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): December 20, 2021

Acadia Pharmaceuticals Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	000-50768	06-1376651
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

12830 El Camino Real, Suite 400 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))

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.

Acadia Pharmaceuticals Inc. (the "Company") announced on December 20, 2021 that it plans to resubmit its supplemental New Drug Application (sNDA) for pimavanserin for the treatment of hallucinations and delusions associated with dementia focused on Alzheimer's disease psychosis (ADP). Resubmission of the sNDA to the U.S. Food and Drug Administration (FDA) is planned for the first quarter of 2022. The resubmission is intended to demonstrate pimavanserin's clinically meaningful benefit in ADP patients, without worsening of cognition or motor function in this elderly population. The resubmission will include data from two positive, placebo-controlled studies that prospectively met their primary endpoints: the pivotal Phase 3 HARMONY study and the -019 study. Additional analyses from HARMONY and -019 will also be provided that validate the primary conclusions from each study and address the concerns raised in the FDA's complete response letter.

A copy of ACADIA's press release issued December 20, 2021 is furnished herewith as Exhibit 99.1. A copy of the presentation for the related conference call is furnished herewith as Exhibit 99.2.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated December 20, 2021
99.2	Regulatory Update on sNDA for Pimavanserin
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

Acadia Pharmaceuticals Inc.

Dated: December 20, 2021

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

Exhibit 99.1

Acadia Pharmaceuticals Announces Plan for a Resubmission of its Supplemental New Drug Application to U.S. FDA for NUPLAZID® (pimavanserin)

- Acadia plans to resubmit its sNDA in the first quarter of 2022

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

SAN DIEGO, CA, December 20, 2021 – Acadia Pharmaceuticals Inc. (Nasdaq: ACAD) announced today that it plans to resubmit its supplemental New Drug Application (sNDA) for pimavanserin for the treatment of hallucinations and delusions associated with dementia focused on Alzheimer's disease psychosis (ADP). Resubmission of the sNDA to the U.S. Food and Drug Administration (FDA) is planned for the first quarter of 2022.

"Following our recent meetings with the FDA, we plan to resubmit our sNDA for pimavanserin, narrowing the proposed indication from dementia-related psychosis to Alzheimer's disease psychosis," said Steve Davis, Chief Executive Officer. "Our resubmission will include new analyses of existing clinical study data supporting the treatment of hallucinations and delusions associated with Alzheimer's disease. We are aware there are challenges to overcoming our complete response letter, but are pleased with the high level of engagement from the FDA over the last three meetings and their willingness to review our resubmission, allowing us to make our case that pimavanserin should be the first drug approved to treat Alzheimer's disease psychosis."

The resubmission is intended to demonstrate pimavanserin's clinically meaningful benefit in ADP patients, without worsening of cognition or motor function in this elderly population. The resubmission will include data from two positive, placebo-controlled studies that prospectively met their primary endpoints: the pivotal Phase 3 HARMONY study[1] and the -019 study[2]. Additional analyses from HARMONY and -019 will also be provided that validate the primary conclusions from each study and address the concerns raised in the FDA's complete response letter.

Conference Call and Webcast Information

Acadia will discuss this regulatory update regarding the resubmission of the sNDA for pimavanserin for the treatment of ADP 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 3072268). A telephone replay of the conference call may be accessed through January 4, 2022 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 3072268). The conference call will also be webcast live on Acadia's website, www.acadia-pharm.com, in the investors section and archived until January 17, 2022.

About Alzheimer's Disease Psychosis

According to the Alzheimer's Association, over six million people in the United States are living with Alzheimer's disease[3]. Studies suggest that 25 to 50 percent of patients diagnosed with Alzheimer's disease have psychosis, commonly consisting of hallucinations and delusions[4]. 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. 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[5]. There is no FDA approved drug for the treatment of Alzheimer's disease psychosis.

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®. NUPLAZID is not approved for dementia-related psychosis. In addition, Acadia is developing pimavanserin in other neuropsychiatric conditions.

About Acadia Pharmaceuticals

Acadia is advancing breakthroughs in neuroscience to elevate life. For more than 25 years we have been working at the forefront of healthcare to bring vital solutions to people who need them most. We developed and commercialized the first and only approved therapy for hallucinations and delusions associated with Parkinson's disease psychosis. Our late-stage development efforts are focused on treating psychosis in patients with dementia, the negative symptoms of schizophrenia and Rett syndrome. Our early-stage development efforts are focused on novel approaches to pain management, cognition and neuropsychiatric symptoms in central nervous system disorders. For more information, visit us at www.acadia-pharm.com and follow us on LinkedIn and Twitter.

