UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 31, 2018

ACADIA Pharmaceuticals Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-50768**	**061376651**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3611 Valley Centre Drive, Suite 300
San Diego, California **92130**
(Address of principal executive offices) **(Zip Code)**

Registrant's telephone number, including area code: (858) 558-2871

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. of Form 8-K):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On October 31, 2018, ACADIA Pharmaceuticals Inc. announced positive top-line results from CLARITY, a randomized, double-blind, placebo-controlled multi-center, sequential parallel comparison design study in major depressive disorder (MDD). A copy of ACADIA's press release announcing the top-line results is attached as Exhibit 99.1.

Trial Design and Top-line Results

CLARITY was a Phase 2, 10-week, randomized, double-blind, placebo-controlled, multi-center, 2-stage sequential parallel comparison design (SPCD) study that evaluated the safety, tolerability and efficacy of pimavanserin (34 mg once daily) as an adjunctive treatment in patients with MDD who had inadequate response to a stable dose of standard antidepressant therapy with either a selective serotonin reuptake inhibitor (SSRI) or a serotonin norepinephrine reuptake inhibitor (SNRI). The study was conducted in collaboration with the MGH Clinical Trials Network & Institute and randomized 207 patients across 28 clinical research centers in the United States.

Consistent with the SPCD design, CLARITY was conducted in two five-week sequential stages. Eligible subjects continued receiving their SSRI/SNRI antidepressant at a stable dose for the duration of the study. Patients were randomly assigned (1:3) to pimavanserin 34 mg/day or placebo in Stage 1. Placebo non-responders in Stage 1 (defined as HAMD-17 total score >14 and a percent-reduction from baseline in HAMD-17 total score of <50% at week 5) were re-randomized (1:1) to receive pimavanserin 34 mg/day or placebo. The primary endpoint of the study was the change in HAMD-17 total score for Stage 1 and Stage 2. Treatment differences from Stage 1 and Stage 2 were combined as weighted averages.

In the trial, pimavanserin met the overall primary endpoint of the weighted average results of Stage 1 and Stage 2 by significantly reducing the HAMD-17 total score compared to placebo (p=0.039). In addition, in Stage 1 (n=207) patients on pimavanserin demonstrated a highly significant improvement in HAMD-17 (p=0.0003). Importantly, this group of patients saw a benefit over placebo in the first week of treatment (p=0.0365). Stage 2 (n=58) results did not demonstrate significant separation in this small set of placebo non-responders.

On the key secondary endpoint, pimavanserin demonstrated statistically significant reductions compared to placebo in the Sheehan Disability Scale (SDS) score (p=0.004). Positive results were also observed for seven other secondary endpoints listed below with nominal p values: Clinical Global Impression-Severity (p=0.0084), Clinical Global Impression-Improvement (p=0.0289), Short Form-12 Mental Component Summary (p<0.0001), Karolinska Sleepiness Scale (p=0.0205), Massachusetts General Hospital Sexual Functioning Index (p=0.0003), Barratt Impulsiveness Scale (p=0.0075), as well as response rates (p=0.0065), defined as a 50% or greater reduction on the HAMD-17 total scale.

A post-hoc comparison between pimavanserin (n=51) and placebo (n=123) for patients consistently receiving either placebo or pimavanserin for the entire 10-week period also yielded meaningful separation with positive p-values at all weeks starting from week 2 to week 10 in favor of pimavanserin for both the primary endpoint, HAMD-17 (week 10, p=0.0076), and the key secondary endpoint, SDS (week 10, p=0.0094).

Safety and Tolerability

In CLARITY, pimavanserin was generally well-tolerated. Discontinuations due to adverse events were 1.2% for pimavanserin and 3.2% for placebo. One subject in each of the pimavanserin and placebo groups reported serious adverse events (SAEs). These SAEs were deemed not to be related to the study drug by the investigators and both subjects completed the study. No deaths were reported in the study.

Item 9.01 Financial Statements and Exhibits.

(d) The following exhibit is furnished herewith:

99.1 Press release dated October 31, 2018

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: October 31, 2018

ACADIA Pharmaceuticals Inc.

