Intra-Cellular THERAPIES

June 18, 2024

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Such forward-looking statements include statements regarding, among other things, our expectations regarding the commercialization of CAPLYTA; our plans to conduct clinical or non-clinical trials and the timing of developments with respect to those trials, including enrollment, initiation or completion of clinical conduct, or the availability or reporting of results; plans to make regulatory submissions to the FDA and the timing of such submissions; whether clinical trial results will be predictive of future real-world results; whether CAPLYTA will serve an unmet need; the goals of our development programs; and our beliefs about the potential utility of our product candidates. All such forward-looking statements are based on management's present expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These risks and uncertainties include, but are not limited to, the following: there are no guarantees that CAPLYTA will be commercially successful; we may encounter issues, delays or other challenges in commercializing CAPLYTA; whether CAPLYTA receives adequate reimbursement from third-party payors; the degree to which CAPLYTA receives acceptance from patients and physicians for its approved indications; challenges associated with execution of our sales activities, which in each case could limit the potential of our product; results achieved in CAPLYTA in the treatment of schizophrenia and bipolar depression following commercial launch of the product may be different than observed in clinical trials, and may vary among patients; challenges associated with supply and manufacturing activities, which in each case could limit our sales and the availability of our product; risks associated with our current and planned clinical trials; we may encounter unexpected safety or tolerability issues with CAPLYTA following commercial launch for the treatment of schizophrenia or bipolar depression or in ongoing or future trials and other development activities; there is no guarantee that a generic equivalent of CAPLYTA will not be approved and enter the market before the expiration of our patents; there is no guarantee that our planned supplemental NDA for the treatment of major depressive disorder (MDD) will be submitted or approved, if at all, on the timeline that we expect; our other product candidates may not be successful or may take longer and be more costly than anticipated; product candidates that appeared promising in earlier research and clinical trials may not demonstrate safety and/or efficacy in larger-scale or later clinical trials or in clinical trials for other indications; our proposals with respect to the regulatory path for our product candidates may not be acceptable to the U.S. Food and Drug Administration (FDA); our reliance on collaborative partners and other third parties for development of our product candidates; impacts on our business, including on the commercialization of CAPLYTA and our clinical trials, as a result of the COVID-19 pandemic, the conflicts in Ukraine and the Middle East, global economic uncertainty, inflation, higher interest rates or market disruptions; and the other risk factors detailed in our public filings with the Securities and Exchange Commission. All statements contained in this presentation are made only as of the date of this presentation, and the Company undertakes no duty to update this information unless required by law.

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Study 502
Topline Results

Lumateperone as Adjunctive Therapy in Patients with Major Depressive Disorder

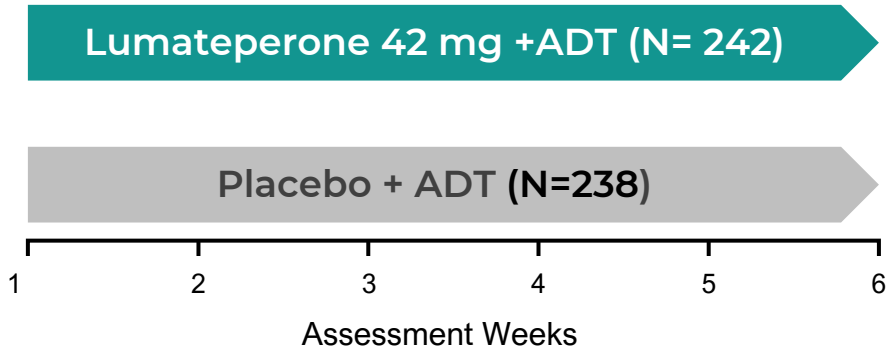
CAPLYTA (lumateperone) is FDA-approved for the treatment of depressive episodes associated with bipolar I or bipolar II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate and for the treatment of schizophrenia in adults. The safety and efficacy have not been established for other uses.

Study 502 Study Design

Objective: To evaluate lumateperone 42 mg as adjunctive treatment in adult patients with MDD who are having inadequate response to antidepressant monotherapy (ADT)

Global, multicenter, randomized, double-blind, placebo-controlled clinical trial

Screening Period
Up to 2 weeks



Safety Follow-up
1 week

Key inclusion criteria

- 18 to 65 years of age
- Meet DSM-5 criteria for MDD
- MADRS ≥ 24; CGI-S ≥ 4; QIDS-SR-16 ≥ 14
- Inadequate response (<50% improvement) to 1 to 2 courses of prior ADT