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.**

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 regarding the timing of future events. 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. 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, 2020 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 Tariot PN, et al. N Engl J Med. 2021; 385(4):309-319.
2 Ballard C, et al. Lancet Neurol. 2018;17(3):213-222. Ballard C, et al. J Prev Alzheimers Dis. 2019;6(1):27-33.
3 2021 Alzheimer's Disease Facts and Figures and Acadia market research.
4 Plassman BL, et al. Prevalence of Dementia in the United States: The Aging Demographics, and Memory study. Neuroepidemiology. 2007;29(1-2):125-132.

[5] 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.
Deb Kazenelson
818-395-3043
media@acadia-pharm.com

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

Exhibit 99.2

ACADIA

Regulatory Update on sNDA for NUPLAZID® (pimavanserin)

December 20, 2021

Call Agenda

ACADIA

Introduction	**Mark Johnson** | Vice President, Investor Relations
CEO Opening Remarks	**Steve Davis** | Chief Executive Officer
Regulatory Update	**Serge Stankovic, M.D., M.S.P.H** | President
CEO Closing Remarks	**Steve Davis** | Chief Executive Officer
Q&A	Also available for Q&A: **Mark Schneyer** | Chief Financial Officer **Brendan Teehan** | Chief Operating Officer, Head of Commercial

Forward-Looking Statements

This presentation contains forward-looking statements. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed in or implied by such forward-looking statements. Each of these statements is based only on current information, assumptions and expectations that are inherently subject to change and involve a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements about (i) plans for, including timing and progress of commercialization of, NUPLAZID® or for the clinical development of our product candidates, including pimavanserin and trofinetide; (ii) benefits to be derived from and efficacy of our product candidates, including the use of pimavanserin in dementia-related psychosis, schizophrenia or other neurological or psychiatric indications, potential advantages of NUPLAZID versus existing antipsychotics or antidepressants, and expansion opportunities for NUPLAZID; (iii) estimates regarding the prevalence of Parkinson's disease psychosis, dementia-related psychosis, schizophrenia and the potential use of trofinetide in Rett syndrome; (iv) potential markets for any of our products, including NUPLAZID and trofinetide; (v) our estimates regarding our future financial performance, cash position or capital requirements; and (vi) currently anticipated impacts of COVID-19 on Acadia's business, including its commercial sales operations, current and planned clinical trials, supply chain, and guidance for full-year 2021 NUPLAZID net sales and certain expense line items.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions (including the negative thereof) intended to identify forward-looking statements. Given the risks and uncertainties, you should not place undue reliance on these forward-looking statements. For a discussion of the risks and other factors that may cause our actual results, performance or achievements to differ, please refer to our annual report on Form 10-K for the year ended December 31, 2020 as well as our subsequent filings with the SEC. The forward-looking statements contained herein are made as of the date hereof, and we undertake no obligation to update them for future events.

CEO Opening Remarks

Steve Davis

CEO

sNDA Resubmission for Pimavanserin

ACADIA

Resubmission focused on Alzheimer's Disease Psychosis (ADP)

- ADP represents the majority of DRP patients and is the largest dementia subgroup

- Efficacy demonstrated across clinical studies and endpoints:
  - Improvement of psychosis symptoms and reduction of relapse risk

- Safety profile with pimavanserin, a selective serotonin $5HT_{2A}$ inverse agonist/antagonist includes:
  - No worsening of cognition (core dementia symptom)
  - No onset of worsening of extrapyramidal symptoms (EPS), including motor functioning
  - Supported by >6 years post-marketing data in patients with PDP

Acadia plans to resubmit sNDA specifically for ADP in 1Q22

DRP = Dementia-Related Psychosis; **PDP** = Parkinson's Disease Psychosis
NUPLAZID (pimavanserin) is only approved in the U.S. by the FDA for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.
Provided December 20, 2021 as part of an oral presentation and is qualified by such; contains forward-looking statements; actual results may vary materially; Acadia disclaims any duty to update.

