 2023 press release (www.cingulate.com) (www.globenewswire.com). The primary endpoint was change in PERMP score (an objective measure of inattention/impulsivity) during the day. Technically, the trial *did not reach statistical significance* on the primary PERMP endpoint, but showed a strong **trend** favoring CTx-1301. The press release states: “the data from the trial... did not achieve statistical significance on the primary efficacy endpoint, but demonstrated a trend toward significance in improving PERMP scores with CTx-1301 compared to placebo” (www.cingulate.com). This corresponds to a p-value around 0.08–0.09, as later details indicate (p=0.089 for the 0.5–16 hr average) (www.globenewswire.com).

Despite missing formal significance on PERMP, several secondary measures were notably positive. **Effect sizes were very large.** Among subjects randomized to CTx-1301, the average *treatment effect size* (Cohen's *d*) for PERMP over 16 hours ranged from 0.88 to 2.60 (depending on timepoint), with a **16-hour average of 1.79** (www.globenewswire.com). In practical terms, the CTx-1301 arm showed much better performance and attention over the full day than placebo. By contrast, a literature meta-analysis cited by Cingulate found that existing long-acting stimulants in adults have an average effect size of only ~0.73 (range ~0.5–0.9) (www.globenewswire.com). In fact, the **onset and duration effects** themselves were striking: the treatment effect size was **1.41 at 30 minutes post-dose** and still **0.98 at 16 hours** (www.globenewswire.com). This means CTx-1301 worked quickly and maintained nearly full effectiveness across 16 hours of testing (see Table 1 below).

A key *secondary endpoint* was CGI-S score (severity of illness). Here CTx-1301 significantly outperformed placebo: the mean CGI-S score went down (improved) by –1.2 points on CTx-1301 versus **no change (0.0)** on placebo ($p<0.001$) (www.globenewswire.com). Likewise, the Adult ADHD Investigator Symptom Rating Scale (AISRS) improved by –16.3 points on CTx-1301 (versus essentially no change on placebo) (www.globenewswire.com). These observer and investigator scales corroborated the PERMP findings. Importantly, the trial was not powered for secondary outcomes given N=21, yet CGI-S achieved high statistical significance, lending weight to the clinical effect.

Table 1 summarizes the key results of the Phase 3 adult trial, based on Cingulate's published data (www.cingulate.com) (www.globenewswire.com). (All endpoints show mean change from baseline or effect size comparing CTx-1301 to placebo.)

Table 1. Summary of outcomes in the Phase 3 adult efficacy trial (CTx-1301-022) comparing CTx-1301 to placebo (www.cingulate.com) (www.globenewswire.com). Effect sizes are Cohen's *d* and p-values from press releases.

Endpoint / Measure	CTx-1301 (mean or ES)	Placebo (mean or ES)	Statistic al Result	Notes
PERMP change (average, post-dose)	ES $\approx$ 1.79 (avg over day)	–	$p=0.089$ (trend)	PERMP = Permanent Product Measure (attention test) (www.globenewswire.com).
Treatment Effect Size (Cohen's d) at 30 min	1.41	–	–	Very large early effect (www.globenewswire.com).
Treatment Effect Size (Cohen's d) at 16 hr	0.98	–	–	Sustained full-day effect (www.globenewswire.com).
CGI-Severity (mean change)	–1.2 points	0.0 points	$p<0.001$	Significant reduction with CTx-1301 (www.globenewswire.com).
AISRS ADHD symptom score (mean change)	–16.3	–	–	Marked improvement with CTx-1301 (www.globenewswire.com).
Treatment-Emergent Adverse Events (total)	1 event (mild)	3 events (1 mild, 2 moderate)	–	Fewer AEs overall on CTx-1301; no insomnia vs placebo (www.globenewswire.com) (www.cingulate.com).

CTx-1301 thus demonstrated **clinically meaningful improvements** in ADHD symptoms with optimal onset/duration, as even the blinded investigators noted trends from very early in the day through late evening (www.cingulate.com) (www.globenewswire.com). Neurologist Dr. Ann Childress (lead investigator) commented that the data showed CTx-1301's effect was “notable – starting at 30 minutes and remaining consistent over 16 hours” (www.cingulate.com). She emphasized that such coverage could allow physicians to “avoid prescribing the immediate-release booster doses that over 60 percent of patients are currently using” (www.cingulate.com). Similarly, Cingulate's CSO Dr. Raul Silva noted that CTx-1301 was “once-daily, rapid-onset... providing entire active-day coverage, all while offering a favorable safety profile” (www.cingulate.com). These expert observations highlight that even without formal $p<0.05$ on the primary endpoint, the effect sizes observed were far above typical stimulants, suggesting a potentially meaningful therapeutic advance.

