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): July 20, 2020

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

Delaware	**000-50768**	**06-1376651**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(IRS Employer Identification No.)**

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**ACAD**	**The Nasdaq Stock Market LLC**

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.

(a) On July 20, 2020, ACADIA Pharmaceuticals Inc. (the "Company") announced that the U.S. Food and Drug Administration (FDA) has accepted for filing its supplemental New Drug Application (sNDA) for NUPLAZID® (pimavanserin) for the treatment of hallucinations and delusions associated with dementia-related psychosis (DRP).

The FDA has assigned a standard review with a PDUFA (Prescription Drug User Fee Act) action date of April 3, 2021. The FDA has also informed the Company that it has not identified any potential review issues at this point in their evaluation and at this time they are not planning to hold an Advisory Committee meeting.

The sNDA is supported by results from the pivotal Phase 3 HARMONY study, which met its primary endpoint, demonstrating that pimavanserin significantly reduced the risk of relapse of psychosis by 2.8 fold compared to placebo (hazard ratio = 0.353; one-sided p=0.0023). The sNDA also includes positive efficacy results from two additional placebo-controlled studies, both of which met their respective primary endpoints: The Phase 2 (-019) study in patients with Alzheimer's disease psychosis and the Phase 3 (-020) study in patients with Parkinson's disease psychosis. The sNDA includes a large safety database from completed and ongoing studies representing over 1500 patients with neurodegenerative disease.

(b) Also on July 20, 2020, the Company announced top-line results from its 298 patient Phase 3 CLARITY study which combined two identical, double-blind, placebo-controlled studies evaluating the efficacy, safety and tolerability of pimavanserin as an adjunctive treatment for major depressive disorder (MDD). The combined efficacy and safety analysis was pre-specified prior to data unblinding following feedback from the FDA.

The study did not achieve statistical significance on the primary endpoint which was the 17-item Hamilton Depression Rating Scale (HAMD-17) total score change from baseline to week 5. Pimavanserin 34 mg, given once-daily as an adjunctive treatment to standard antidepressant therapy was associated with a mean reduction of 9.0 in HAMD-17 total score compared to 8.1 for placebo as an adjunctive treatment (p=0.296).

Positive results were observed on the key secondary endpoint, the Clinical Global Impression – Severity (CGI-S) score, a clinician assessment of a patient's severity of depression (nominal p=0.042). In the study, pimavanserin was generally well-tolerated when added to existing antidepressant therapy, and similar rates of adverse events were observed between pimavanserin (58.1%) and placebo (54.7%).

The Phase 3 CLARITY study is a combination of CLARITY-2 and CLARITY-3, which were both 6-week, parallel-designed, randomized, double-blind, placebo-controlled, multi-center studies designed to evaluate the efficacy and safety of pimavanserin as adjunctive treatment in patients with MDD who have an inadequate response to standard antidepressant therapy with either a selective serotonin reuptake inhibitor (SSRI) or a serotonin norepinephrine reuptake inhibitor (SNRI). A total of 298 patients were randomized to receive six weeks of oral treatment with either 34 mg of pimavanserin or placebo, once daily, in addition to their ongoing antidepressant. The primary endpoint was change from baseline on the HAMD-17 total score.

Copies of ACADIA's press releases issued July 20, 2020 are furnished herewith as Exhibits 99.1 and 99.2.

Forward-Looking Statements

Statements in this Current Report 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 major depressive disorder, the hallucinations and delusions associated with dementia-related psychosis or other central nervous system disorders, the potential results of clinical trials of pimavanserin in other indications, and the expected growth in patients with dementia. 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 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, 2019 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 Current Report to reflect events or circumstances after the date hereof, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release dated July 20, 2020, "ACADIA Announces U.S. FDA Accepted for Filing the Supplemental New Drug Application for NUPLAZID® (pimavanserin) for the Treatment of Hallucinations and Delusions Associated with Dementia-Related Psychosis"
99.2	Press release dated July 20, 2020, "ACADIA Pharmaceuticals Announces Top-line Results from the Phase 3 CLARITY Study Evaluating Pimavanserin for the Adjunctive Treatment of Major Depressive Disorder"
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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: July 20, 2020

ACADIA Pharmaceuticals Inc.

