BUDOPRUTUG, A LOW-FUCOSYLATED ANTI-CD19 MONOCLONAL ANTIBODY, IN ADULTS WITH PRIMARY IMMUNE THROMBOCYTOPENIA: INITIAL PHASE 1B STUDY RESULTS

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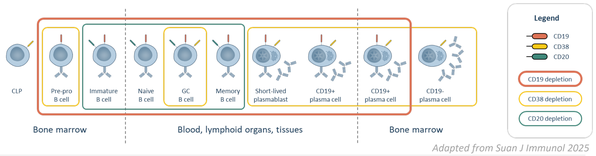
BACKGROUND & SIGNIFICANCE

IMMUNE THROMBOCYTOPENIA

- Immune thrombocytopenia (ITP) is a rare autoantibody-mediated disorder characterized by reduced platelets and increased risk of bleeding.[1,2]
- 80% of patients with ITP fail first line therapy, and 40% fail second line, often requiring multiple lines of treatment.[1,2]

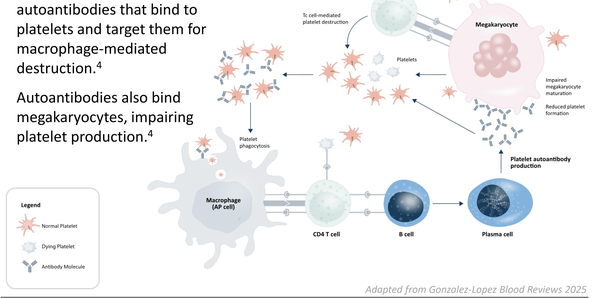
CD19 RATIONALE IN ITP

- CD19 is expressed from the early pro-B stage through maturation and differentiation to plasmablasts and on plasma cell subsets, providing the potential for budoprutug to provide deep and sustained depletion of B cells, including autoantibody-producing cells.[3]



Adapted from Suan J Immunol 2025

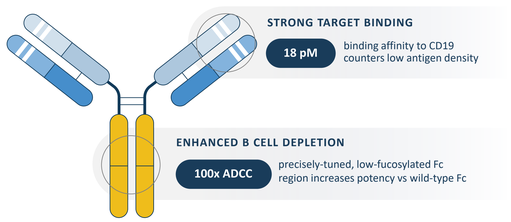
- Targeting CD19 has the potential to eliminate pathogenic, autoantibody producing B cells, which are a critical disease driver in ITP.[4]
- B cells secrete anti-platelet autoantibodies that bind to platelets and target them for macrophage-mediated destruction.[4]
- Autoantibodies also bind megakaryocytes, impairing platelet production.[4]



Adapted from Gonzalez-Lopez Blood Reviews 2025

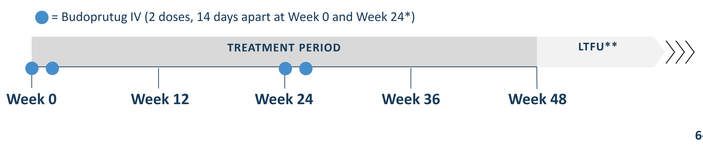
BUDOPRUTUG

- Budoprutug (TNT119) is an investigational anti-CD19 mAb bioengineered with picomolar binding affinity for CD19 and a low-fucosylated Fc region for enhanced ADCC.
- In an early clinical study in patients with primary membranous nephropathy, another autoantibody-mediated condition, budoprutug demonstrated rapid and sustained B-cell depletion, immunological remission, and resolution of proteinuria.[5,6]



STUDY OVERVIEW

STUDY SCHEMA



DOSE ESCALATION†

250 mg → 500 mg → 1000 mg

6-9 participants per cohort enrolled sequentially

**Cohort 1 participants (250 mg dose) are allowed to receive the second cycle of budoprutug up to Week 48.*
*** LTFU until B-cell recovery (>LLN or >80% of Baseline)*
†Decision to dose escalate made after data review and recommendation by the Safety Review Committee

PRIMARY & SELECTED SECONDARY ENDPOINTS

- **Primary:** Safety
- **Secondary:** PK, B-cell counts, platelet counts

STUDY POPULATION

- Aged ≥18 years and diagnosed with primary ITP
- Platelet count <30,000/µL on 2 occasions 14-15 days apart despite ≥1 prior therapy
- $CD19^+$ B cell count ≥80 cells/µL, or ≥40 cells/µL if B-cell depleting therapy was received 24 weeks to 2 years prior to screening
- No prior B-cell depleting therapy (e.g., rituximab) within 24 weeks or chronic use of anticoagulants or antiplatelet agents within 14 days of Week 0
- Participants receiving corticosteroids or TPO-RAs must be on a stable dose over the 14 days prior to Week 0

RESULTS

PARTICIPANT DEMOGRAPHICS AND CHARACTERISTICS

Data as of June 1st, 2026	250 mg (N=6)	500 mg (N=9)
Age (median, range)	42 (22-75)	41 (18-58)
Gender (M/F)	2/4	5/4
Time since diagnosis (median, range)	6.5 years (0.5-12)	15 years (0.6-40)
Prior lines of therapy (median, range)	7.5 (4-18)	6 (2-15)
Prior therapy:		
Corticosteroids (n)	6	9
IVIg (n)	2	5
TPO-RA (n)	4	7
Rituximab (n)	4	2
Splenectomy (n)	0	1
Baseline:		
Platelet count x10^3/µL (median, range)	13 (4-29)	7 (2.5-12)
$CD19^+$ B-cells/µL (median, range)	117.5 (87-287)	156 (82-343)