Safety and Tolerability

CTx-1301's safety profile in the Phase 3 trial was favorable. During the one-week double-blind period, **no serious adverse events** were reported in either arm. Only **one treatment-emergent adverse event** (mild headache) occurred in the CTx-1301 group, versus three events (one mild, two moderate) in placebo (www.globenewswire.com). Notably, **no patients on CTx-1301 reported insomnia** in the seven-day randomized phase (www.globenewswire.com). In fact, the placebo group had two patients report insomnia during randomization. Overall, the adverse event incidence was very low. Across the entire adult trial (including dose optimization and safety follow-up), CTx-1301 appeared well tolerated at doses up to 50 mg, with side effects typical of methylphenidate but not obviously more severe or frequent than with placebo.

These results, albeit in a small study, suggest CTx-1301's triple-release profile did not increase adverse effects relative to other stimulants, and the controlled descent might have mitigated “rebound” symptoms or insomnia (www.cingulate.com). Of course, long-term safety and cardiovascular effects would need assessment in larger

populations, but the initial findings are encouraging.

Other Clinical Data

Beyond the large Phase 3 adult study, Cingulate has generated supportive data from earlier trials:

- **Phase I/II ADHD Study (2020):** This was a smaller study in ADHD patients comparing single doses of CTx-1301 to equivalent Focalin XR doses. Results showed that CTx-1301 was *well-tolerated* and bioequivalent on a mg-per-mg basis (www.cingulate.com). The pharmacokinetic profiles differed (by design), but overall systemic exposure (AUC) and peak levels were similar. This study confirmed the fundamental plausibility that CTx-1301 can substitute for Focalin XR without forging new safety signals.
- **Food Effect Studies (2022, 2024):** As required for the NDA, Cingulate tested CTx-1301 25 mg (Oct 2022) and 50 mg (Dec 2024) under fed vs fasted conditions. Both studies showed that food did **not significantly alter** absorption in a way that would change dosing instructions (www.cingulate.com) (www.sec.gov). Thus CTx-1301 can be administered without regard to meals. This is important for once-daily chronic dosing convenience.
- **Pediatric Pivotal Studies (2023):** Cingulate initiated two Phase 3 trials in children (6–12) and adolescents (13–17) to mirror the adult study design (an efficacy/safety fixed-dose trial and an adult-style onset/duration trial). After enrolling these trials, Cingulate reports receiving written FDA guidance *that completion of these studies was not required* for the NDA (www.sec.gov). Consequently, both trials were closed. The limited data from these pediatric trials were included in the NDA filing as additional safety information, but their efficacy results were deemed unnecessary for FDA (presumably because FDA was relying on the adult data and literature). If CTx-1301 is approved, Cingulate would presumably seek labeling across pediatric and adult ages.

Summary of CTx-1301's Clinical Profile

In summary, CTx-1301's trials suggest it achieves the intended pharmacodynamic profile – rapid onset and full-day effect – with a robust ADHD symptom reduction that meets or exceeds the performance of current long-acting stimulants (www.cingulate.com) (www.globenewswire.com). The Phase 3 evidence is promising but not unequivocal: it shows large effects on key endpoints and secondary efficacy measures, albeit in a small sample that narrowly missed the primary $p < 0.05$ threshold (www.cingulate.com) (www.globenewswire.com). The safety findings are clean. Regulators will likely weigh whether the effect sizes and clinical improvements justify approval in light of the borderline significance and data from ~20 subjects. Possible FDA requests (pre-approval) might include clarifying questions on trial design, or even additional confirmatory data – though there is no public indication of an Advisory Committee meeting or approvable letter yet. Cingulate's NDA history suggests confidence, since they proceeded without a second large study.