Timeline from CRL to Resubmission

2Q21: Complete Response Letter (CRL) regarding the sNDA in dementia-related psychosis

3Q21: Type A, End of Review Meeting

- FDA stated they would evaluate pimavanserin by individual subgroups of dementia
- Acadia presented additional analyses to demonstrate consistency of effect across subgroups
- FDA advised the best path forward is to conduct additional studies by subgroup
- FDA also advised that we could request another meeting to further discuss potential resubmission without additional clinical work

3Q21: Type B Meeting to Discuss Breakthrough Therapy Designation

- Brief discussion on breakthrough therapy designation
- Followed by more in-depth discussion on subgroup analyses

4Q21: Type B Meeting to Discuss ADP Resubmission

- Acadia presented additional analyses supporting efficacy in ADP from two positive, placebo-controlled studies:
  - Consistent effect observed in ADP patients in HARMONY study across multiple analyses
  - Analyses support validity of the -019 ADP study results to address FDA's concerns
- FDA restated their previous advice that the conduct of an additional study in ADP would appear to be the path capable of providing the strongest data in support of a resubmission. FDA also stated they are prepared to consider our arguments in support of ADP approval without additional clinical studies in a resubmission

1Q22: Resubmission of sNDA of NUPLAZID® (pimavanserin) focused on ADP

Regulatory Update

Serge Stankovic

President

Alzheimer's Disease Psychosis

Alzheimer's Disease Psychosis (ADP)[1]:

- There are >6M Alzheimer's patients in the U.S., representing 60 – 80% of all dementia patients
  - ~30% (>1.8M patients in the U.S.) experience psychosis
  - ~50% of ADP patients diagnosed
  - No approved treatments for ADP

ADP represents a serious unmet medical need with no FDA-approved drugs

- Off-label use of multi-receptor acting antipsychotics associated with no/limited proven efficacy and potentially substantial toxicity (oftentimes leading to treatment discontinuation):
  - Seriously impacts patient's ability to function and increases caregiver burden
  - Higher risk to severe dementia and nursing home placement

[1]2021 Alzheimer's Disease Facts and Figures and Acadia market research.
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HARMONY Study: Alzheimer's Disease Subgroup

ACADIA

HARMONY Study[1]

Pimavanserin showed consistent and clinically meaningful reduction in risk of psychosis relapse in AD subgroup (~40% reduction)

	Overall	AD Subgroup	
Open-label portion of study (12 weeks)			
Response Rate (Sustained at weeks 8 and 12)	**61.8%**	**59.8%**	
Complete Response Rates (Remission Rates)	**33.6%**	**32.1%**	
	Overall *N=194*	**AD Subgroup** *N=123*	**AD (34 mg)** *N=116*
Double-blind portion of study (26 weeks)			*Ad-hoc Analysis*:*
Relapse Rate (Placebo)	**28.3%**	**22.6%**	**23.7%**
Relapse Rate (Pimavanserin)	**12.6%**	**13.1%**	**10.5%**
Hazard Ratio (HR)	**0.35**	**0.62**	**0.47**

Examples of analyses for HARMONY supporting antipsychotic efficacy in AD patients:

- 34 mg relative performance
- Responder analyses
- Exposure-response relationship
- SAPS–H+D and CGI–I severity scores
- Additional analyses of consistency across dementia subgroups

