A Study To Evaluate The Safety Of CMTX-101 In People With Cystic Fibrosis

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Adults ≥18 years of age at the time of screening. 2. If enrolled in the CFF Patient Registry, must provide registry information. 3. Confirmed CF diagnosis based on current CF Foundation (CFF)-sponsored guidelines. 4. For participants on modulator therapy, they must be on a stable dose of modulator therapy for at least 3 months. 5. Willing and capable of providing induced sputum for evaluation at defined study timepoints. 6. Positive P. aeruginosa growth of ≥104 CFU/gram from a sample of induced sputum at the screening visit. 7. FEV1 ≥50% (Part1) or ≥35% (Part 2) of predicted normal value at screening. 8. Currently receiving inhaled antibiotic therapy, either tobramycin or aztreonam alone, or as part of CAT. At least one 28-day cycle completed within 8 weeks prior to screening visit. 9. Women of childbearing potential (WOCBP) must have a negative serum beta-human chorionic gonadotropin test during screening and agree to use an effective method of contraception for the duration of the study and for 4 months after the last infusion of study drug. A female participant is considered of childbearing potential unless postmenopausal or surgically sterilized and at least 3 months has passed since sterilization procedure. Female surgical sterilization procedures include tubal ligation, bilateral salpingectomy, hysterectomy, or bilateral oophorectomy. A female participant is considered postmenopausal if she has had spontaneous amenorrhea for at least 2 years with an appropriate clinical profile (e.g., age appropriate, history of vasomotor symptoms). • Effective methods of contraception include (a) abstinence, (b) partner vasectomy, (c) intrauterine devices, (d) hormonal implants (such as Implanon), or (e) other hormonal methods (birth control pills, injections, patches, vaginal rings). 10. Male participants with a female partner must use a medically accepted contraceptive regimen during his participation in the study and for 4 months after study drug infusion. • Acceptable methods of contraception for male participants include condoms with spermicide, surgical sterilization of the participant (i.e., vasectomy) at least 26 weeks before screening, or sexual abstinence (i.e., refraining from heterosexual intercourse) if that is the preferred and usual lifestyle of the participant.

•Males with infertility documentation are not required to use contraception. 11. Male participants must agree to abstain from sperm donation through 4 months after study drug administration. 12. Capable of providing informed consent. 13. Capable and willing to complete all study visits and perform all procedures required by the protocol.

Exclusion Criteria:

1. Body mass index (BMI) \<14 at screening and baseline. 2. Has a known history or evidence of human immunodeficiency virus (HIV) infection or chronic hepatitis B screening. 3. Tests positive for hepatitis C virus (HCV) RNA at screening. 4. Pulmonary exacerbation within 28 days of baseline. 5. Requirement for continuous (24 hour/day) oxygen supplementation; periodic use is permitted. 6. Participation in smoking or vaping activity in the last 6 months. 7. History of, or planned, organ transplantation. 8. Elevated liver function tests obtained at screening. 1. ALT \>5 × ULN or AST \>5 × ULN, or 2. Total bilirubin \>3 × ULN or Total bilirubin \>1.5 × ULN combined with either ALT \>3 × ULN or AST \>3 × ULN. ULN reflects local laboratory ranges. 9. Greater than 5 ml of hemoptysis on one occasion or \>30 mL of hemoptysis in a 24-hour period within 28 days of baseline. 10. Infection with other more pathogenic organisms such as Mycobacterium abscessus or Burkholderia spp., where the investigator feels that the participant either is not or will not remain clinically stable throughout the duration of the study. 11. Acute clinical illness requiring a new (oral, parenteral, or inhaled) antibiotic(s) ≤30 days prior to the baseline visit. Does not include chronic suppressive medications or cyclic dosing medications such as inhaled antibiotics. 12. Women who are pregnant, planning to become pregnant during the study period or for 4 months following last infusion of study drug, or breastfeeding. 13. Active treatment of any mycobacterial or fungal organisms ≤30 days prior to baseline visit. Chronic treatment for suppression of fungal populations is allowable. 14. Anticipated need to change chronic (either inhaled or oral) antibiotic regimens during the study period. Participants must agree to maintain their current chronic antibiotic regimen from the screening visit for the duration of the follow-up period (approximately 30 days). 15. Known allergy to any component of the study drug. 16. Participant with an estimated glomerular filtration rate \<60 mL/min/1.73 m2. 17. Any significant finding that, in the opinion of the investigator, would make it unsafe for the participant to participate in this study or would not be in the best interest of the participant. 18. Enrolled in an interventional clinical study within ≤60 days of the baseline visit, or participating in a clinical study while enrolled in this clinical study (inclusive of vaccine studies). 19. Currently or previously enrolled in this study.

Conditions & Interventions

Interventions:
DRUG: CMTX-101, DRUG: Placebo
Conditions:
Persistent Infection, Cystic Fibrosis
Keywords:
Pseudamonas auriginosa

More Information

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