A Phase 2 Study of PTX 100 in Patients With Relapsed/Refractory CTCL

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Adult patient ≥18 years of age at the time of signing the informed consent. 2. Patient is capable of giving adequate signed informed consent 3. Have a confirmed diagnosis of CTCL with histological confirmation 4. Patients must have greater than or equal to Stage Ib disease. 5. Has received and failed (or intolerant of) at least 2 prior lines of prior systemic therapy for their disease. 6. Has measurable disease defined by at least one of the following, within 28 days prior to start of study treatment: by evaluable by mSWAT or quantifiable by flow cytometry or morphology in blood or measurable by Lugano Criteria. 7. On a stable dose of systemic corticosteroid (\< 10 mg prednisone or equivalent) are permitted. Participants on a stable dose of topical corticosteroids are permitted. 8. Washout period- must be 2 weeks (4 weeks for monoclonal antibodies) or 5 -half-lives (whichever is longer) since any prior anti-cancer therapy. 9. Must be human T-cell lymphotropic virus type 1 (HTLV1) negative. 10. Has an ECOG PS of 0 to 2. 11. Life expectancy of 3 months or greater 12. Has adequate bone marrow function. 13. Has adequate hepatic function. 14. Has adequate Renal function. 15. Has adequate coagulation function. 16. Patients with Human Immunodeficiency virus (HIV) must be on established and stable effective anti-retroviral therapy for at least 4 weeks and have an HIV viral load of less than 400 copies/mL. 17. Male patients are eligible to participate if they agree to use a highly effective contraception during the treatment period and for at least 3 months after the last dose of study treatment and refrain from donating sperm during this period. 18. Female patients are eligible to participate if they are not pregnant, not breastfeeding, and at least one of the following conditions applies: -Not a woman of childbearing potential (WOCBP). * OR * A WOCBP who agrees to use a contraceptive method that is highly effective (with a failure rate of \< 1% per year) or be abstinent from heterosexual intercourse as their preferred method and usual lifestyle, beginning the time of informed consent, during the treatment period and for at least 3 months after the last dose of study treatment. 19. A WOCBP must have a negative serum pregnancy within 72 hours of the first dose of study treatment. 20. Must be willing and able to adhere to the study as judged by the Investigator.

Exclusion Criteria:

1. Patients with known central nervous system involvement. 2. Patients who require the use of strong inhibitors or inducers of CYP enzymes or transporters (e.g., CYP3A4, 2D6, 2C19) or (P-gp, BCRP, OATP1B1, OATP1B3, OAT1. OAT3, OCT2, MATE1 and MATE2-K). Patients who are receiving these medications at Screening can be enrolled into the trial if they discontinue them for at least 14 days or 5 half-lives, whichever is longer, before they commence PTX-100. An alternative pharmacological treatment should be instituted by the treating clinician based on clinical judgement. 3. Significant cardiovascular disease. A history of, or concurrent interstitial lung disease or severely impaired lung function. 5. Active viral, bacterial, fungal infection or other serious infection requiring ongoing systemic treatment. Routine antimicrobial prophylaxis is permitted. 6. Medical history of another malignant tumor within the past 5 years. Exceptions are patients with basal cell carcinoma of the skin, squamous cell carcinoma of the skin or carcinoma in situ who have undergone curative therapy with no evidence of disease. 7. On an immunomodulatory drug for concomitant or intercurrent conditions or who have received any of these agents within 4 weeks of baseline. 8. Patients with active viral (any etiology) hepatitis are excluded. However, patients with serologic evidence of chronic hepatitis B virus (HBV) infection (defined by a positive hepatitis B surface antigen test and a positive anti-hepatitis core antigen antibody test) who have a viral load below the limit quantification (HBV deoxyribose nucleic acid titer \< 1000 cps/mL or 200 IU/mL) and are not currently on viral suppressive therapy may be eligible and should be discussed with the Medical Monitor. Patients with a history of hepatitis C virus infection who have completed curative antiviral treatment and have a viral load below the limit of quantification may be eligible and should be discussed with the Medical Monitor. 9. A history or current evidence of any condition, laboratory abnormality or other circumstance that might confound the results of the study or interfere with patient participation for the full duration of the study. 10. Prior allogeneic or autologous hematopoietic transplantation 11. Has a known psychiatric disorder that would interfere with compliance with the requirements of the study. 12. Is a consumer of illicit or recreational drugs or has a recent history (within the last year) of drug or alcohol abuse or dependence that in the judgment of the Investigator, would interfere with compliance with the requirements of the study.

Conditions & Interventions

Interventions:
DRUG: PTX-100
Conditions:
CTCL
Keywords:
Relapsed or refractory Cutaneous T Cell Lymphoma, CTCL, PTX-100, Mycosis Fungoides, Sezary Syndrome, T Cell Lymphoma, Non-Hodgkin Lymphoma, Cutaneous Lymphoma

More Information

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