Response Rate = Percentage of subjects who acheived ≥30% SAPS – H+D improvement and CGI – I much improved at both Weeks 8 and 12.
Complete Response Rate = Percentage of subjects who responded that acheived SAPS – H+D (score=0) prior to randomization.
SAPS – H+D = Scale for the Assessment of Positive Symptoms – Hallucinations + Delusions; **CGI – I =** Clinical Global Impression Scale – Improvement
[1]Tariot PN, et al. N Engl J Med. 2021; 385(4):309-319 and Acadia data on file.
*The 34 mg subgroup of the AD subgroup was a post-hoc/exploratory analysis.
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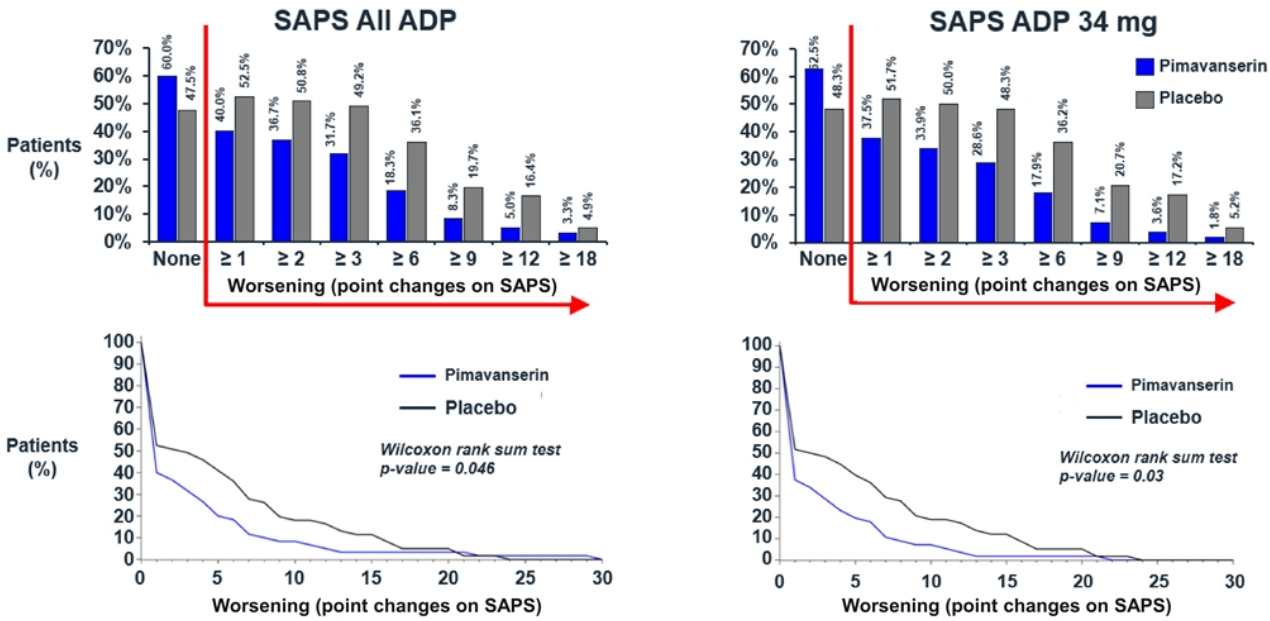
HARMONY Study: Responder Analysis



For subjects who never worsened from Baseline (i.e., improved during double-blind phase), their maximum worsening score was set to 0 for the purpose of evaluating maximum worsening of symptoms.
Subjects who do not have post=baseline SAPS H+D scores are not included in this analysis.
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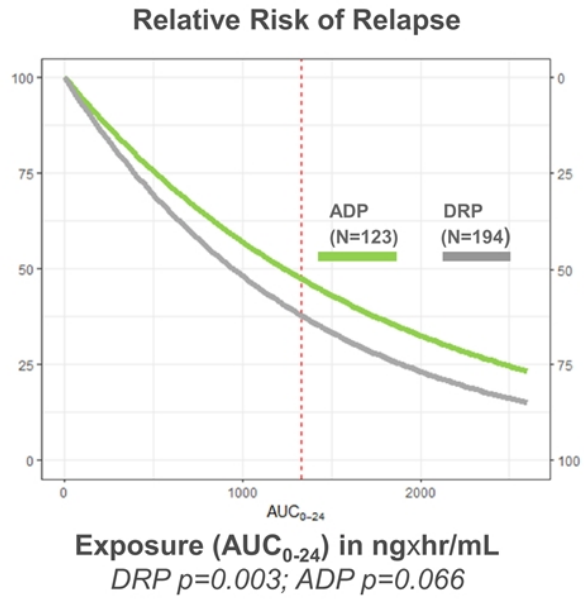
HARMONY Study: Exposure-Response Relationship



- Exposure-Response relationship indicator of true drug effect vs. spurious finding
- Higher pimavanserin exposure associated with decreased relapse rate
- Very consistent improvement in ADP subgroup, similar to overall DRP population

Cox proportional hazards model with pimavanserin AUC0-24 as a continuous variable.
Red line indicates median AUC0-24 of 1330 ng×hr/mL from a 34 mg daily dose.
NUPLAZID (pimavanserin) is only approved in the U.S. by the FDA for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.
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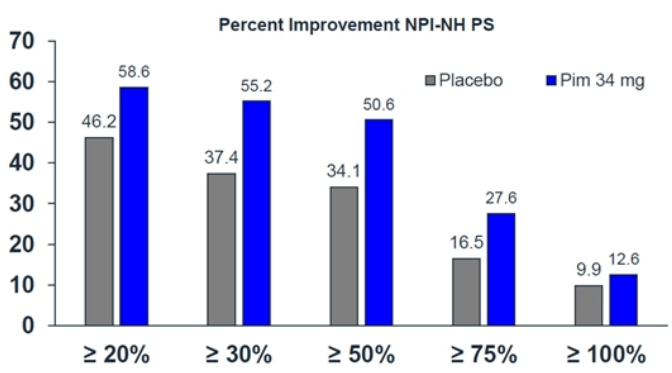
HARMONY Study: Consistent Efficacy Observed Across Dementia Subgroups