By: /s/ Austin D. Kim
Name: Austin D. Kim
Title: Executive Vice President, General Counsel & Secretary

ACADIA Pharmaceuticals Announces Positive Top-line Results from Phase 2 CLARITY Trial of Pimavanserin for Adjunctive Treatment in Patients with Major Depressive Disorder (MDD)

- Pimavanserin met primary endpoint with statistically significant overall improvement in HAMD-17 total score compared to placebo (p=0.039)

- Pimavanserin met key secondary endpoint with statistically significant overall improvement in Sheehan Disability Scale compared to placebo (p=0.004)

- Positive results also observed on seven additional secondary endpoints including responder rate, improvement in sexual function, and reduction in daytime sleepiness

- ACADIA to initiate Phase 3 program in adjunctive MDD in 1H 2019

- Conference call and webcast to be held today at 8:30 a.m. Eastern Time

SAN DIEGO, CA, October 31, 2018 – ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD) today announced positive top-line results from CLARITY, a randomized, double-blind, placebo-controlled, multi-center, sequential parallel comparison design (SPCD) study in major depressive disorder (MDD). In the study, 207 adult patients with a confirmed inadequate response to existing first-line SSRI or SNRI therapy for MDD received adjunctive treatment of either 34 mg pimavanserin or placebo in addition to pre-existing first-line therapy for five weeks (Stage 1). Those patients who did not show a response to placebo in Stage 1 were re-randomized to receive either pimavanserin or placebo for a second five week treatment period (Stage 2).

In the trial, pimavanserin met the overall primary endpoint of the weighted average results of Stage 1 and Stage 2 by significantly reducing 17-item Hamilton Depression Rating Scale (HAMD-17) total score compared to placebo (p=0.039). In addition, in Stage 1 (n=207) patients on pimavanserin demonstrated a highly significant improvement in HAMD-17 (p=0.0003). Importantly, this group of patients saw a benefit over placebo in the first week of treatment (p=0.0365). Stage 2 (n=58) results did not demonstrate significant separation in this small set of placebo non-responders.

On the key secondary endpoint, pimavanserin demonstrated statistically significant reductions compared to placebo in the Sheehan Disability Scale (SDS) score (p=0.004).

Positive results were also observed for seven of the eleven other secondary endpoints listed below with nominal p-values: Clinical Global Impression-Severity (p=0.0084), Clinical Global Impression-Improvement (p=0.0289), Short Form-12 Mental Component Summary (p<0.0001), Karolinska Sleepiness Scale (p=0.0205), Massachusetts General Hospital Sexual Functioning Index (p=0.0003), Barratt Impulsiveness Scale (p=0.0075), as well as response rates (p=0.0065), defined as a 50% or greater reduction on the HAMD-17 total score.

In this Phase 2 study, pimavanserin was generally well-tolerated. Discontinuations due to adverse events were 1.2% for pimavanserin and 3.2% for placebo. One subject in each of the pimavanserin and placebo groups reported serious adverse events (SAEs). These SAEs were deemed not to be related to the study drug by the investigators and both subjects completed the study. No deaths were reported in the study.

“We are pleased with the robustness of the data from our Phase 2 CLARITY trial, which shows significant promise for patients with MDD, including early and sustained antidepressant response over placebo, decreased daytime sleepiness, no meaningful weight gain, and improved sexual function. This is important because most people with MDD do not respond to initial antidepressant therapies and experience significant unwanted side effects,” said Serge Stankovic, M.D., M.S.P.H., ACADIA’s Executive Vice President, Head of Research & Development. “Pimavanserin is a selective serotonin inverse agonist, or SSIA, that shows great potential as an antidepressant. We look forward to engaging with the FDA and initiating a Phase 3 program in the first half of 2019.”

“The results of this study suggest pimavanserin may represent a novel approach to adjunctive treatment for patients suffering from major depressive disorder. The selective serotonergic mechanism of action may provide additional benefit for patients who do not adequately respond to SSRI or SNRI treatment,” said Professor Maurizio Fava, M.D., Executive Vice Chair, Department of Psychiatry, Massachusetts General Hospital (MGH) and Associate Dean for Clinical & Translational Research, Harvard Medical School. “The majority of patients with MDD do not respond adequately to initial antidepressant therapy and the treatment effect seen in this study combined with a favorable tolerability profile provides evidence that adjunctive therapy with pimavanserin may benefit patients suffering from inadequate response in major depressive disorder.”

About CLARITY

CLARITY was a Phase 2, 10 week, randomized, double-blind, placebo-controlled, multi-center, 2-stage sequential parallel comparison design (SPCD) study that evaluated the safety, tolerability, and efficacy of pimavanserin (34 mg once daily) as an adjunctive treatment in patients with MDD who had an inadequate response to a stable dose of standard antidepressant therapy with either a selective serotonin reuptake inhibitor (SSRI) or a serotonin norepinephrine reuptake inhibitor (SNRI). The study was conducted in collaboration with the MGH Clinical Trials Network & Institute (CTNI) and randomized 207 patients across 28 clinical research centers in the United States.