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

EXHIBIT 99.1

ACADIA Announces U.S. FDA Accepted for Filing the Supplemental New Drug Application for NUPLAZID® (pimavanserin) for the Treatment of Hallucinations and Delusions Associated with Dementia-Related Psychosis

- If approved, NUPLAZID would be the first and only treatment indicated for dementia-related psychosis

- Prescription Drug User Fee Act (PDUFA) date set for April 3, 2021

- Conference call and webcast to be held today at 4:30 p.m. Eastern Time

SAN DIEGO – July 20, 2020 – ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing its supplemental New Drug Application (sNDA) for NUPLAZID® (pimavanserin) for the treatment of hallucinations and delusions associated with dementia-related psychosis (DRP).

“We are pleased that the FDA has accepted our sNDA for filing and we will be working closely with the FDA to facilitate completion of the review in a timely manner,” said Steve Davis, ACADIA’s Chief Executive Officer. “If approved, NUPLAZID would be the first therapy indicated for the treatment of hallucinations and delusions associated with dementia-related psychosis. We look forward to potentially bringing this important treatment advancement to patients, caregivers and physicians.”

The FDA has assigned a standard review with a PDUFA (Prescription Drug User Fee Act) action date of April 3, 2021. The FDA has also informed the company that it has not identified any potential review issues at this point in their evaluation and at this time they are not planning to hold an Advisory Committee meeting.

Dementia is highly prevalent, affecting approximately 8 million people in the U.S., and is expected to grow as the population ages. Approximately 30 percent, or 2.4 million people, experience dementia-related psychosis and only half of them, or 1.2 million, are diagnosed and treated[1,2].

The sNDA is supported by results from the pivotal Phase 3 HARMONY study, which met its primary endpoint, demonstrating that pimavanserin significantly reduced the risk of relapse of psychosis by 2.8 fold compared to placebo (hazard ratio = 0.353; one-sided p=0.0023). The sNDA also includes positive efficacy results from two additional placebo-controlled studies, both of which met their respective primary endpoints: The Phase 2 (-019) study in patients with Alzheimer’s disease psychosis and the Phase 3 (-020) study in patients with Parkinson’s disease psychosis. The sNDA includes a large safety database from completed and ongoing studies representing over 1500 patients with neurodegenerative disease.

NUPLAZID was approved in the U.S. in 2016 as the first and only treatment for hallucinations and delusions associated with Parkinson’s disease psychosis. Pimavanserin was granted Breakthrough Therapy Designation by the FDA for the treatment of hallucinations and delusions associated with DRP in October 2017.

Conference Call and Webcast Information

ACADIA will provide a corporate update via conference call and webcast today at 4:30 p.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 1486597). A telephone replay of the conference call may be accessed through July 27, 2020 by dialing 855- 859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 1486597). The conference call will also be webcast live on ACADIA's website, www.acadia-pharm.com, in the investors section and will be archived there until August 20, 2020.

About HARMONY

HARMONY was a Phase 3 study designed to evaluate the efficacy and safety of pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis across a broad population of patients with the most common clinically diagnosed subtypes of dementia including: Alzheimer's disease, dementia with Lewy bodies, Parkinson's disease dementia, vascular dementia, and frontotemporal dementia spectrum disorders. A total of 392 patients were enrolled in the study, with an average age of 74.5 years and a mean Mini-Mental State Examination (MMSE) score of 16.7. The primary endpoint in the study was time to relapse in the double-blind period as represented by the Kaplan-Meier curve and the hazard ratio. Top-line results were presented at the Clinical Trials on Alzheimer's Disease (CTAD) Meeting in December 2019.