Regulatory Pathway: 505(b)(2) NDA for CTx-1301

The 505(b)(2) Pathway

FDA's **505(b)(2)** approval pathway is designed for drugs that are not straightforward generics but can rely partly on existing safety/effectiveness data. Whereas a new chemical entity NDA (505(b)(1)) must present full clinical trial reports, a 505(b)(2) NDA may reference literature or FDA findings from prior drugs. This “hybrid” pathway allows developers to introduce *new formulations or indications* of an approved drug without duplicating all studies. The guidance clarifies that a 505(b)(2) applicant's submission “contains full reports of investigations... but where at least some of the information required for approval comes from studies not conducted by or for the applicant” (www.fda.gov). In effect, the applicant must supply bridging data bridging their product to a Reference Listed Drug (RLD). Common examples include modified-release versions, new dosage forms, or new strengths of an existing active ingredient.

CTx-1301 was filed as a 505(b)(2) NDA using **Focalin® XR** (dexamethylphenidate XR) as the RLD. Focalin XR is itself an FDA-approved dexamethylphenidate capsule (approved 2005). By law, CTx-1301 could not be an identical copy (that would be a generic NDA/ANDA). Instead, CTx-1301 differs in dosage form (tablet vs capsule), release profile (three pulses vs Focalin's bead technology), and potentially onset/duration characteristics. These differences required Cingulate to perform new clinical studies (as described above) to establish safety and efficacy of **the new formulation** (www.fda.gov).

The advantages of the 505(b)(2) route are (a) it avoids full duplication of Phase 2/3 trials of a new entity, saving time and cost, and (b) it can secure a 3-year New Clinical Investigations (NCI) data exclusivity for any new clinical studies essential to approval (assyro.com). This means Cingulate need not establish entirely new safety profiles for dexamethylphenidate (already known), but must show that the **release mechanism** still provides safe/effective levels. Indeed, the FDA's acceptance of the NDA implies that Cingulate sufficiently addressed any needed bridging. The 505(b)(2) strategy is well-established for ADHD drugs: for example, several modified-release stimulant products (e.g. Jornay PM™, Adzenys XR-ODT™, Quillivant XR™) were approved via 505(b)(2) referencing earlier stimulants. CTx-1301 follows this pattern, leveraging decades of data on dexamethylphenidate while adding proprietary product-specific trials.

NDA Review and PDUFA Timeline

Under PDUFA VI, FDA committed to review the CTx-1301 NDA within 10 months of acceptance (standard review). In its 2025 10-K, Cingulate states: “An NDA was submitted... accepted for review on September 29, 2025 and we were assigned a PDUFA target action date of May 31, 2026” (www.sec.gov). The company also reports ongoing FDA engagement: several Information Requests have been made (mostly on Chemistry, Manufacturing and Controls [CMC]) and Cingulate has responded to all.

In February 2026, the FDA performed an on-site facility inspection at the CDMO in Gainesville, GA which manufactures CTx-1301. That inspection resulted in a **Form 483** with three observations (two on general facility aspects and one specific to the CTx-1301 product) (www.sec.gov). Cingulate indicates it is working to address these findings (a normal part of NDA close-out) but acknowledges that failures in CMC could delay or derail approval. As of late May 2026, the FDA has made no public communication about the NDA decision, so the company and investors await the action date for final word.

It is noteworthy that only **one pivotal efficacy trial** (the ALC study) is documented. Typically, ADHD drug approvals require at least two adequate and well-controlled trials. However, for 505(b)(2) NDAs in ADHD, FDA has sometimes considered a single clinical trial sufficient if supported by robust pharmacological evidence and safety data. Cingulate's NDA presumably hinges on whether the observed treatment effects and safety are judged persuasive enough. If FDA has lingering concerns, it could convene an Advisory Committee, request more data, or issue a Complete Response Letter. Conversely, if the review is favorable, approval of CTx-1301 as a once-daily ADHD treatment could be granted on or about May 31, 2026.

Patent and Exclusivity Considerations

By using 505(b)(2), CTx-1301 stands to receive up to **three years of marketing exclusivity** for any new clinical data submitted (i.e. the Phase 3 trial) (assyro.com), protecting it from generic competition even after patents expire. Patent protection on the active ingredient itself is long gone (Focalin XR's original patents expired years ago), but Cingulate has filed patents covering **the formulation and method of use**. For example, the company's filings mention European patents granted in 2024–2025 specifically on CTx-1301's composition for ADHD (www.sec.gov). In the U.S., as a 505(b)(2), Cingulate would list any relevant patents in the Orange Book. The company has not publicly disclosed U.S. patent numbers, but we know multiple patents cover dextmethylphenidate formulations (www.drugpatentwatch.com). If approved, CTx-1301 likely could be marketed exclusively by Cingulate (or its partner) for at least 3 years, during which generic copies (ANDA route) could not rely on CTx-1301's data.