250 mg and 500 mg COHORTS: STUDY POPULATION

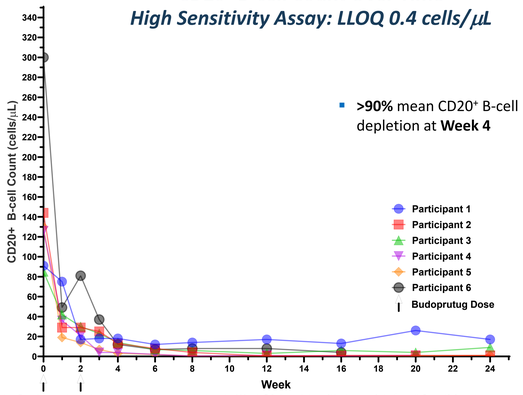
- As of June 1, 2026 a total of 15 participants were enrolled in the 250 mg and 500 mg dose cohorts
- Both cohorts represent patients with heavily pretreated, persistent or chronic ITP, with these notable differences:
  - Participants in 250 mg cohort had greater prior rituximab exposure compared to participants in 500 mg cohort
  - Participants in the 500 mg cohort had a longer disease duration (median 15 years vs 6.5 years)

250 mg and 500 mg COHORTS: SAFETY AND TOLERABILITY

- Median (range) follow-up for participants in Cohort 1 and 2: 38 weeks (28-44), and 12 weeks (3-20), respectively
- Overall, budoprutug was generally safe and well tolerated in participants receiving 250 mg and 500 mg doses
  - No serious adverse events (SAEs) or deaths were reported
  - All adverse events (AEs) were Grade 1 to Grade 2 per NCI CTCAE Version 5.0
    - Majority of AEs belonged to the gastrointestinal System Organ Class
  - There were no treatment discontinuations due to an AE
  - No infusion-related reactions
- No participants had hypogammaglobulinemia

250 mg COHORT EFFICACY: B-CELL DEPLETION

$CD20^+$ B-cell Count Over Time
High Sensitivity Assay: LLOQ 0.4 cells/µL

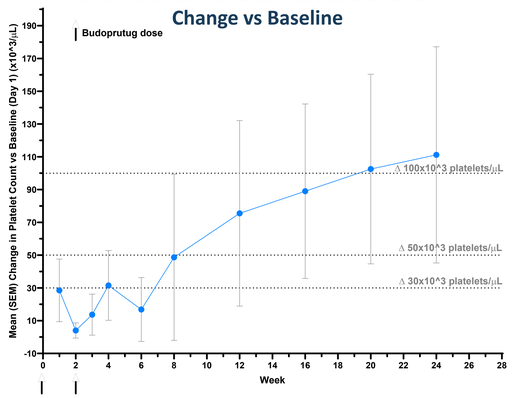


- **>90%** mean $CD20^+$ B-cell depletion at **Week 4**

Note: B-cell counts and platelet counts presented up to Week 24, last date with data points for all 6 participants

250 mg COHORT EFFICACY: PLATELET RESPONSE

Mean Increase in Absolute Platelet Count Change vs Baseline



- At **Week 24**, mean (SEM) increase in platelet count from baseline was **111 (66) x 10^3 platelets/µL**
- Participants continue to be followed

Platelet Response Assessment

250 mg Cohort (N=6)	Platelet Count Criteria	n/N (%)
Durable Response[1,7]	≥30 × 10^3/µL and ≥2x BL at 6 mos	4/6 (67%)
Complete Response[8]	≥100 × 10^3/µL and absence of bleeding	2/6 (33%)
Response[1,7,8]	30 - 100 × 10^3/µL and ≥2x BL	4/6 (67%)

Responses require confirmation on two separate occasions at least 7 days apart through Week 24

- Of note, **the two participants with complete response have maintained platelet levels ≥100 x 10^3/µL for ≥24 and ≥28 weeks, respectively.**
  - Both of these participants previously relapsed on rituximab
- Of the four participants who had prior rituximab, three responded, two of whom had durable and complete responses (per criteria above)

CONCLUSIONS

- Safety data to date indicate **acceptable safety and tolerability profile;** no SAEs, or AEs leading to discontinuations
- **B-cell levels were depleted** by average of >90% by Week 4 in the low dose cohort
- **Durable response** achieved in 4/6 participants in low dose cohort, with 2/6 experiencing platelet levels ≥100 x 10^3/µL for 24+ weeks (follow-up continues)
- Low dose cohort results to date support **continued clinical evaluation of budoprutug in ITP**
- Enrollment in the 1000 mg dose cohort is ongoing

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ADCC antibody-dependent cellular cytotoxicity; **BL** baseline; **Ig** immunoglobulin; **IV** intravenous; **IVIg** intravenous immunoglobulin; **LLN** lower level of normal; **LTFU** long-term follow-up; **mAb** monoclonal antibody; **PK** pharmacokinetics; **SEM** standard error of the mean; **TPO-RA** thrombopoietin receptor agonists

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REFERENCES

1. Neunert Blood Adv 2019; 2. Gafter-Gvili Euro J Int Med 2023; 3. Suan J Immunol 2025; 4. Gonzalez-Lopez Blood Reviews 2025; 5. Cortazar ASN 2024; 6. Cortazar ASN 2025; 7. Neunert Blood Adv 2024; 8. Rodeghiero Blood 2009

ADDITIONAL INFORMATION

NCT07043946
https://clinicaltrials.gov/study/NCT07043946

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