# Acadia Pharmaceuticals Provides Business and Pipeline Updates at 43rd Annual J.P. Morgan Healthcare Conference

January 14, 2025

SAN DIEGO--(BUSINESS WIRE)--Jan. 14, 2025-- Acadia Pharmaceuticals Inc. (Nasdaq: ACAD) today announced multiple business updates and progress on the Company's CNS and rare disease drug candidates, which will be discussed today during a presentation by Catherine Owen Adams, Chief Executive Officer, at the 43rd Annual J.P. Morgan Healthcare Conference in San Francisco, CA.

“2025 is shaping up to be an exciting year as we build on the success of our two growing brands, NUPLAZID and DAYBUE, which together are projected to generate more than $1 billion in net sales this year,” said Catherine Owen Adams, Chief Executive Officer. “In addition to growing our strong commercial franchises, we are laying the foundation for future growth through global expansion and pipeline advancement. Today, we announced our submission of a marketing authorization application for DAYBUE with the European Medicines Agency and anticipate beginning Managed Access Program–related sales in Europe as early as the second quarter. We are also pleased to share updates on our R&D pipeline—both today and at our first R&D Day in mid-2025—as our lead programs near data readouts. By expanding our reach beyond the U.S. and continuing to advance our pipeline, we believe Acadia is poised for sustained top-line growth and increasing positive cash flow.”

**Key 2025-2026 Milestones:**

- Announced today that the marketing authorization application for DAYBUE ™ has been submitted to the European Medicines Agency (EMA) with expected approval in the first quarter of 2026.
- Initiation of Managed Access Programs in Europe in the second quarter of 2025, potentially resulting in the Company’s first revenues from outside the U.S.
- Enrollment of the last patient in the COMPASS PWS Phase 3 study of ACP-101 in Prader-Willi Syndrome anticipated in the fourth quarter of 2025, followed by top-line results announcement in the first half of 2026.
- Enrollment of the last patient in the RADIANT Phase 2 study of ACP-204 in Alzheimer’s disease psychosis expected in the first quarter of 2026, followed by top-line results announcement in mid-2026.
- Initiation of a Phase 2 study of ACP-204 for a second indication in Lewy Body Dementia in the third quarter of 2025.
- The Company will host its first ever R&D Day in mid-2025.
- Annual net sales for the full-year 2025 expected to exceed $1 billion for the first time in Company history.

Today’s presentation will take place at 9:00 a.m. Pacific Time / 12:00 p.m. Eastern Time. A live webcast of the presentation will be accessible on the Company’s website, Acadia.com, under the investors section and an archived recording will be available on the website for approximately one month following the presentation.

*About Acadia Pharmaceuticals*

Acadia is advancing breakthroughs in neuroscience to elevate life. Since our founding 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 FDA-approved drug to treat hallucinations and delusions associated with Parkinson’s disease psychosis and the first and only approved drug in the United States and Canada for the treatment of Rett syndrome. Our clinical-stage development efforts are focused on Prader-Willi syndrome, Alzheimer’s disease psychosis and multiple other programs targeting neuropsychiatric symptoms in central nervous system disorders. For more information, visit us at Acadia.com and follow us on LinkedIn and X.

*Forward-Looking Statements*

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements other than statements of historical fact and can be identified by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential,” “continue” and similar expressions (including the negative thereof) intended to identify forward-looking statements. Forward-looking statements contained in this press release, include, but are not limited to, statements about: (i) our business strategy, objectives and opportunities, including support for and innovations in our pipeline assets and business development opportunities, and potential for enhanced shareholder value; (ii) plans for, including timing, development and progress of commercialization, and expected regulatory timelines for trofinetide in the EU; (iii) plans for our pipeline, including the timing and conduct of our clinical trials, anticipated enrollment milestones and the timing and results of data from our clinical trials; and (iv) our estimates regarding our future financial performance, profitability and capital requirements, including our full year 2024 financial guidance and potential achievement of our milestone of annualized net sales in 2025. Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements. Such risks, uncertainties and other factors include, but are not limited to: our dependency on the continued successful commercialization of NUPLAZID® and DAYBUE and our ability to maintain or increase sales of NUPLAZID or DAYBUE; our plans to commercialize DAYBUE outside the U.S., including in Canada; the costs of our commercialization plans and development programs, and the financial impact or revenues from any commercialization we undertake; our ability to obtain necessary regulatory approvals for our product candidates and, if and when approved, market acceptance of our products; the risks associated with clinical trials and their outcomes, including risks of unsuccessful enrollment and negative or inconsistent results; our dependence on third-party collaborators, clinical research organizations, manufacturers, suppliers and distributors; the impact of competitive products and therapies; our ability to generate or obtain the necessary capital to fund our operations; our ability to grow, equip and train

our specialized sales forces; our ability to manage the growth and complexity of our organization; our ability to maintain, protect and enhance our intellectual property; and our ability to continue to stay in compliance with applicable laws and regulations. Given the risks and uncertainties, you should not place undue reliance on these forward-looking statements. For a discussion of these and other risks, uncertainties and other factors that may cause our actual results, performance or achievements to differ, please refer to our quarterly report on Form 10-Q quarter ended September 30, 2024, filed with the SEC on November 7, 2024, available at www.sec.gov. The forward-looking statements contained herein are made as of the date hereof, and we undertake no obligation to update them after this date, except as required by law.

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*Investor Contact:*
Acadia Pharmaceuticals Inc.
Al Kildani
(858) 261-2872
ir@acadia-pharm.com

*Media Contact:*
Acadia Pharmaceuticals Inc.
Deb Kazenelson
(818) 395-3043
media@acadia-pharm.com

Source: Acadia Pharmaceuticals Inc.