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IGNITE

Tirabrutinib

A Phase 3, Multi-regional, Open-Label, Randomized Study of Tirabrutinib vs Rituximab and Temozolomide in Participants with Relapsed/Refractory Primary Central Nervous System Lymphoma (PCNSL)

A complete listing of sites and additional information for this clinical trial can be found at **clinicaltrials.gov/study/NCT07104032**.

For more information, email
medicalinformation@deciphera.com

Tirabrutinib is an oral, highly selective and potent, second-generation small molecule inhibitor of Bruton's tyrosine kinase.
Tirabrutinib is an investigational drug that has not been approved by the US FDA, European Commission, or any other regulatory agency.

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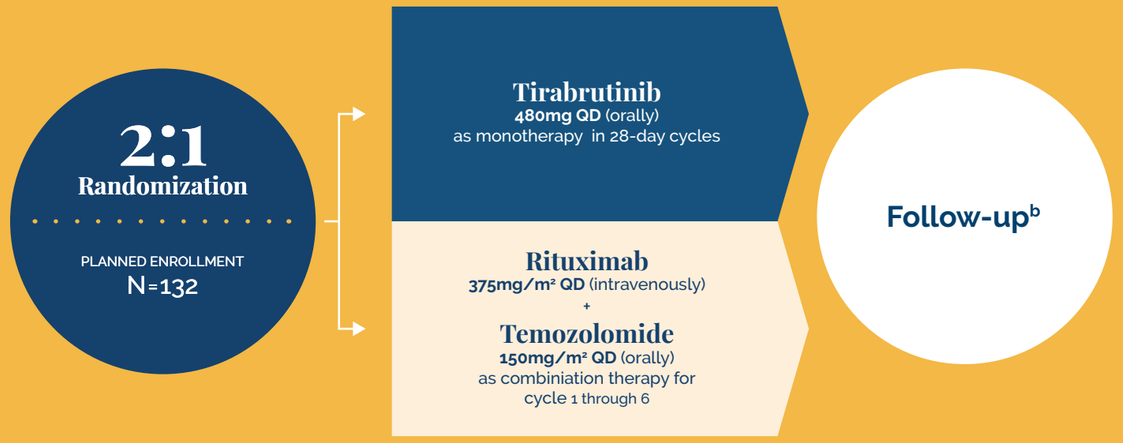
Study Design

Phase 3, multi-regional, open-label, randomized study evaluating the efficacy and safety of tirabrutinib monotherapy, compared with rituximab + temozolomide (R-TMZ) combination therapy in participants with relapsed/refractory PCNSL



Primary Outcome Measures

Estimated Timeframe: up to 24 months

- Progression free survival (PFS) based on blinded independent review committee (BIRC)

Secondary Outcome Measures

Estimated Timeframe: up to 48 months

- Overall response rate (ORR)
- Overall survival (OS)
- Complete response rate (CRR)
- Best overall response (BOR)
- Time to response (TTR)
- Time to complete response (TTCR)
- Duration of response (DOR)
- Disease free survival (DFS)
- Change from baseline in corticosteroid dose

Select Inclusion Criteria

- Male or female ≥18 years of age
- Pathologically confirmed diagnosis of B-cell PCNSL
- Relapsed or refractory B-cell PCNSL with at least 1 prior high-dose methotrexate (HD-MTX) based therapy for PCNSL:
  - Relapsed disease: Participants who achieved a response (CR, CRu, PR) to the last treatment and subsequently experienced disease progression
  - Refractory disease: Participants whose best response to the last treatment was stable disease or PD
- One or more bi-dimensionally measurable brain lesions with a minimum diameter equal or greater than 1 centimeter (cm) × 1 cm in gadolinium-enhanced magnetic resonance imaging (MRI)
- Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0-2
- Adequate bone marrow, renal, and hepatic function per central lab values
- Participants must agree to comply with all defined contraceptive requirements

Select Exclusion Criteria

- Participants with isolated intraocular or spinal PCNSL with no brain lesions
- Participants with non-B-cell PCNSL
- Participants with systemic presence of lymphoma
- Refractory to temozolomide with or without rituximab-containing regimens in the last PCNSL treatment
- Concomitant systemic corticosteroid exposure on an ongoing basis within 14 days before starting study drug per Investigator assessment with the exception of the following:
  - Equivalent of up to 10 milligram per day (mg/day) of prednisone for a disease other than PCNSL
  - Equivalent of up to 50 mg/day of prednisone (equal to 8 mg/day dexamethasone) for participants with lesions of the brain and/or spinal cord
- Active malignancy, other than PCNSL requiring systemic therapy
- Poorly controlled comorbidity, or history of medical conditions contraindicated per Investigator assessment
- Participants who are unable to swallow oral medication
- Prior Bruton's tyrosine kinase (BTKi) inhibitor treatment

Abbrieviations: CR=complete response; CRu=unconfirmed or uncertain complete response, PR=partial response; PD=progressive disease; QD=once daily

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