PlaTform: A MULTICENTER, MULTI-ARM, ACADEMIC PLATFORM TRIAL EVALUATING NOVEL AGENTS AND COMBINATIONS IN RELAPSED OR REFRACTORY PERIPHERAL T-CELL LYMPHOMAS

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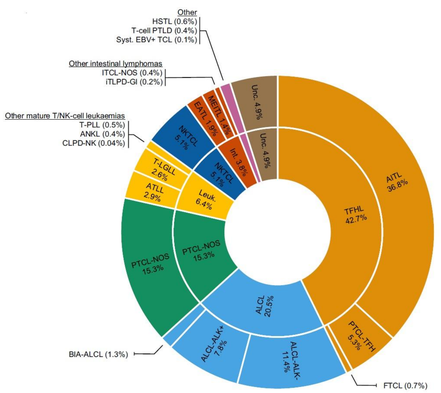
INTRODUCTION

Peripheral T-cell lymphomas (PTCLs):

- Heterogeneous and aggressive group of rare mature T- or NK-cell neoplasms
- Poor prognosis and limited therapeutic advances
- Urgent need for flexible, biomarker- and histology-driven trial designs to identify active therapies and define optimal patient subsets for future registration strategies.



Grange T *et al*, HemaSphere 2025

METHODS

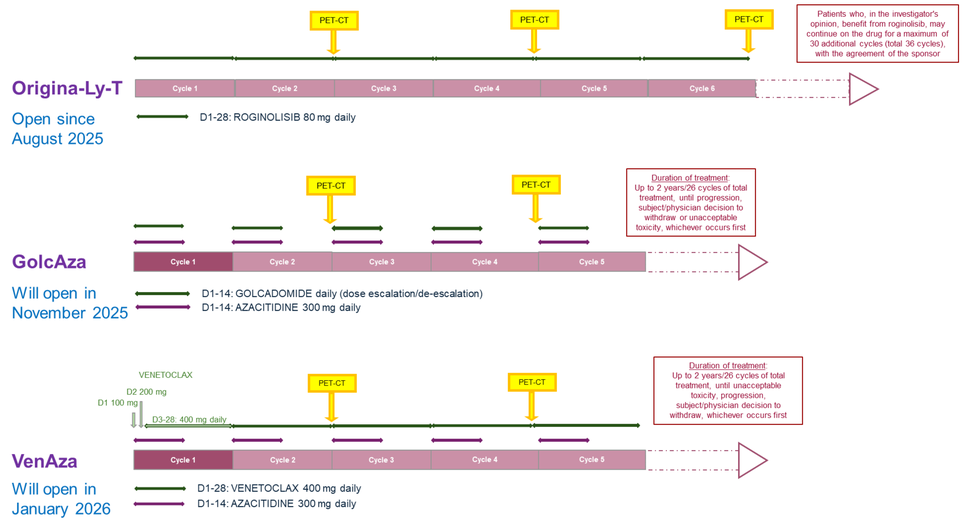
- Patients are enrolled and randomly assigned to available sub-studies, unless specific contraindications apply
- Sub-studies may be phase 1, phase 1/2 or phase 2
- A shared screening process and centralized pathology review enable harmonized inclusion and integrated translational analyses
- In phase 1 sub-studies, the number of patients is adapted to the specific objectives of each sub-study
- Each phase 2 sub-study will include up to 31 evaluable patients
- The primary endpoint of phase 1 is the determination of the maximum tolerated dose and recommended phase 2 dose, based on a Bayesian Optimal Interval (BOIN) or Bayesian Continual Monitoring with Reassessment (BCMR) design
- The primary endpoint of phase 2 is modified progression-free survival (mPFS), defined as the time to disease progression, relapse, unplanned lymphoma therapy, or death. Hypothesis: Improvement of the median mPFS from 3.7 months to 7.4 months (HR = 0.5). Secondary endpoints include overall and complete response rates, duration of response, overall survival, and safety
- Exploratory objectives include correlation of genomic and immunological features with outcomes, including patient-derived xenograft generation and next-generation sequencing profiling
- 20 French centers.

Eligibility criteria

- ≥18 years of age
- Histologically confirmed R/R PTCL (excluding cutaneous T-cell lymphoma, T-cell large granular lymphocytic leukemia, and T-lymphoblastic lymphoma)
- Measurable disease per Lugano 2014 criteria
- ECOG performance status 0–2 (or 3 if related to lymphoma)
- Adequate organ function
- Fresh or archival tumor tissue required for central review and biomarker analyses
- Each sub-study includes additional, specific inclusion and exclusion criteria.

Sub-Studies:

- Origina-Ly-T: This phase 2 sub-study evaluates **roginolisib**, a novel, oral, non–ATP-competitive, allosteric small-molecule inhibitor of PI3Kδ, in patients with R/R PTCL.
- GolcAza: This phase 1 sub-study evaluates the combination of **golcadomide** and **oral azacitidine** in patients with R/R follicular helper T-cell lymphoma.
- VenAza: This phase 2 sub-study evaluates the combination of **venetoclax** and **oral azacitidine** in patients with R/R follicular helper T-cell lymphoma.
- **Additional sub-studies** may be initiated in the future to explore other investigational agents.



STUDY DESIGN

PlaTform (NCT07018752) is a French, academic, multicenter, open-label, multi-arm phase 1/2 platform trial evaluating novel agents and combinations in relapsed/refractory (R/R) PTCL within a master protocol framework.

CONCLUSION

PlaTform represents a novel academic initiative dedicated to R/R PTCL, designed to accelerate therapeutic innovation for this underserved patient population.

ACKNOWLEDGEMENTS

We thank the patients and their families for their participation in the clinical trials, iOnctura for providing access to roginolisib, Bristol Myers Squibb for providing access to golcadomide and azacitidine, and AbbVie for providing access to venetoclax.

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