The HARMONY study included a 12-week open-label stabilization period during which patients with dementia-related psychosis began treatment with pimavanserin 34 mg once daily. In the open-label period, a significant majority (61.8%) of eligible subjects (N=351) met the sustained treatment response criteria at Week 8 and Week 12 and entered the double-blind period. Following the open-label period, patients who met pre-specified criteria for treatment response were then randomized into the double-blind period of the study to continue their pimavanserin dose (34 mg or 20 mg per day) or switched to placebo and followed for up to 26 weeks or until a relapse of psychosis occurred. Pimavanserin met its primary endpoint and was stopped at the pre-planned interim analysis for positive efficacy, demonstrating that pimavanserin significantly reduced the risk of relapse of psychosis by 2.8 fold compared to placebo (hazard ratio = 0.353; one-sided p=0.0023).

Pimavanserin was well-tolerated over the entire nine-month study duration, and pimavanserin treatment was not associated with a decline in cognition, as measured by the MMSE score, or the onset or worsening of extrapyramidal symptoms, as measured by the Extrapyramidal Symptom Rating Scale A (ESRS-A) score, compared to placebo. In the double-blind period, low rates of adverse events were observed, 41.0% of patients on pimavanserin and 36.6% on placebo. Discontinuations in the double-blind period due to adverse events were low, 2.9% for pimavanserin and 3.6% for placebo. Rates of serious adverse events were also low, 4.8% in the pimavanserin group and 3.6% in the placebo group. One death was reported in the open-label period and one death was reported in the pimavanserin group during the double-blind period. Investigators determined neither death was related to the study drug.

About Dementia-Related Psychosis

Approximately 8 million people in the United States are living with dementia, a condition with a core feature of declining cognition (changes in memory, decision-making abilities, language, etc.) resulting in functional impairment. Dementia is a manifestation of an underlying condition which is often progressive and neurodegenerative in nature.[3] In addition to cognitive decline, dementing illnesses almost universally lead to neuropsychiatric symptoms, including hallucinations, delusions, and changes in behavior.

It is estimated that 2.4 million Americans (or 30% of people with dementia) experience dementia-related hallucinations and delusions[1,2]. These symptoms may be frequent and severe and may recur over time. A hallucination is defined as a perception-like experience that occurs without an external stimulus and is sensory (seen, heard, felt, tasted, sensed) in nature. A delusion is defined as a false, fixed belief that is resolutely held despite evidence to the contrary. Dementia-related psychosis occurs in many types of dementia, including Alzheimer's disease, dementia with Lewy bodies, Parkinson's disease dementia, vascular dementia, and frontotemporal dementia. Serious consequences have been associated with psychosis in patients with dementia, such as repeated hospital admissions, increased likelihood of nursing home placement, faster progression of dementia, and increased risk of morbidity and mortality[4].

About Pimavanserin

Pimavanserin is a selective serotonin inverse agonist and antagonist preferentially targeting 5-HT_{2A} receptors. These receptors are thought to play an important role in neuropsychiatric disorders. In vitro, pimavanserin demonstrated no appreciable binding affinity for dopamine (including D2), histamine, muscarinic, or adrenergic receptors. Pimavanserin 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®. ACADIA submitted a supplemental new drug application (sNDA) for pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis on June 3, 2020. The FDA has accepted for filing the sNDA for DRP with a PDUFA date of April 3, 2021. NUPLAZID is not approved for dementia-related psychosis. In addition, ACADIA is developing pimavanserin in other neuropsychiatric conditions.

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 commercialized the first and only medicine approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. ACADIA's development efforts are focused on pimavanserin for additional neuropsychiatric conditions, trofinetide for Rett syndrome, and an early-stage muscarinic receptor program. 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 pimavanserin as a potential treatment for the hallucinations and delusions associated with dementia-related psychosis, the expected growth in patients with dementia and other statements that are not

historical facts. 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 development, and approval and commercialization. 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, 2019 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.

Important Safety Information and Indication for NUPLAZID (pimavanserin)

Indication

NUPLAZID is indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

Important Safety Information

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

- **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.**
- **NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.**

- **Contraindication:** NUPLAZID is contraindicated in patients with a history of a hypersensitivity reaction to pimavanserin or any of its components. Rash, urticaria, and reactions consistent with angioedema (e.g., tongue swelling, circumoral edema, throat tightness, and dyspnea) have been reported.
- **Warnings and Precautions:** QT Interval Prolongation
  - NUPLAZID prolongs the QT interval. The use of NUPLAZID should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong QT interval including Class 1A antiarrhythmics or Class 3 antiarrhythmics, certain antipsychotic medications, and certain antibiotics.
  - NUPLAZID should also be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and presence of congenital prolongation of the QT interval.