Primary Endpoint

Mean change in MADRS total score at Week 6

Key Secondary Endpoint

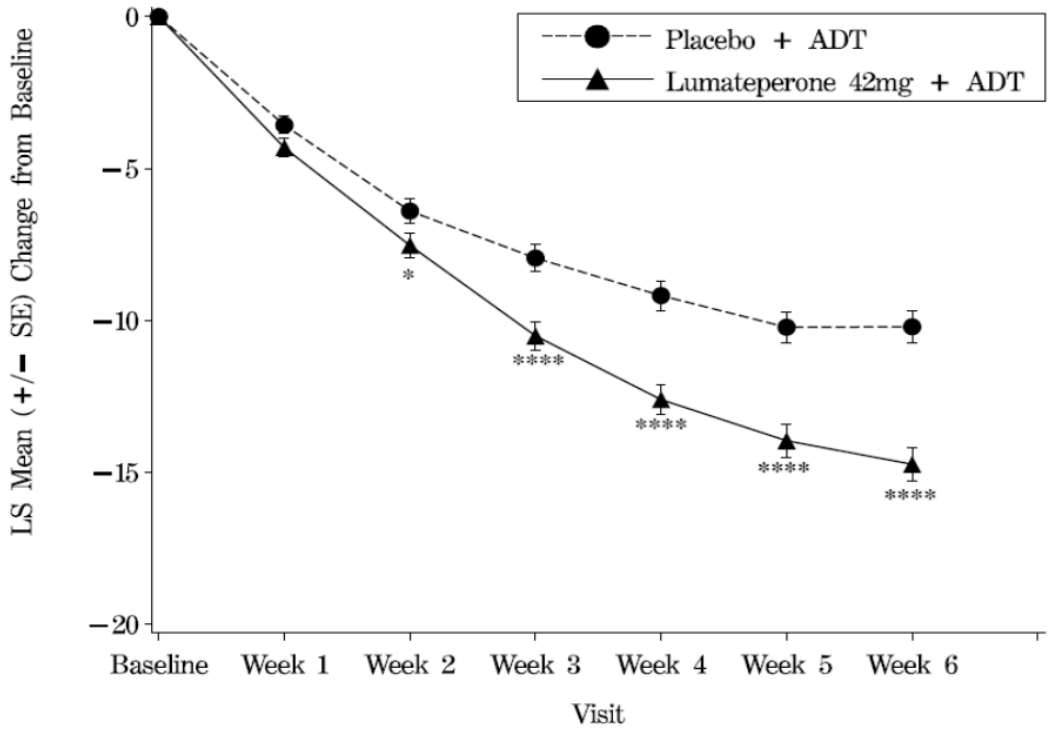
Mean change in CGI-S at Week 6

Demographics

	Lumateperone 42 mg + ADT (N=242)	Placebo + ADT (N=238)
Age (years), Mean ± SD	45.6 ± 12.79	46.4 ± 12.16
Sex, n(%)		
Male	73 (30.2)	73 (30.7)
Female	169 (69.8)	165 (69.3)
Race, n (%)		
White	235 (97.1)	223 (93.7)
Black or African American	6 (2.5)	8 (3.4)
Asian	1 (0.4)	3 (1.3)
Other	0	4 (1.7)

Lumateperone Demonstrated a Statistically Significant Reduction on the MADRS Total Score Compared to Placebo at Week 6

MADRS Total Score



LS mean difference vs placebo

-4.5 points

p < 0.0001

(actual p=0.0000000072782)

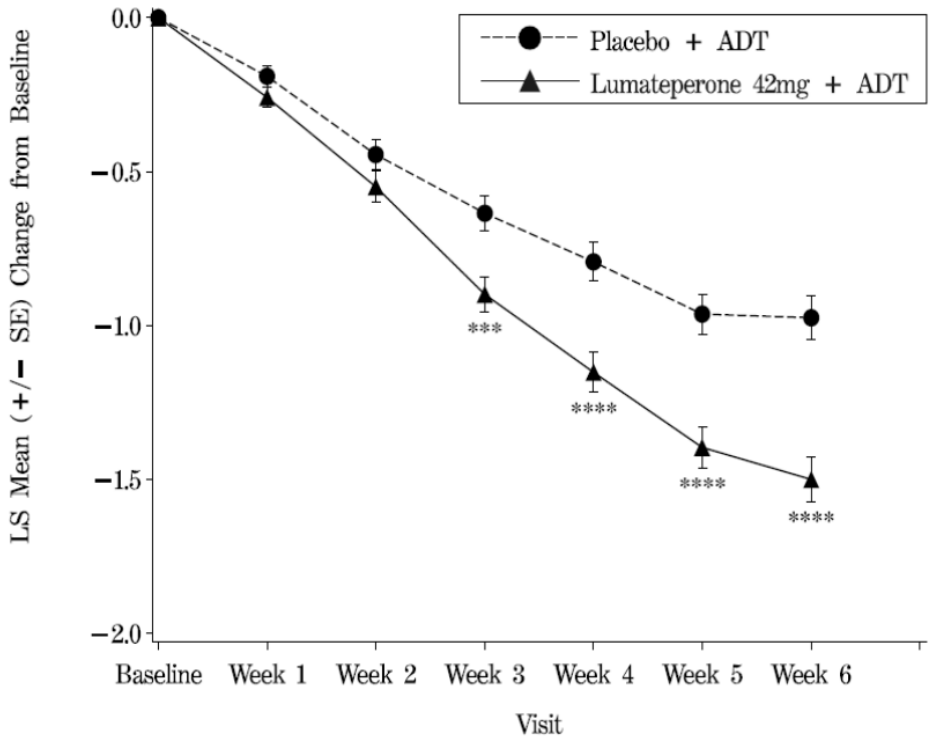
Cohen's d effect size:

