A Phase 3, Multicenter, Open-Label Extension Study to Assess the Safety and Efficacy of ARD-101 in Patients with Prader-Willi Syndrome

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Up to 18 years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- must have completed treatment through End of Treatment [EoT] in Study AVK-101-301 - willing and able to adhere to scheduled visits, treatment plans, laboratory tests, and procedures related to study evaluations - female of childbearing potential, must have a negative urine pregnancy test before receiving treatment - all male patients and female patients of childbearing potential must agree to consistent use of a highly effective method of contraception during the entire duration of the study and for 90 days after the last dose of study drug - female patients must also refrain from egg donation and in vitro fertilization from the time of signing the informed consent form through the duration of the study and for at least 90 days after the last dose of study drug. - male patients must also refrain from donating sperm during the study and for at least 90 days after the last dose of study drug - see link to clincialtrials.gov for complete Inclusion criteria

Exclusion Criteria:

- received an investigational drug, other than ARD-101, within 30 days of the first study visit - see link to clinicaltrial.gov for complete exclusion criteria

Conditions & Interventions

Interventions:
Drug: ARD-101
Conditions:
Children's Health, Diabetes & Endocrine, Rare Diseases
Keywords:
Prader-Willi Syndrome, PWS

More Information

Description: People who have Prader-Willi Syndrome (PWS) and have completed study treatment through Visit 6 on the AVK-101-301 study are being asked to join this study. The goals of this study are to see how ARD-101 affects eating behaviors in people with hyperphagia and PWS by looking at their scores on a 9-question survey, and to understand how safe (how many side effects participants have) and tolerable (how well participants can tolerate any side effects) ARD-101 is over the long-term.
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