- **Adverse Reactions:** The common adverse reactions (³2% for NUPLAZID and greater than placebo) were peripheral edema (7% vs 2%), nausea (7% vs 4%), confusional state (6% vs 3%), hallucination (5% vs 3%), constipation (4% vs 3%), and gait disturbance (2% vs <1%).
- **Drug Interactions:**
    - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole) increases NUPLAZID exposure. Reduce NUPLAZID dose to 10 mg taken orally as one tablet once daily.
    - Coadministration with strong or moderate CYP3A4 inducers reduces NUPLAZID exposure. Avoid concomitant use of strong or moderate CYP3A4 inducers with NUPLAZID.

Dosage and Administration

Recommended dose: 34 mg capsule taken orally once daily, without titration.

NUPLAZID is available as 34 mg capsules and 10 mg tablets.

Please read the full Prescribing Information including **Boxed WARNING**.

References

1 Plassman BL, et al. Prevalence of dementia in the United States: The Aging Demographics, and Memory study. *Neuroepidemiology*. 2007;29(1-2):125-132.
2 2017 Alzheimer's Disease Facts and Figures and ACADIA market research.
3 Dementia. (2019, September 19). Retrieved from https://www.who.int/news-room/fact-sheets/detail/dementia.
4 Connors MH et al. *Am J Geriatr Psychiatry* 2018;26(3). Peters ME et al. *Am J Psychiatry* 2015;172(5). Haupt M et al. *Int J Geriatr Psychiatry* 1996;11(11). Naimark D et al. *J Am Geriatr* Soc 1996;44(3). Stern Y et al. *Neurology* 1994;44(12).

Media Contact:
ACADIA Pharmaceuticals Inc.
Stephanie Fagan
(858) 212-0534
media@acadia-pharm.com

Investor Contact:
ACADIA Pharmaceuticals Inc.
Mark Johnson, CFA
(858) 261-2771
ir@acadia-pharm.com

EXHIBIT 99.2

ACADIA Pharmaceuticals Announces Top-line Results from the Phase 3 CLARITY Study Evaluating Pimavanserin for the Adjunctive Treatment of Major Depressive Disorder

- The study did not achieve statistical significance on the primary endpoint

- Conference call and webcast to be held today at 4:30 p.m. Eastern Time

SAN DIEGO, CA, July 20, 2020 – ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD) today announced top-line results from its 298 patient Phase 3 CLARITY study which combined two identical, double-blind, placebo-controlled studies evaluating the efficacy, safety and tolerability of pimavanserin as an adjunctive treatment for major depressive disorder (MDD). The combined efficacy and safety analysis was pre-specified prior to data unblinding following feedback from the FDA.

The study did not achieve statistical significance on the primary endpoint which was the 17-item Hamilton Depression Rating Scale (HAMD-17) total score change from baseline to week 5. Pimavanserin 34 mg, given once-daily as an adjunctive treatment to standard antidepressant therapy was associated with a mean reduction of 9.0 in HAMD-17 total score compared to 8.1 for placebo as an adjunctive treatment (p=0.296).

Positive results were observed on the key secondary endpoint, the Clinical Global Impression – Severity (CGI-S) score, a clinician assessment of a patient's severity of depression (nominal p=0.042).

"We observed a consistent improvement of depressive symptoms over time with pimavanserin but, unfortunately, the robust positive results from our CLARITY-1 study were not replicated," said Serge Stankovic, ACADIA's President. "While these results do not support the product profile to pursue a broad adjunctive MDD indication, we will continue to analyze the data and the findings from our earlier positive depression studies as we assess next steps. All of us at ACADIA thank the patients, their families and the investigators who participated in the Phase 3 CLARITY study."

In the study, pimavanserin was generally well-tolerated when added to existing antidepressant therapy, and similar rates of adverse events were observed between pimavanserin (58.1%) and placebo (54.7%).