0.56

MADRS: Montgomery-Åsberg Depression Rating Scale
Mean baseline MADRS total scores for lumateperone 42 mg and placebo were 30.8 and 31.5, respectively
mITT population: Lumateperone N=232, Placebo N=237
*p<0.05 ****p<0.0001

Lumateperone Demonstrated a Statistically Significant Reduction on the CGI-S Score Compared to Placebo at Week 6

CGI-S Score



p < 0.0001

(actual p=0.0000001470207)

Cohen's d effect size:

0.51

CGI-S: Clinical Global Impression Scale
Mean baseline CGI-S total scores for lumateperone 42 mg and placebo were 4.6 and 4.7, respectively
mITT population: Lumateperone N=232, Placebo N=237
***p<0.001 ****p<0.0001

Lumateperone Robustly Improved Depressive Symptoms as Reported by Patients

Change From Baseline to Day 43 in QIDS-SR-16 Total Score

Measurement Statistics	Lumateperone 42 mg + ADT (N=242)	Placebo + ADT (N=238)
Baseline, Mean (SD)	17.9 (2.56)	18.0 (2.48)
Change from Baseline to Day 43		
n	234	232
LS Mean (SE)	-7.9 (0.35)	-5.7 (0.35)
LSMD vs Placebo (SE)	-2.2 (0.46)	—
95% CI	(-3.12, -1.33)	—
P-Value	<0.0001 (actual p=0.0000014498357)	—

QIDS-SR-16: Quick Inventory of Depressive Symptomatology Self Report

Favorable Safety and Tolerability Profile Generally Consistent with Prior Lumateperone Trials

- Lumateperone 42 mg plus ADT was generally safe and well tolerated in patients with MDD
- Adverse events generally consistent with prior lumateperone studies
  - Most common adverse events (≥ 5% lumateperone group and greater than twice placebo): dizziness, somnolence, dry mouth, nausea, diarrhea, and fatigue
  - Adverse events were mostly mild to moderate and resolved within the duration of the study
- One serious adverse event reported in the lumateperone group during the double-blind treatment period that was not drug-related (polypectomy in pre-planned colonoscopy)

Lumateperone Adjunctive MDD Program Highlights

- Strong and consistent efficacy across **two positive Phase 3** pivotal trials

Primary Endpoint: Change from baseline vs. placebo on the MADRS Total Score at Week 6 (mITT study population)

		Least Squares (LS) MeanReduction vs. Baseline[1]	LS mean difference[1]	p value	Cohen's d effect size
STUDY 501	Lumateperone 42 mg +ADT	14.7	-4.9	<0.0001	0.61
	placebo +ADT	9.8			
STUDY 502	Lumateperone 42 mg+ADT	14.7	-4.5	<0.0001	0.56
	placebo +ADT	10.2			

[1] rounded to nearest tenth; ADT: Antidepressant therapy

- Across both trials, lumateperone 42 mg was also significant on the CGI-S (key secondary endpoint) as well as on the QIDS-SR-16 (patient-rated scale)
- Adverse events were generally similar to prior studies of lumateperone
- In the pooled safety data of Studies 501 and 502, the most common adverse events (≥5% and greater than twice placebo) with lumateperone versus placebo were: dizziness (16.6% vs 5.0%), dry mouth (12.6% vs 3.3%), somnolence (12.2% vs 2.3%), nausea (8.5% vs 4.0%) and fatigue (7.2% vs 1.2%)
- Lumateperone 42 mg plus antidepressant was generally safe and well tolerated in patients with MDD

Thank you