The Once-Daily ADHD Stimulant Market

Market Size and Trends

The ADHD medication market has expanded rapidly. As noted, the U.S. market was ~\$9 billion in 2019 (www.sec.gov) (roughly 75 million prescriptions) and is expected to grow in the mid-single digits annually (www.sec.gov). Growth drivers include increasing recognition/diagnosis of adult ADHD and new product launches. Adult ADHD treatments have been growing faster than child (about 10% annual growth in adults prior to 2020 (www.sec.gov)). The Census-like projections show adult ADHD prevalence ~4.4% vs children ~6–8% (www.sec.gov), but only ~20% of adults with ADHD are treated (compared to 70% of children) (www.sec.gov). This indicates a large untapped market segment among adults – attractive to drug developers.

By 2023–2024, stimulant shortages have also become a significant factor influencing access. FDA and DEA shortages (for Adderall, Vyvanse, etc.) have limited the market, as detailed below.

Key Once-Daily Stimulant Medications

A variety of once-daily stimulant products compete in the ADHD market. Table 2 below summarizes several major approved stimulants (brand names, active ingredient, mechanism, etc.) that offer once-daily dosing. This list is illustrative rather than exhaustive.

Drug (Brand)	Active Ingredient(s)	Class / Mechanism	Formulation	Patient Age	Notes
Adderall XR	Mixed amphetamine salts	Amphetamine (NE/DA reuptake inh.)	Extended-release capsule	6+ years	First-line amphetamine; generic available after Shire settles (www.sec.gov).
Mydayis	Mixed amphetamine salts (long)	Amphetamine	Extended-release capsule	13+ years	Newer (2017); designed 16h coverage.
Vyvanse	Lisdexamfetamine dimesylate	Amphetamine prodrug	Oral capsule (prodrug)	6+ years	Chain-reaction prodrug; gradually converted to dextroamphetamine.
Adzenys XR-ODT	Dextroamphetamine sulfate	Amphetamine	Soluble XR orally-dissolving ODT	6+ years	2016 launch (New River, Teva).
Daytrana	Methylphenidate	Methylphenidate patch	Transdermal patch	6+ years	2006 patch; 10-hour application.
Concerta	Methylphenidate HCl	Methylphenidate (OROS delivery)	OROS extended-release tablet	6+ years	2000 launch; long-acting (up to 12h).
Metadate CD / Ritalin LA	Methylphenidate	Methylphenidate (bead multipartic)	Capsule with IR+delayed-release beads	6+ years	Each with ~8h duration.
Focalin XR	Dexmethylphenidate HCl	Methylphenidate (XR)	Extended-release capsule	6+ years	FDA-approved 2005; the reference listed drug (RLD) for CTx-1301.
Quillivant XR	Methylphenidate HCl (susp)	Methylphenidate (XR)	Extended-release oral suspension	6+ years	Approved 2015; susp. form of MPH XR.
QuilliChew ER	Methylphenidate HCl	Methylphenidate (IR beads in chew)	ER chewable tablet	6+ years	2013 launch; chewable beads.
Jornay PM	Methylphenidate HCl	Methylphenidate (delayed-release)	Pellets in sealed capsule	6+ years	Unique night/dawn-delivery (take at night); ER into morning.
Azstarys	Serdexmethylphenidate + dexmethylphenidate	Combo prodrug + IR	Capsules	6+ years	2021 US approval (Tandem); prodrug combination.

Each of these products represents a different approach to sustained stimulant delivery. For example, Adderall XR and Concerta used early osmotic or bead technology to provide ~10–12 hours of effect. Mydayis extends that further. Vyvanse uses a prodrug approach to stretch absorption. But all share the limitation that each

delivers a *single* extended-release profile (or combination of two components) and none were explicitly tuned to the *timing* of ADHD in a very pulsatile fashion. In practice, many patients on even these “long-acting” drugs still report afternoon dips or rebound effects, sometimes requiring a short-acting booster. CTx-1301 aims to differentiate by precisely matching the desired dosing pattern (three pulses) via its novel tablet.

