

September 24, 2024

Dear Prader-Willi Syndrome Community,

We are pleased to share an update on the 12-week, pivotal Phase 3 COMPASS PWS study evaluating the efficacy and safety of carbetocin nasal spray (ACP-101), an investigational drug, for the treatment of hyperphagia in Prader-Willi syndrome. The study was initiated in the United States in November 2023 and will include approximately 170 children and adults aged 5 to 30 years of age.

Key Updates:

- Clinical study sites in the United States, Canada, and the United Kingdom are participating in the Phase 3 COMPASS PWS study and are accepting patients. Additional sites are pending in the United States, Canada, and Europe.
- Participants who complete the 12-week Phase 3 study will be eligible to enroll in a long-term, 36-month open-label extension study designed to investigate the safety and tolerability of long-term treatment with carbetocin nasal spray.

For more information on the COMPASS PWS study, including who can participate and which trial sites are enrolling new participants, please visit the trial website at CompassPWS.com. The website features a “Find a Research Site” tool that is updated on an ongoing basis as trial sites open and are accepting referrals. To be contacted about potential participation, there is a form to fill out on the website. If you have visited the COMPASS PWS website and registered participation interest, your information has been appropriately recorded and passed on to the closest clinical trial site available. The sites will determine if interested families are suitable to participate.

If you have questions about the Phase 3 COMPASS PWS study, please contact us at compasspws@acadia-pharm.com. We remain steadfast in our commitment to pursue this investigational treatment to address a severely unmet need for those living with Prader-Willi syndrome. We are grateful for the community’s participation, partnership, and continual inspiration through your unwavering dedication to your loved ones.

Thank you for your continued support.

All our best,
The Acadia Prader-Willi Syndrome Team

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