Consistent with the SPCD design, the study was conducted in two, five week sequential stages. Eligible subjects continued receiving their SSRI or SNRI antidepressant at a stable dose for the duration of the study. Patients were randomly assigned (1:3) to pimavanserin 34 mg/day or placebo in Stage 1. Placebo non-responders in Stage 1 (defined as HAMD-17 total score >14 and a percent-reduction from baseline in HAMD-17 total score of <50% at week 5) were re-randomized (1:1) to Stage 2 to receive pimavanserin 34 mg/day or placebo. The primary endpoint of the study was the change in HAMD-17 total score for Stage 1 and Stage 2. Treatment differences from Stage 1 and Stage 2 were combined as weighted averages.

A post-hoc comparison between pimavanserin (n=51) and placebo (n=123) for patients consistently receiving either placebo or pimavanserin for the entire 10 week period also yielded meaningful separation with positive p-values at all weeks starting from week 2 to week 10 in favor of pimavanserin for both the primary endpoint, HAMD-17 (week 10, p=0.0076), and the key secondary endpoint, SDS (week 10, p=0.0094).

Conference Call and Webcast Information

ACADIA will discuss top-line results from its Phase 2 trial of pimavanserin for adjunctive treatment of patients with major depressive disorder via conference call and webcast today at 8:30 a.m. Eastern Time. The conference call can be accessed by dialing 855-638-4820 for participants in the U.S. or Canada and 443-877-4067 for international callers (reference passcode 8786247). A telephone replay of the conference call may be accessed through November 30, 2018 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 8786247). The conference call will also be webcast live on ACADIA's website, www.acadia-pharm.com, in the investors section and archived until November 30, 2018.

About Major Depressive Disorder (MDD)

According to the National Institute of Mental Health, MDD affects approximately 16 million adults in the United States[1], with approximately 2.5 million adults treated with adjunctive therapy[2,3]. MDD is a condition characterized by depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities for more than two weeks, as well as impaired social, occupational or other important functioning. The majority of people who suffer from MDD do not respond adequately to initial antidepressant therapy[4].

About Pimavanserin

Pimavanserin is a selective serotonin inverse agonist (SSIA) preferentially targeting 5-HT_{2A} receptors. These receptors are thought to play an important role in depression, psychosis, and other neuropsychiatric disorders. ACADIA is evaluating pimavanserin in an extensive clinical development program across multiple indications with significant unmet need including dementia-related psychosis, schizophrenia inadequate response, schizophrenia-negative symptoms, and major depressive disorder. Pimavanserin (34 mg) was approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis by the U.S. Food and Drug Administration in April 2016 under the trade name NUPLAZID®. NUPLAZID is not approved for the adjunctive treatment of patients with major depressive disorder.

About ACADIA Pharmaceuticals

ACADIA is a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders. ACADIA has developed and is commercializing the first and only medicine approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. In addition, ACADIA has ongoing clinical development efforts in additional areas with significant unmet need, including dementia-related psychosis, schizophrenia inadequate response, schizophrenia-negative symptoms, major depressive disorder, and Rett syndrome. This press release and further information about ACADIA can be found at: www.acadia-pharm.com.

Forward-Looking Statements

Statements in this press release that are not strictly historical in nature are forward-looking statements. These statements include, but are not limited to, statements related to: the potential benefits of pimavanserin as adjunctive treatment for MDD or other central nervous system disorders as well as the potential results of clinical trials of pimavanserin in other indications. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks and uncertainties inherent in drug discovery, development, approval and commercialization, and the fact that past results of clinical trials may not be indicative of future trial results. For a discussion of these and other factors, please refer to ACADIA's annual report on Form 10-K for the year ended December 31, 2017 as well as ACADIA's subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and ACADIA undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

References

[1]National Institute of Mental Health. (2017). Major Depression. Retrieved from http://www.nimh.nih.gov/health/statistics/major-depression.shtml.

[2]IMS NSP, NPA, NDTI MAT-24 month data through Aug-2017.

[3]PLOS One, Characterization of Treatment Resistant Depression Episodes in a Cohort of Patients from a US Commercial Claims Database, Oct 2013, Vol 8, Issue 10.

[4]Rush AJ, et al. (2007) Am J. Psychiatry 163:11, pp. 1905-1917 (STAR*D Study).

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