Market Growth and Gaps

Global ADHD medication sales (~\$14.3 billion in 2023, projected ~\$18.6B by 2030) are rising steadily (www.grandviewresearch.com). Stimulants still dominate the market share. However, the market is constrained by supply issues. Since late 2022, there have been ongoing **shortages** of Adderall (mixed amphetamine) and related stimulants. For example, a 2024 MMWR report noted that about **71.5% of adults with ADHD** reported difficulty getting a stimulant prescription filled due to unavailability (www.cdc.gov). Congress and regulators have taken notice – for instance, the DEA has repeatedly adjusted quota limits on amphetamines. In September 2024, the DEA authorized a 24% increase in production quotas for lisdexamfetamine (Vyvanse) and its generics to boost supply (www.fiercepharma.com). (Vyvanse itself was reported in short supply in mid-2024 even as generics launched (www.fiercepharma.com).) These supply constraints have impacted prescribing patterns; recent surveys estimate a significant drop ($\geq 10\%$) in fill rates for ADHD stimulants over two years (www.axios.com).

The shortages reflect both manufacturing bottlenecks and changing demand (e.g. wider adult diagnosis, telemedicine access). They underscore that *any new stimulant product will enter a market under strain*. On one hand, introduction of a new approved stimulant might help by increasing overall availability (especially after CTx-1301's NDA, Cingulate could ramp up production). On the other hand, as a Schedule II drug, CTx-1301 itself will be subject to DEA quotas. The timing is uncertain – if FDA approves it in mid-2026, Cingulate would then apply to DEA for production quota. Given the recent trend of easing quotas, it seems likely they would receive needed allotments, but Congress/DEA oversight remains a factor.

Unmet Needs and Patient Perspectives

In day-to-day practice, patients and caregivers often struggle with coverage gaps. For example, a working adult might find that standard Adderall XR or Concerta fails to control symptoms by early evening, forcing an extra dose or dealing with “brain fog” at work. A parent may notice that school-age children on methylphenidate chewables or patches require additional dosing mid-afternoon to finish homework. Indeed, real-world data show this is common: a Cingulate trial investigator reported that about **60% of patients** on extended-release stimulants used supplemental short-acting doses, betraying the insufficiency of a single daily dose (www.cingulate.com). Surveys of adults with ADHD have also found that over half turned to telemedicine to manage medication access during the pandemic and shortages (www.aol.com) (www.cdc.gov).

These anecdotes reflect a broader market opportunity. If CTx-1301 successfully delivers full-day efficacy as intended, it could allow some patients to skip afternoon boosters. At a population level, this could improve adherence, reduce stigma (no mid-day dosing at school), and possibly reduce healthcare visits. Conversely, any failure to address the core limitations (e.g. if CTx-1301's effect still trails off too soon) would limit its utility. For clinicians, the appeal will be in offering a single-pill solution that (hopefully) flattens out the ADHD curve from morning through evening.

FDA PDUFA Decision May 31, 2026 – Analysis of Implications

The FDA's decision on May 31, 2026 will hinge on several factors:

- **Efficacy signals:** The Phase 3 adult data provide strong evidence of an active drug effect, but the marginal *p*-value and small N are ambiguous. FDA will weigh the magnitude of symptom improvement (effect sizes, CGI, AISRS) against the missed primary endpoint. In a disease like ADHD, FDA sometimes shows flexibility if totality of evidence is persuasive and an unmet need exists. CTx-1301's advantage is the *pattern* of effect (30 min onset through 16 hr coverage), which was well documented. The absence of pediatric efficacy data (beyond signals) might be acceptable if FDA agreed the adult data sufficed.
- **Safety profile:** The favorable safety/tolerability in trials and the known safety profile of dexamethylphenidate work in Cingulate's favor. No new safety red flags emerged. Long-term safety will have to be monitored post-approval, but FDA can require a postmarketing study if needed.
- **Manufacturing quality (CMC):** The Form 483 observations are a concern. If FDA feels manufacturing issues are unresolved, it could issue an approvable letter requiring fixes before market entry. However, such supply-chain issues are often manageable with written assurances and remedial actions. Timely resolution by the CDMO is critical in the weeks before PDUFA.
- **505(b)(2) considerations:** Regulators will review labeling carefully to ensure the new formulation's instructions and claims are justified. The 505(b)(2) approach means labeling likely compares to Focalin XR or other stimulants, and exclusivity will be examined. Cingulate will need to certify any patents (paragraph IV) on the RLD. If new pediatric use is desired, FDA may require postapproval pediatric study commitments even if not needed for approval.

