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Challenge Your Thinking

PrisMN: Phase 2 Study to Evaluate the Safety and Efficacy of Budoprutug, a Low-Fucosylated Anti-CD19 mAb, in Primary Membranous Nephropathy

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PrisMN
A NEW LENS ON PMN

INTRODUCTION

Primary membranous nephropathy (PMN) is a rare, autoantibody-mediated disease that can cause proteinuria, nephrotic syndrome, and progressive loss of renal function.

In ~75% of PMN patients the disease is caused by autoantibodies directed against the phospholipase A2 receptor (PLA2R) forming immune complexes that are deposited in the glomerular subepithelial space.[1,2]

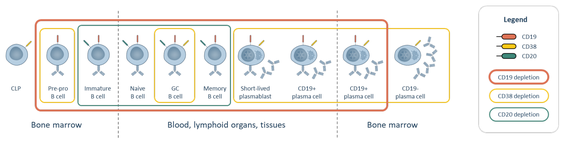
Current treatment[3] includes supportive care with renin-angiotensin-aldosterone system inhibitors (RAASi) and, in higher-risk patients, off-label immunosuppressive therapies such as calcineurin inhibitors and rituximab.

While these treatments have improved prognosis, few patients achieve a sustained complete remission.

There remains an unmet need for new, safe, effective, and durable treatment options for patients with PMN.

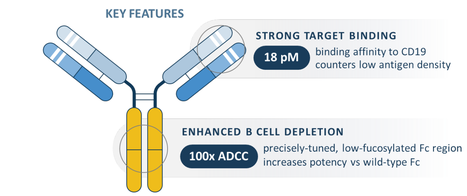
STUDY RATIONALE

- **CD19** is expressed across all stages of B-cell development, providing potential for profound and durable depletion of B cells and pathogenic autoantibodies.[4]



Adapted from Suan J Immunol 2025

- **Budoprutug** (TNT119) is an anti-CD19 mAb bioengineered with picomolar binding affinity for CD19 and a low-fucosylated Fc region for enhanced ADCC.



AIM

This Phase 2 study (PrisMN, NCT07096843) is designed to evaluate the efficacy and safety of **budoprutug in patients with moderate to severe PMN**.

PHASE 1B RESULTS

- Budoprutug was well tolerated in 5 patients with moderate to severe PMN, with no study discontinuations due to an adverse event, and no dose-limiting toxicities as previously reported[5]
- All patients achieved >95% peripheral B-cell depletion and complete (3) or partial (2) clinical remission by week 48[5]
- Long-term disease control up to 3 years after initial dosing observed in 4 patients with available data[6]

PHASE 2 STUDY DESIGN

- **Global, open-label, dose escalation study** enrolling 45 adult patients with **moderate to severe PMN**
- **Key inclusion criteria:**
  - 18-75 years of age
  - Confirmed diagnosis of PMN, no secondary causes of MN
  - UPCR ≥ 2.0 g/g
  - PLA2R antibody positive
  - Adequate trial of ACEi/ARB, with stable dose for ≥ 4 weeks
  - eGFR ≥ 35 mL/min/1.73m^2
  - ≥ 6 months since any prior B-cell depleting agent

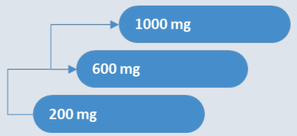
Primary Objective:
- Safety and tolerability

Secondary Objectives:
- PK and PK/PD
- PD markers (B cells, anti-PLA2R, total Ig)
- Efficacy: clinical complete and partial remission at week 48 (UPCR and eGFR)

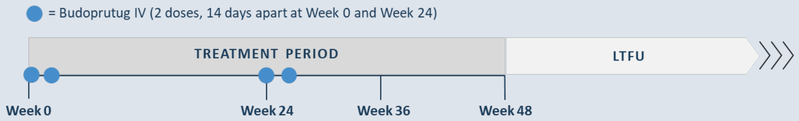
Budoprutug dosing:
- Dose escalation starts at previous Phase 1b dose (200 mg) and escalates to 1000 mg IV budoprutug

OPEN-LABEL, DOSE ESCALATION STUDY N = 45

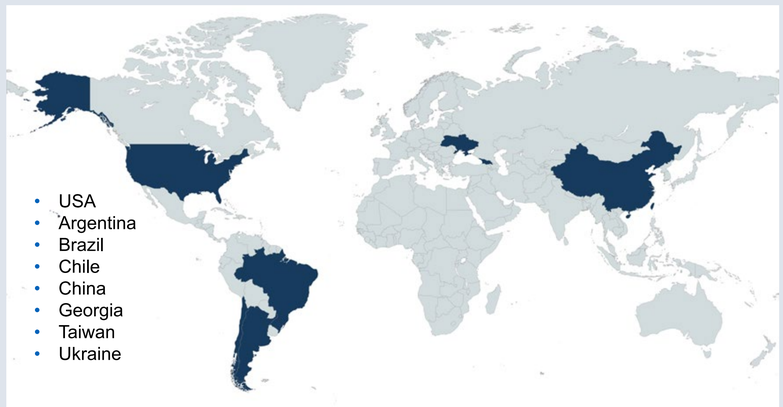
15 patients per cohort, enrolled sequentially



Budoprutug administration:
- Participants will each receive an IV dose of budoprutug on the first day of weeks 0, 2, 24, and 26, and will be followed through week 48, with extended follow-up for B-cell recovery as needed.



Global footprint with ~45 sites across 8 countries:



Scan the QR code for the clinicaltrials.gov entry

Scan the QR code for the pdf of the poster

CONCLUSIONS

- There remains an **unmet need** for new, safe, effective, and durable treatment options for **patients with PMN**.
- **Budoprutug** is a an **anti-CD19 mAb** that has been shown to robustly deplete peripheral B cells.
- Clinical **proof-of-concept** for **budoprutug in patients with PMN** has been demonstrated in a Phase 1b study.
- This **Phase 2 study** aims to evaluate the efficacy and safety of budoprutug in patients with moderate to severe PMN (PrisMN, NCT07096843).
- PrisMN is ongoing and **actively recruiting patients.**

ACKNOWLEDGEMENTS

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ACEi angiotensin-converting enzyme inhibitors, **ADCC** antibody-dependent cell cytotoxicity, **ARB** angiotensin II receptor blockers, **eGFR** estimated glomerular filtration rate, **Ig** immunoglobulin, **IV** intravenous; **LTFU** long term follow-up, **MN** membranous nephropathy, **PD** pharmacodynamic, **PK** pharmacokinetic, **PLA2R** phospholipase A2 receptor, **PMN** primary membranous nephropathy, **UPCR** urine protein creatinine ratio