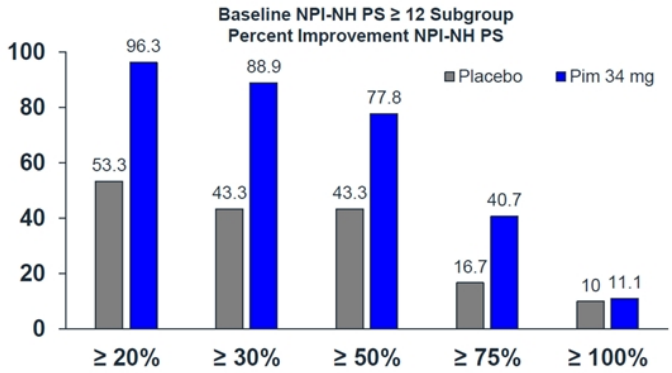
- Similar levels of efficacy observed across subgroups in the open-label period
- Observed consistently low relapse rates across subgroups in the double-blind randomized period
- PDD response only different in response of patients randomized to placebo:
  - Potential result of this subgroup being on concomitant dopaminergic agents
- Symptoms of psychosis present in a similar fashion regardless of dementia type

PDD = Parkinson's Disease Dementia.

Study -019[1,2]: Primary Efficacy and Responder Analyses

NPI-NH PS at 6 Weeks (Primary Endpoint)	Placebo	Pim 34 mg	Delta	Effect size	P-value
MMRM LSM Change (N=178)	**-1.93**	**-3.76**	**-1.84**	**0.320**	**0.0451**
Baseline NPI-NH PS ≥12 Subgroup (N=57)	-5.72	-10.15	-4.43	0.734	0.0114





NPI – NH PS = Neuropsychiatric Inventory – Nursing Home Version Psychosis Score; **LSM** = least squares mean; **MMRM** = mixed – effect model repeated measures.
*Nominal p-value (exploratory).
[1]Ballard C, et al. Lancet Neurol. 2018;17(3):213-222. [2]Ballard C, et al. J Prev Alzheimers Dis. 2019;6(1):27-33.
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Study -019: Providing Independent Evidence of Efficacy in ADP

In the resubmission Acadia plans to address FDA's concerns outlined in CRL

- Study -019 contributes to substantial evidence of efficacy

Study -019 was a randomized, double-blind, placebo-controlled study that met its pre-specified, primary endpoint

- Single center (Clive Ballard, MD) included multiple care homes (N=133) and qualified raters (N=20)
- Protocol deviation sensitivity analyses suggest no impact on the conclusions of the primary outcome in the study

CEO Closing Remarks

Steve Davis

CEO

sNDA Resubmission for Pimavanserin

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Program Development Pipeline

ACADIA

Program	Indication	Phase 1	Phase 2	Phase 3	Marketed
NUPLAZID® (pimavanserin)[1]	Parkinson's Disease Psychosis				
Pimavanserin[2]	Alzheimer's Disease Psychosis				
Trofinetide[3]	Rett Syndrome				
Pimavanserin	Negative Symptoms of Schizophrenia				
ACP-044	Postoperative Pain				
ACP-044	Osteoarthritis Pain				
ACP-319[4]	Schizophrenia and Cognition in Alzheimer's				

[1]NUPLAZID (pimavanserin) is only approved in the U.S. by the FDA for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.
[2]Acadia received a CRL for its sNDA for pimavanserin for the treatment of DRP. Acadia is planning to resubmit the sNDA for the treatment of dementia focused on Alzheimer's disease psychosis.
[3]Acadia has an exclusive license to develop and commercialize trofinetide in North America from Neuren Pharmaceuticals.
[4]Acadia has an exclusive worldwide license to develop and commercialize ACP-319 and other M1 PAM program compounds from Vanderbilt University.
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Q&A Session