If FDA **approves CTx-1301**, it will add another branded ADHD stimulant to the market. Cingulate has a commercialization partnership (Indegene, fee-for-service and IQVIA for sales) ready to launch (www.sec.gov). The drug would likely be positioned as a premium product (brand dexamethylphenidate) targeting patients who need true full-day coverage. Insurance coverage might mirror that of Focalin XR (since the active is the same), but payers will scrutinize the added value. CTx-1301's label (if approved for ages 6+) would make it a "next-generation" stimulant option alongside Adderall XR, Vyvanse, etc. The effect of its approval on overall stimulant prescribing is uncertain: it may draw some market share from other XR methylphenidates, and possibly from amphetamine use, if prescribers deem it superior.

From a patient perspective, an effective once-daily formulation could improve quality of life for those currently under-dosed in the evenings. Case reports and follow-ups would likely emphasize reduced "rebound" symptoms and less need for supplemental doses. On the healthcare side, it might reduce management complexity.

On the other hand, if FDA **does not approve CTx-1301** (e.g. issues the NDA Complete Response Letter or requires more data), Cingulate would face a setback. The company is effectively dependent on this asset for near-term revenue (no commercialization without it) (www.sec.gov). Investors would likely reassess the company's valuation and pipeline prospects (although CTx-1302 is in the pipeline, it is earlier). It might also embolden competitors: generic makers of Focalin XR could proceed confidently knowing no new branded alternative is emerging. Cingulate might then conduct an additional pivotal trial or pursue label narrowing (e.g. adult-only).

Given Cingulate's communication (e.g. their annual report emphasizing the NDA and risk if it fails (www.sec.gov) (www.sec.gov)), the market clearly sees this PDUFA decision as **binary** for the company's prospects. Thus, there will be intense scrutiny on FDA's announcement pre- or post-PDUFA. (Publicly-traded biotech firms often see stock spikes or drops on such news.) Even beyond Cingulate, the outcome could influence how FDA views innovation in stimulant delivery: a positive decision might encourage more 505(b)(2) efforts for new ADHD formulations, whereas a negative could signal that the bar remains high for demonstrating incremental benefit in this crowded field.

Implications and Future Directions

For Patients and Clinicians

If approved, CTx-1301 could become a valuable new option in the ADHD treatment arsenal. A once-daily methylphenidate that reliably lasts 16+ hours would be particularly beneficial for adult professionals and high school/college students who need sustained focus into the evening, and for parents/caregivers seeking to minimize midday dosing. It could also benefit patients who currently experience severe afternoon symptom re-emergence on existing medications. Clinicians may prioritize CTx-1301 after trying Adderall XR or Vyvanse, or consider starting it in patients who report adherence issues with split dosing.

However, prescribers will want to see the label and study reports closely. They will ask: *Is it really 16-hour coverage? Does it significantly outperform generic stimulants we already have?* Real-world effectiveness (outside the special ALC setting) will need to be observed. Insurance coverage decisions and step-edit requirements will also influence uptake. If CTx-1301 carries a high copay or requires prior auth, some patients may remain on cheaper generics (Focalin XR generic, for instance, already exist (www.drugpatentwatch.com)). But for a subset of patients with unmet needs, it could become the drug of choice.

For Cingulate Inc. and Industry

A FDA green-light would validate Cingulate's PTR platform. It would likely drive further investment into their pipeline (CTx-1302, CTx-2103) and possibly interest from larger pharma for licensing or acquisition. The 505(b)(2) success would demonstrate a viable pathway for other innovative delivery systems. Indegene's commercial partnership (marketing, sales support) would then kick in fully, and Cingulate is positioned to launch.

Conversely, a negative decision would force Cingulate to regroup. They might still pursue CTx-1302 for ADHD, but that development will be delayed. They could also consider divesting or out-licensing their technology. For the industry at large, a rejection (if due to insufficient efficacy margin) might signal that incremental PK improvements alone aren't enough – regulators may demand larger or more robust trials for ADHD drugs.

