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CARbetocin Efficacy and Safety Study in PWS

Research is uncovering new approaches to treating the hallmark symptoms of Prader-Willi syndrome. Levo Therapeutics is currently enrolling patients with PWS in our Phase 3 clinical trial investigating intranasal carbetocin (LV-101) in children ages 7-18 as a treatment for hyperphagia and behavior associated with Prader-Willi syndrome.

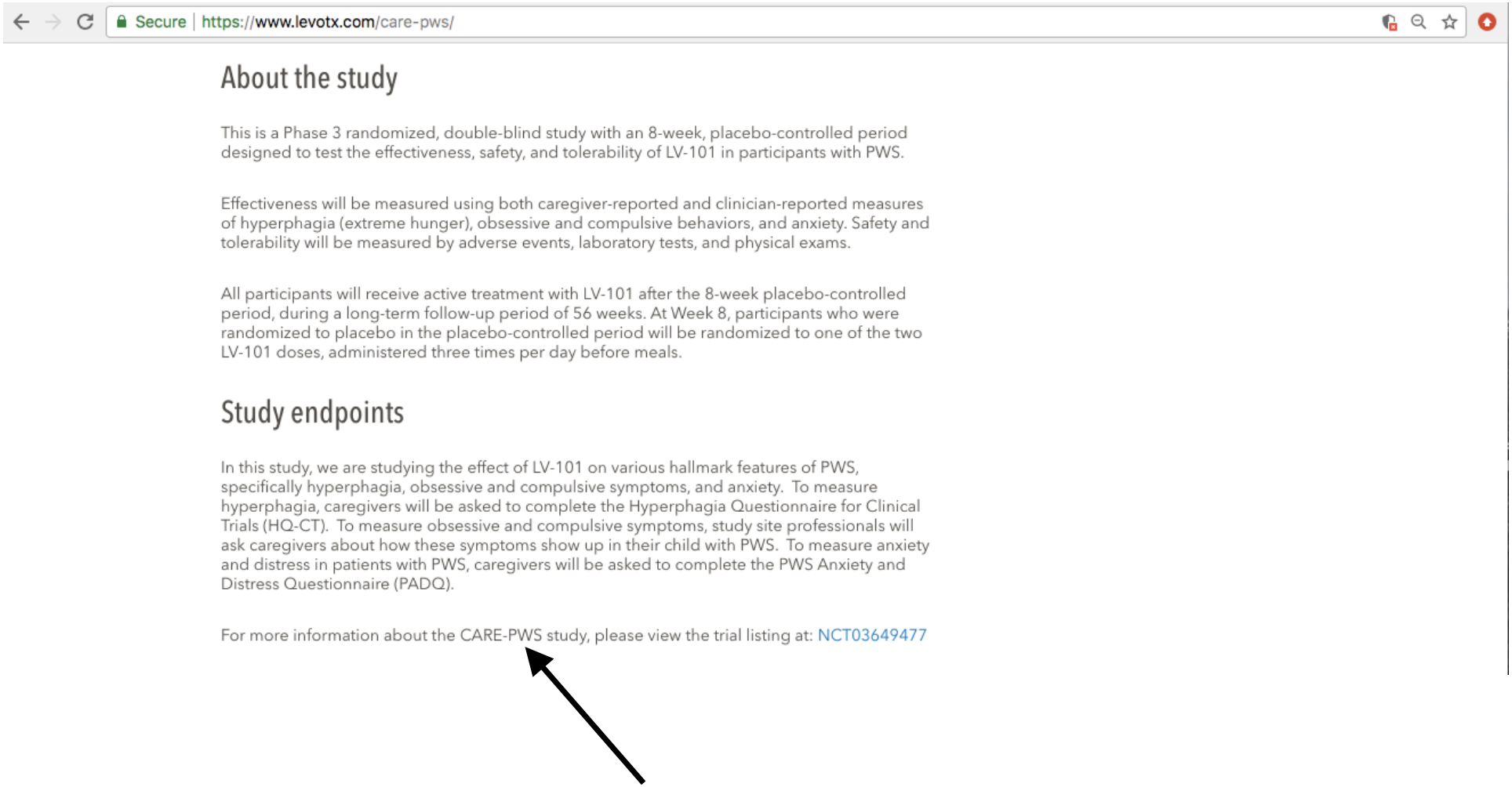
CAREPWS

About intranasal carbetocin (LV-101)

Intranasal carbetocin is similar to the naturally-occurring hormone oxytocin, but with greater selectivity for the effect of interest – stimulation of oxytocin receptors. These receptors are involved in the regulation of both social-emotional and feeding behaviors.

