

Open-label Extension Study to Evaluate Metreleptin in Patients With Partial Lipodystrophy

NCT06679270

Status	RECRUITING
Phase	Phase 3
Sponsor	Amryt Pharma
Enrollment	24 participants

Key Eligibility Criteria

Inclusion (7)

- Age ≥13 years of age, inclusive, at the time of signing the informed consent form (ICF).
- Subjects must have completed the Parent study APG-20 and, in the opinion of the Investigator and Sponsor, have been compliant with study procedures through Parent study Month 12 visit.
- Negative pregnancy test (urine or serum) for female subjects of childbearing potential
- Female subjects must be postmenopausal (defined as cessation of menses for at least 1 year), surgically sterile (hysterectomy, bilateral oophorectomy, or tubal ligation), or willing to use a highly effective method of contraception (such methods include combined [estrogen and progestogen containing] hormonal contraception associated with inhibition of ovulation: oral/intravaginal; transdermal/progestogen-only hormonal contraception associated with inhibition of ovulation: oral/injectable; implantable/intrauterine device [IUD]/intrauterine hormone-releasing system [IUS]/bilateral tubal occlusion/vasectomized partner/sexual abstinence) for the duration of the study (from the time they sign an ICF, until 4 weeks after the last dose of study treatment). Hormonal contraception alone (including oral, injectable, transdermal, and implantable) is not acceptable; an additional barrier method must be used. Intravaginal hormonal contraception or IUS alone are allowed per Investigator's discretion. Subjects on oral contraceptives will not be required to discontinue medication. Subjects will not be permitted to commence oral contraceptives while taking study treatment during the study.
- Subjects who are blood/egg/sperm donors should be willing to halt donations during the study and for 4 weeks following their last dose of study treatment.

... and 2 more (see full listing online)

Exclusion (8)

- Severe hypersensitivity reactions to the study treatment of the Parent study APG-20.
- Known to have tested positive for human immunodeficiency virus (HIV) or known to be diagnosed with HIV-related LD. Positive HIV test in countries requiring HIV testing.
- Are immunocompromised or receiving immunomodulatory drugs.
- Estimated glomerular filtration rate (eGFR) <30 mL/min/1.73m² calculated by Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) for subjects ≥18 years of age and by Bedside Schwartz for subjects <18 years of age.
- Diagnosis of clinically significant hematological abnormalities (including but not limited to clinically significant leukopenia, neutropenia, bone marrow abnormalities, leukemia or lymphoma, or clinically significant pathological lymphadenopathy).

... and 3 more (see full listing online)

Locations (7 total)

University of Alabama, Birmingham, Alabama, United States
Flourish Research, Boca Raton, Florida, United States
Massachusetts General Hospital, Boston, Massachusetts, United States
... and 4 more locations

<https://clinicaltrials.gov/study/NCT06679270>

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