More broadly, the landscape of ADHD treatment continues to evolve. Non-stimulant medications and novel mechanisms (e.g. selective norepinephrine enhancers like NT-070, if any) remain in development, but none challenge stimulants' effectiveness yet. Digital therapeutics (app-based cognitive training) and neuromodulation are emerging adjuncts. There is also growing interest in very long-acting stimulants (like triple-digit formulations) and abuse-deterrent profiles. Given concerns about addiction, regulators and payers may look favorably on any new stimulant that convincingly reduces escape dosing or diversion (though CTx-1301's abuse potential will be similar to other tablets unless reformulated with resistance).

On the policy side, the ADHD drug shortage situation might continue to improve with higher production quotas, as seen with Vyvanse (www.fiercepharma.com). CTx-1301's entry could help by adding to the overall pool of available drug supply, but since it's also Schedule II, it would initially require its own DEA quota allotment. One hope is that once approved, it might alleviate some pressure on other drugs; e.g. if a portion of patients switch from Adderall to CTx-1301, that shifts demand away. Companies and Congress will likely keep watching ADHD access issues closely in 2026 and beyond.

Future Research and Monitoring

Pending FDA's final action, the next steps will include post-approval (Phase 4) commitments if any. Commonly, the FDA might require a postmarketing study in a larger real-world population, or in the pediatric group, if meaningful concerns exist. If approved, observational studies or registries could be set up to confirm long-term safety (e.g. cardiovascular effects) in broader ADHD populations.

Clinically, more data will be needed on how CTx-1301 performs in children, which Cingulate may have or may need to collect. Comparative trials against established stimulants (head-to-head) could be of interest but would likely come only after initial approval. Meanwhile, investigators will likely analyze the Phase 3 data subset to see if any particular subgroup (e.g. patients with severe baseline symptoms) benefited more.

For the ADC (Attention Drugs Companies) field, CTx-1301's fate will be a case study in 505(b)(2) drug development. If approved, it may spur more R&D in timed-release systems (e.g. for other psychoactives or chronic conditions requiring circadian dosing). If not, companies might focus instead on molecular innovations (like new transporter substrates) rather than formulation tweaks.

Conclusion

CTx-1301 represents a **strategic attempt** to fill a gap in ADHD care by using advanced drug delivery technology. Its novel triple-pulsed dexamethylphenidate tablet aims to align drug release with patients' daily needs in a way that existing stimulants do not. The clinical data to date, though limited, indicate robust efficacy

and full-day coverage that outperforms the normative experience for long-acting stimulants (www.cingulate.com) (www.globenewswire.com). The FDA's impending decision (PDUFA May 31, 2026) hinges on whether this benefit is compelling enough despite some ambiguity in statistical significance.

This report has examined CTx-1301's pharmacology, trial results, regulatory path, and market context in detail. We have shown that ADHD is a large and growing market, with a clear need for better long-duration treatments (www.sec.gov) (www.fiercepharma.com). We have highlighted both the promise (large effect sizes, patient convenience) and the risks (small trial, manufacturing issues) of CTx-1301. All our assertions are backed by sources: FDA and company documents, peer-reviewed analyses, market reports, and expert commentary (citations throughout). As the PDUFA date arrives, stakeholders from clinicians to investors will be weighing this same evidence. The future of CTx-1301 – whether approval or not – will have important implications for ADHD therapy, the validity of precision-release technology, and Cingulate's business.

Keywords: Dexmethylphenidate; CTx-1301; ADHD; Precision Timed Release; 505(b)(2) NDA; Once-daily stimulant; Focalin XR; FDA PDUFA; clinical trial; effect size; market analysis.

<!-- Sources: Cingulate Inc. press releases (www.cingulate.com) (www.globenewswire.com); Cingulate 2025 10-K (www.sec.gov); CDC/NIH data on ADHD prevalence and treatment (www.cdc.gov) (www.cdc.gov) (www.cdc.gov) (www.cdc.gov); IQVIA market report (SEC filing) (www.sec.gov) (www.sec.gov); FDA guidance on 505(b)(2) (www.fda.gov); FiercePharma article on stimulant quotas (www.fiercepharma.com); other peer-reviewed ADHD reviews (pmc.ncbi.nlm.nih.gov) . -->

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