About the Phase 3 CLARITY Study

The Phase 3 CLARITY study is a combination of CLARITY-2 and CLARITY-3, which were both 6-week, parallel-designed, randomized, double-blind, placebo-controlled, multi-center studies designed to evaluate the efficacy and safety of pimavanserin as adjunctive treatment in patients with MDD who have an inadequate response to standard antidepressant therapy with either a selective serotonin reuptake inhibitor (SSRI) or a serotonin norepinephrine reuptake inhibitor (SNRI). A total of 298 patients were randomized to receive six weeks of oral treatment with either 34 mg of pimavanserin or placebo, once daily, in addition to their ongoing antidepressant. The primary endpoint was change from baseline on the HAMD-17 total score.

Phase 3 CLARITY Study Results:

Efficacy Analysis

- Statistical significance not achieved on the primary endpoint: HAMD-17 (p=0.296).
- Positive results observed on key secondary endpoint: CGI-S (nominal p=0.042).
- Positive results observed on Karolinska Sleepiness Scale (KSS) score (nominal p=0.005).
- Clinically meaningful separation was not achieved on the other secondary endpoints.

Safety and Tolerability

- Similar rates of adverse events were observed between pimavanserin (58.1%) and placebo (54.7%).
- Adverse events reported in greater than 5% of patients on pimavanserin and greater than placebo were diarrhea, dry mouth and headache.
- Discontinuations due to adverse events were 2.7% for both pimavanserin and placebo.
- Two subjects 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.
- The adjunctive use of pimavanserin did not result in clinically significant differences in vital signs, metabolic parameters or extrapyramidal symptoms compared to placebo.

ACADIA previously announced plans to combine its CLARITY-2 and CLARITY-3 Phase 3 studies evaluating pimavanserin for the adjunctive treatment of MDD with a pre-specified statistical analysis plan. The two Phase 3 studies concluded with slightly more than 50% enrollment.

Patients who completed the Phase 3 study were eligible to participate in the ongoing 52-week open-label extension study to evaluate the long-term safety and tolerability of pimavanserin as adjunctive treatment to standard antidepressants in MDD.

About the CLARITY-1 Study

CLARITY-1 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 SSRI or a SNRI. The study was conducted in collaboration with the Massachusetts General Hospital Clinical Trials Network & Institute and randomized 207 patients across 27 clinical research centers in the U.S. and was completed in 2018.

In the trial, pimavanserin met the primary endpoint by significantly reducing the HAMD-17 total score compared to placebo (p=0.039). On the key secondary endpoint, pimavanserin demonstrated statistically significant reductions compared to placebo in the Sheehan Disability Scale score (p=0.004). Positive results were also observed for seven other secondary endpoints including the CGI-S score (p=0.008) and the KSS score (p=0.021).

In the parallel design portion (Stage 1) of this SPCD study, adding pimavanserin to SSRI or SNRI therapy also significantly reduced HAMD-17 scores compared to placebo (p=0.0003). On the key secondary endpoint, pimavanserin also demonstrated statistically significant reductions compared to placebo in the Sheehan Disability Scale score (p=0.004).

About the Open-Label Comorbid Parkinson's Disease and Depression Study

This was an 8-week, open-label, single-arm Phase 2 study evaluating the efficacy and safety of pimavanserin as an adjunct to a SSRI or a SNRI or as a monotherapy in adults with both Parkinson's disease and depression (n=47) and was completed in 2019. In the study, patients treated with pimavanserin had significant improvement on the primary endpoint, the HAMD-17 total score change in baseline to week 8 ($p<0.0001$), with significant improvement seen as early as week 2 ($p<0.0001$). Improvement of ³50% on the HAMD-17 total score was observed in 60.0% of patients at week 8, with 44.4% of patients reaching remission (HAMD-17 £7).

Additional results from this study showed that Parkinson's disease patients treated with pimavanserin for depression also demonstrated improvement on multiple secondary endpoints compared to baseline, including the CGI-S score ($p<0.0001$) and the SCOPA-Global Sleep Quality scale ($p<0.0001$).

