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September 24, 2025 ■ General

Acadia Pharmaceuticals Announces Phase 3 COMPASS PWS Trial of Intranasal Carbetocin (ACP-101) for Hyperphagia in Prader-Willi Syndrome Did Not Meet Primary Endpoint

SAN DIEGO—(BUSINESS WIRE)—Sep. 24, 2025—Acadia Pharmaceuticals Inc. (Nasdaq: ACAD) today announced top-line results from the Phase 3 COMPASS PWS trial evaluating the efficacy and safety of intranasal carbetocin (ACP-101) in patients with hyperphagia in Prader-Willi syndrome (PWS). Intranasal carbetocin did not demonstrate a statistically significant improvement over placebo on the study's primary endpoint, change from baseline to Week 12 on the Hyperphagia Questionnaire for Clinical Trials (HQ-CT), nor was there separation from placebo on any secondary endpoint. The safety and tolerability profile of intranasal carbetocin was consistent with previous clinical trials, showing a low rate of adverse events.

"We are disappointed by these findings, especially for Prader-Willi syndrome patients, their families and the entire community," said Elizabeth H.Z. Thompson, Ph.D., Acadia's Head of Research and Development. "I want to thank the many patients, families, study site personnel, and physicians who participated in the COMPASS PWS study as well as the intranasal carbetocin clinical development program, for their dedication and contributions in this important study. We are committed to sharing a summary of the data in the future to ensure learning for the PWS community; however, given these results, we do not intend to investigate intranasal carbetocin any further."

COMPASS PWS was a 12-week, double-blind, randomized, placebo-controlled global Phase 3 trial evaluating the efficacy and safety of intranasal carbetocin 3.2 mg three times daily (TID) in 175 enrolled children and adults aged five to 30 years with PWS.

"Despite this disappointment, Acadia is well-positioned to deliver long-term, sustainable growth supported by two approved products projected to generate over \$1 billion in net sales in 2025, and a robust pipeline that includes eight disclosed and multiple undisclosed programs," said Catherine Owen Adams, Acadia's Chief Executive Officer. "Looking ahead, we anticipate seven Phase 2 or 3 study starts through 2026 and four data readouts by the end of 2027. For more details on our programs, I encourage you to revisit our recent R&D Day presentation on our website."

About Acadia Pharmaceuticals

Acadia is advancing breakthroughs in neurological and rare diseases 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 Alzheimer's disease psychosis, Lewy Body Dementia psychosis and multiple other programs targeting neuroscience and neuro-rare diseases. 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 "intends," "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "forecasts" and similar expressions (including the negative thereof) intended to identify forward-

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statements of historical fact and can be identified by terms such as “intends,” “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. Forward-looking statements contained in this press release, include, but are not limited to, statements about: our clinical development plans related to intranasal carbetocin (ACP-101); our plans to share a summary of the data in the future; the safety and tolerability of intranasal carbetocin; our estimates regarding our future financial performance, including our full year 2025 financial guidance; and our business strategy, objectives and opportunities, including the timing for and clinical and market potential of our pipeline assets, and potential for enhanced shareholder value. 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, assumptions 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 ability to generate or obtain the necessary capital to fund our clinical development plans; the risks associated with clinical trials and their outcomes, including risks of negative or inconsistent results; 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, assumptions and other factors that may cause our actual results, performance or achievements to differ, please refer to our quarterly report on Form 10-Q for the quarter ended June 30, 2025 filed with the Securities and Exchange Commission on August 7, 2025, as well as our subsequent filings with the Securities and Exchange Commission from time to time. 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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