About the study

This is a Phase 3 randomized, double-blind study with an 8-week, placebo-controlled period designed to test the effectiveness, safety, and tolerability of LV-101 in participants with PWS.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About the study
This is a Phase 3 randomized, double-blind study with an 8-week, placebo-controlled period designed to test the effectiveness, safety, and tolerability of LV-101 in participants with PWS.
Effectiveness will be measured using both caregiver-reported and clinician-reported measures of hyperphagia (extreme hunger), obsessive and compulsive behaviors, and anxiety. Safety and tolerability will be measured by adverse events, laboratory tests, and physical exams.
All participants will receive active treatment with LV-101 after the 8-week placebo-controlled period, during a long-term follow-up period of 56 weeks. At Week 8, participants who were randomized to placebo in the placebo-controlled period will be randomized to one of the two LV-101 doses, administered three times per day before meals.
Study endpoints
In this study, we are studying the effect of LV-101 on various hallmark features of PWS, specifically hyperphagia, obsessive and compulsive symptoms, and anxiety. To measure hyperphagia, caregivers will be asked to complete the Hyperphagia Questionnaire for Clinical Trials (HQ-CT). To measure obsessive and compulsive symptoms, study site professionals will ask caregivers about how these symptoms show up in their child with PWS. To measure anxiety and distress in patients with PWS, caregivers will be asked to complete the PWS Anxiety and Distress Questionnaire (PADQ).
For more information about the CARE-PWS study, please view the trial listing at: NCT03649477