Conference Call and Webcast Information

ACADIA will provide a corporate update via conference call and webcast today at 4:30 p.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 1486597). A telephone replay of the conference call may be accessed through July 27, 2020 by dialing 855- 859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 1486597). The conference call will also be webcast live on ACADIA's website, www.acadia-pharm.com, in the investors section and will be archived there until August 20, 2020.

About Major Depressive Disorder

According to the National Institute of Mental Health, MDD affects approximately 17 million adults in the U.S.[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. Continuing depression has been consistently linked with greater economic burden, with higher rate of healthcare utilization and reduced work productivity.[4] The majority of people who suffer from MDD do not respond adequately to initial antidepressant therapy or discontinue due to side effects or safety concerns.[5,6]

About Pimavanserin

Pimavanserin is a selective serotonin inverse agonist and antagonist preferentially targeting 5-HT_{2A} receptors. The serotonin system is thought to play an important role in neuropsychiatric disorders. In vitro, pimavanserin demonstrated no appreciable binding affinity for dopamine (including D2), histamine, muscarinic, or adrenergic receptors. Pimavanserin 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®. ACADIA submitted a supplemental new drug application (sNDA) for pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis on June 3,

2020. The FDA has accepted for filing the sNDA for DRP with a PDUFA date of April 3, 2021. NUPLAZID is not approved for dementia-related psychosis. In addition, ACADIA is developing pimavanserin in other neuropsychiatric conditions.

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 commercialized the first and only medicine approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. ACADIA's development efforts are focused on pimavanserin for additional neuropsychiatric conditions, trofinetide for Rett syndrome, and an early-stage muscarinic receptor program. 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 major depressive disorder 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 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, 2019 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.

Important Safety Information and Indication for NUPLAZID (pimavanserin)

Indication

NUPLAZID is indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

Important Safety Information

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

- **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.**

- **NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.**

- **Contraindication:** NUPLAZID is contraindicated in patients with a history of a hypersensitivity reaction to pimavanserin or any of its components. Rash, urticaria, and reactions consistent with angioedema (e.g., tongue swelling, circumoral edema, throat tightness, and dyspnea) have been reported.
- **Warnings and Precautions:** QT Interval Prolongation
  - NUPLAZID prolongs the QT interval. The use of NUPLAZID should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong QT interval including Class 1A antiarrhythmics or Class 3 antiarrhythmics, certain antipsychotic medications, and certain antibiotics.
  - NUPLAZID should also be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and presence of congenital prolongation of the QT interval.
- **Adverse Reactions:** The common adverse reactions (≥2% for NUPLAZID and greater than placebo) were peripheral edema (7% vs 2%), nausea (7% vs 4%), confusional state (6% vs 3%), hallucination (5% vs 3%), constipation (4% vs 3%), and gait disturbance (2% vs <1%).
- **Drug Interactions**:
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole) increases NUPLAZID exposure. Reduce NUPLAZID dose to 10 mg taken orally as one tablet once daily.
  - Coadministration with strong or moderate CYP3A4 inducers reduces NUPLAZID exposure. Avoid concomitant use of strong or moderate CYP3A4 inducers with NUPLAZID.

Dosage and Administration

Recommended dose: 34 mg capsule taken orally once daily, without titration.

NUPLAZID is available as 34 mg capsules and 10 mg tablets.

Please read the full Prescribing Information including **Boxed WARNING**.

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 Greenberg PE, Fournier AA, Sisitsky T, Pike CT, Kessler RC. The economic burden of adults with major depressive disorder in the United States (2005 and 2010). *J Clin Psych.* 2015;76(2):155-162. doi: 10.4088/JCP.14m09298.
5 Rush AJ, et al. (2007) *Am J. Psychiatry* 163:11, pp. 1905-1917 (STAR*D Study).
6 Sansone RA, Sansone LA. Antidepressant adherence: are patients taking their medications? *Innov Clin Neurosci*. 2012;9(5-6):41-46.

Media Contact:
ACADIA Pharmaceuticals Inc.
Stephanie Fagan
(858) 212-0534
media@acadia-pharm.com

Investor Contact:
ACADIA Pharmaceuticals Inc.
Mark Johnson, CFA
(858) 261-2771
ir@acadia-pharm.com