Sujata Lalla-Reddy, MD
Lalla-Reddy Medical Corporation
Clinical Trial Inclusion/Exclusion Book

CytoDyn

A Multi-center, Randomized, Double-blind, Placebo-controlled Trial, Followed by Single-arm Treatment of PRO 140 in Combination With Optimized Background Therapy in Treatment-Experienced HIV-1 Subjects.

INCLUSION:

1. Exclusive CCR5-tropic virus at Screening Visit as determined by Monogram Biosciences Trofile® Assay
2. Treatment-experienced HIV-infected patients with documented genotypic or phenotypic resistance to ART drugs within two or more drug classes who demonstrate evidence of HIV-1 replication despite ongoing antiretroviral therapy and have limited treatment options. Subjects will have two or more fully active, approved drugs available for construction of a viable alternative option
3. Plasma HIV-1 RNA ≥ 400 copies/mL at Screening Visit as determined by Human Immunodeficiency Virus 1 (HIV-1) Quantitative, RNA (Roche Taqman® Real-Time PCR)
4. Laboratory values at Screening of:
    a. Absolute neutrophil count (ANC) ≥1000/mm3
    b. Hemoglobin (Hb) ≥10.5 gm/dL (male) or ≥ 9.5 gm/dL (female)
    c. Platelets ≥100,000 /mm3
    d. Serum alanine transaminase (SGPT/ALT) <5 x upper limit of normal (ULN)
    e. Serum aspartate transaminase (SGOT/AST) <5 x ULN
    f. Bilirubin (total) <2.5 x ULN unless in a subject receiving atazanavir and in the absence of other evidence of significant liver disease
    g. Creatinine ≤1.5 x ULN

EXCLUSION:

1. Documented CXCR4-tropic virus or Dual/Mixed tropic (R5X4) virus as determined by HIV-1 tropism assay.
2. Patients with no viable treatment options (≤ 1 fully active approved drug)
3. Any active infection or malignancy (with the exception of local cutaneous Kaposi's sarcoma)
4. Laboratory test values of ≥ grade 3 DAIDS laboratory abnormality with the exception of the absolute CD4+ count criterion of <200/mm3
5. Unexplained temperature >38.5°C (101.3°F) for three consecutive days within 14 days prior to the first study dose
6. Subjects weighing < 35kg
7. Treatment with any of the following:
    a. Radiation chemotherapy within 30 days prior to the screening visit or during the study
    b. Immunosuppressants within 60 days prior to the screening visit or during the study
    c. Immunomodulating agents (e.g., interleukins, interferons), hydroxyurea, or foscarnet within 60 days prior to the screening visit or during the study
    d. Oral or parenteral corticosteroids within 30 days prior to the Screening Visit or during the study. Subjects on chronic steroid therapy >5 mg/day will be excluded with the following exception

GSK-Protocol #: 201038

Post-authorisation Safety (PAS) Observational Cohort Study to Quantify the Incidence and Comparative Safety of Selected Cardiovascular and Cerebrovascular Events in COPD Patients Using Inhaled UMEC/VI Combination or Inhaled UMEC versus Tiotropium

INCLUSION:

1. A clinical diagnosis of COPD verified by spirometry (defined as a post bronchodilator forced expiratory volume in one second/forced vital capacity [FEV1/FVC] ratio of <0.7).
   At no point will any patients be requested to have spirometry solely for the purposes of participating in this study
2. Initiation of treatment with one of the three study treatments, UMEC/VI, UMEC, or tiotropium according to the decision of the treating physician (an index prescription may precede enrolment visit by up to seven days)
3. Adults over 18 years of age who are willing and able to provide written informed consent
4. Patient with medical records available for at least the 12 month period prior to enrolment
5. Patient able to read and write

EXCLUSION:

1. Current participation in any interventional clinical trials in which treatment regimen and/or monitoring is dictated by a protocol
2. Patients with hypersensitivity to UMEC, vilanterol (VI), or tiotropium or excipients
3. Maintenance treatment with a LAMA-containing medication during the 12 months prior to enrolment. Maintenance treatment is defined as 60 or more days of continuous use.

Theratechnologies Inc. EMR200147-501

A phase 4, observational, multicenter, 10-year prospective cohort Safety study comparing subjects with HIV-associated abdominal lipohypertrophy exposed to EGRIFTA® (tesamorelin for injection) to a similar group of subjects not exposed to EGRIFTA® "

INCLUSION:

All of the following inclusion criteria must be fulfilled:

1. Subject has given written informed consent;
2. Subject is an adult man or woman ≥ 18 years old;
3. Subject has HIV infection;
4. Subject has physical evidence of excess abdominal fat, as determined by the examining study physician.
5. Subject has completed standard of care assessments (mammography, cervical PAP smear, colonoscopy and blood work for HIV-1 RNA, CD4 cell count, renal, hepatic, and hematology, PSA test, lipid panel) prior to being enrolled onto the study.

EXCLUSION:

Each of the following criteria will exclude a subject from participation. Exclusion criteria 1 through 4 are based on the contraindications for *EGRIFTA*®.

1. Disruption of the hypothalamic-pituitary axis, including conditions such as hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation, or head trauma;
2. Active malignancy (newly diagnosed or recurrent), exceptions are basal cell carcinoma, in situ carcinoma of the cervix, in situ anal carcinoma, treated and stable cutaneous squamous cell carcinoma. and stable Kaposi's sarcoma;
3. Known hypersensitivity to tesamorelin and/or mannitol;
4. Pregnancy or lactation;
5. Use of *EGRIFTA*® within 6 months prior to baseline;
6. Failure to complete any standard of care assessments.