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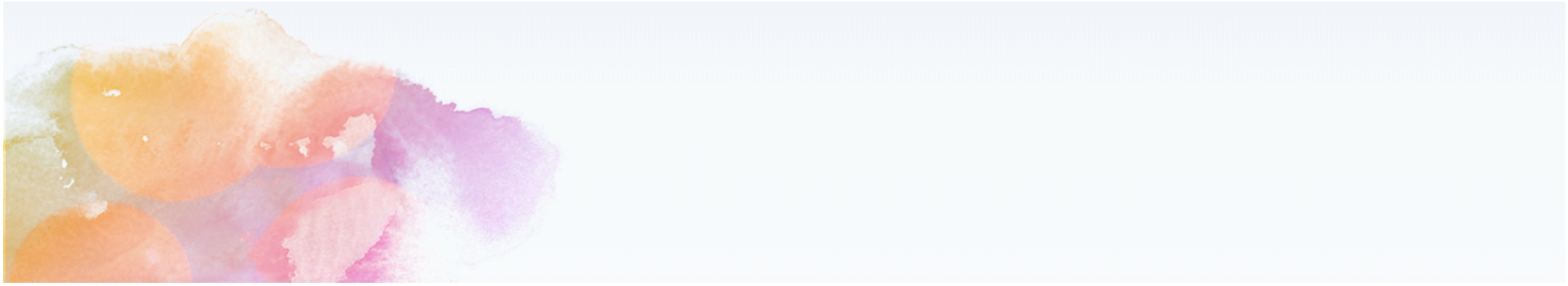
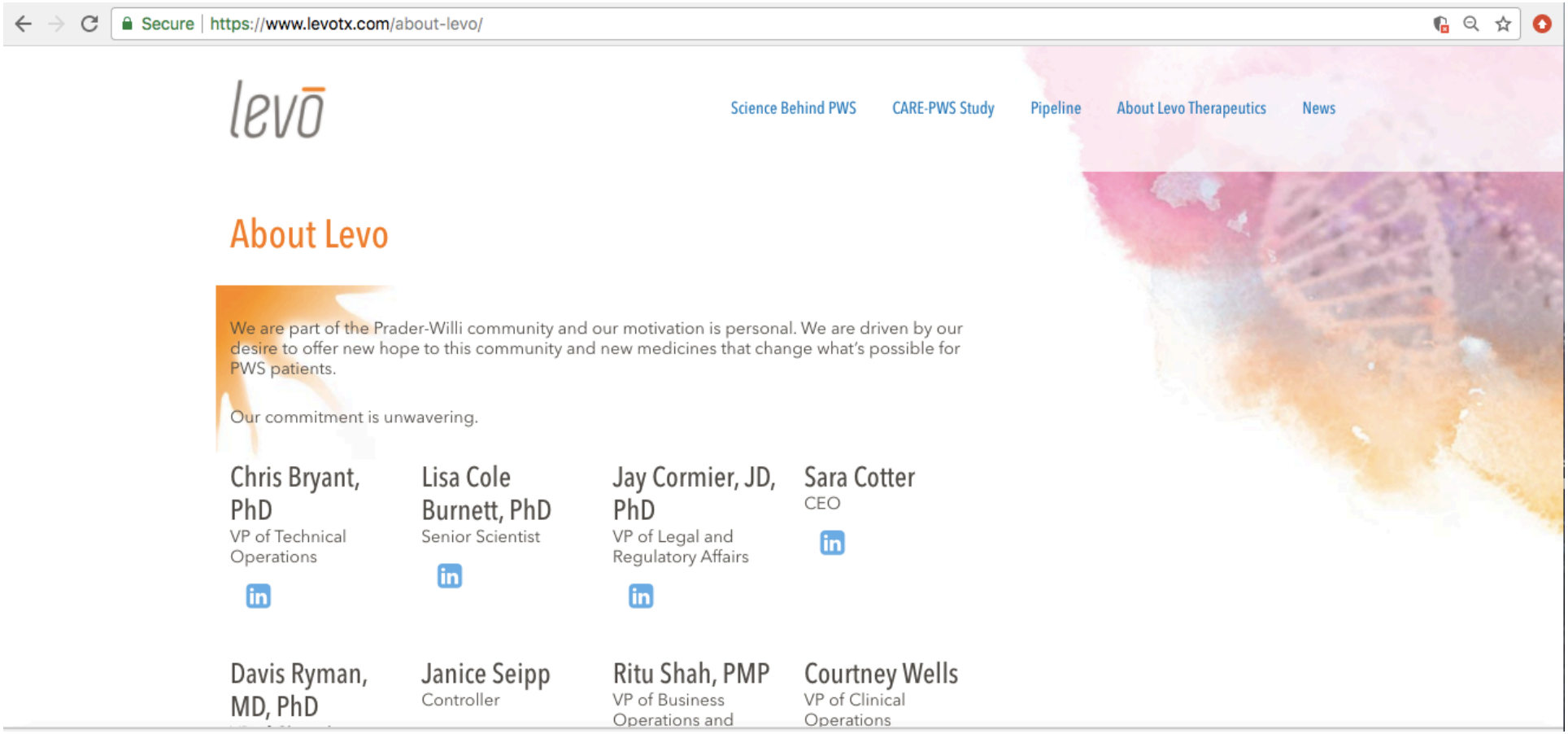
Study sites

Below is a listing of clinical study sites that are currently open and enrolling participants in the CARE-PWS study. Please continue to come back to this website or to the trial listing on www.clinicaltrials.gov (here) for up-to-date information regarding open study sites.

United States

Tennessee
Vanderbilt University School of Medicine
Nashville, Tennessee, United States, 37212
Contact: Hailee Hunt 615-343-0915 hailee.m.hunt@vanderbilt.edu
Principal Investigator: Ronald Cowan, MD
Sub-Investigator: Elizabeth Roof

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About Levo
We are part of the Prader-Willi community and our motivation is personal. We are driven by our desire to offer new hope to this community and new medicines that change what's possible for PWS patients.
Our commitment is unwavering.
Chris Bryant, PhD
VP of Technical Operations
Lisa Cole Burnett, PhD
Senior Scientist
Jay Cormier, JD, PhD
VP of Legal and Regulatory Affairs
Sara Cotter
CEO
Davis Ryman, MD, PhD
Janice Seipp
Controller
Ritu Shah, PMP
VP of Business Operations and
Courtney Wells
VP of Clinical Operations