

A Phase II Trial of the Super-enhancer Inhibitor Minnelide in Advanced Refractory Adenosquamous Carcinoma of the Pancreas (ASCP)

Authors

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Trial registration no:
NCT04896073

Study design



Oral drug



No placebo



Phase II trial



Single arm

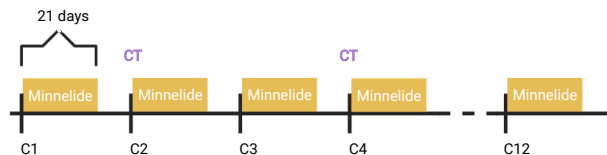


Televisits possible



Up to 25 patients

- Minnelide is a small molecule anti-superenhancer drug that inhibits MYC
- Trial will be conducted using a Simon optimal two-stage phase II trial design
- The first stage will enroll a total of 12 evaluable participants,
- If clinical benefit is shown, the accrual will continue to a total of 25 evaluable participants



- Drug administration for 21 days of a 28-day cycle for 12 cycles until PD or unacceptable toxicity
- Imaging assessment every 2 cycles

End points



Primary end point

Disease control rate (CR + PR + SD for ≥ 16 weeks)



Secondary end points

- Drug safety
- PFS
- OS

Exploratory end points

Serial biopsies to assess effects on:

- Myc expression
- Accessibility of Myc and other superenhancer loci
- Tumor microenvironment – stroma and immune cells
- Post treatment
 - Changes in circulating tumor DNA
 - Circulating immune cell populations

Key eligibility criteria

18

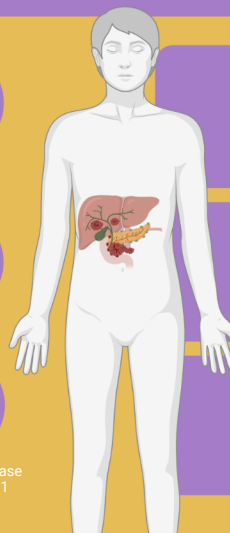
Age 18 years

ECOG PS 0 or 1

ECOG PS 0 or 1

RECIST v1.1

Measurable disease per RECIST v1.1



Histologically confirmed ASCP, having $\geq 30\%$ malignant squamous component

Presence of metastatic, recurrent, or locally advanced unresectable disease

Progression or intolerance ≥ 1 prior systemic treatment for advanced disease

Glossary

ASCP: Adenosquamous carcinoma of the pancreas; PD: progressive disease; CR: Complete response; PR: partial response; SD: stable disease; PFS: Progression free survival; OS: Overall survival; ECOG PS: Eastern Cooperative Oncology Group; RECIST: Response Evaluation Criteria in Solid Tumors; TMB: Tumor mutational burden