NOW ENROLLING

The PROSPECT Study

PROSPECT is an open-label, Phase II study evaluating the efficacy, safety, and pharmacokinetics of an investigational oral medicine called tirabrutinib (ONO-4059), a Bruton's tyrosine kinase (BTK) inhibitor, in patients with primary central nervous system lymphoma (PCNSL).

PROSPECT

Tirabrutinib monotherapy (Part A)

Tirabrutinib monotherapy in patients with relapsed or refractory PCNSL (n=44). Tirabrutinib (480 mg) is taken orally, once a day.

Key Inclusion Criteria*

- Relapsed or refractory PCNSL with at least 1 prior HD MTX-based therapy for PCNSL

Key Exclusion Criteria*

- Prior chemotherapy within 21 days, nitrosourea within 42 days, an antibody drug with anticancer activity (eg, rituximab) within 28 days, prior radiotherapy within 14 days, prior major invasive surgery within 28 days, or allogeneic stem cell transplant within 6 months before starting tirabrutinib treatment

Primary Outcome Measure*

- Overall response rate (ORR)

Select Secondary Outcome Measures*

- Duration of response (DOR)
- Time to response (TTR)
- Best overall response (BOR)

ECOG PS=Eastern Cooperative Oncology Group performance status; HD MTX=high-dose methotrexate; HIV=human immunodeficiency virus; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

About the PROSPECT Study

Current treatment options for primary CNS lymphoma (PCNSL) are limited, and there are no medications approved specifically for the treatment of PCNSL in the United States. New treatment options are needed to improve the prognosis for those with PCNSL.

The PROSPECT study is a clinical trial to evaluate an investigational oral medicine called tirabrutinib in patients with PCNSL. About 112 participants will be enrolled in the Phase II (PROSPECT) study in the United States.

Tirabrutinib monotherapy (Part A)

Tirabrutinib monotherapy in patients with relapsed or refractory PCNSL (n=44). Tirabrutinib (480 mg) is taken orally, once a day.

Key Inclusion Criteria*

- Relapsed or refractory PCNSL with at least 1 prior HD MTX-based therapy for PCNSL

Key Exclusion Criteria*

- Prior chemotherapy within 21 days, nitrosourea within 42 days, an antibody drug with anticancer activity (eg, rituximab) within 28 days, prior radiotherapy within 14 days, prior major invasive surgery within 28 days, or allogeneic stem cell transplant within 6 months before starting tirabrutinib treatment

Primary Outcome Measure*

- Overall response rate (ORR)

Select Secondary Outcome Measures*

- Duration of response (DOR)
- Time to response (TTR)
- Best overall response (BOR)

ECOG PS=Eastern Cooperative Oncology Group performance status; HD MTX=high-dose methotrexate; HIV=human immunodeficiency virus; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

Tirabrutinib in combination with methotrexate-based regimens (Part B)

Tirabrutinib + methotrexate/temozolomide/rituximab (MTR) or tirabrutinib + rituximab/methotrexate/procarbazine/vincristine (R-MPV) in patients with newly diagnosed, treatment-naïve PCNSL (n=68)

Key Inclusion Criteria*

- No prior anti-tumor treatments for PCNSL
- Patients who, in the opinion of the investigator, are suitable to receive treatment with a high-dose methotrexate-containing regimen

Primary Outcome Measures*

- Tirabrutinib dose estimate
- Safety
- Complete response rate (CRR)

Select Secondary Outcome Measures*

- Duration of response (DOR)
- Time to response (TTR)
- Best overall response (BOR)

*Full inclusion and exclusion criteria and primary and secondary outcome measures available at clinicaltrials.gov.

Both Part A and B

Key Inclusion Criteria*

- Measurable brain lesion with a minimum diameter >1.0 cm in gadolinium-enhanced magnetic resonance imaging (MRI) performed within 14 days before starting tirabrutinib treatment
- ECOG PS of 0-2

Key Exclusion Criteria*

- Intraocular PCNSL with no brain lesion
- Patients who are intolerant of contrast-enhanced MRI due to allergic reactions to contrast agents
- Patients with non-B cell PCNSL
- Patients with systemic presence of lymphoma
- Prior BTK inhibitor treatment
- Poorly controlled comorbidity; severe heart, severe lung disease; clinically significant liver diseases that could affect protocol compliance or safety or efficacy assessments
- Active infection, including HIV, cytomegalovirus infection, or SARS-CoV-2, or has had, within 28 days before starting tirabrutinib treatment, an infection (other than nail trichophytosis) that requires hospitalization or an intravenous antibiotic
- Active malignancy, other than PCNSL, requiring systemic therapy

About the PROSPECT Study

Current treatment options for primary CNS lymphoma (PCNSL) are limited, and there are no medications approved specifically for the treatment of PCNSL in the United States. New treatment options are needed to improve the prognosis for those with PCNSL.

The PROSPECT study is a clinical trial to evaluate an investigational oral medicine called tirabrutinib in patients with PCNSL. About 112 participants will be enrolled in the Phase II (PROSPECT) study in the United States.

This study is actively recruiting. Information about local site coordination is available on clinicaltrials.gov.

To learn more about this study, use the QR code below, visit clinicaltrials.gov (search for NCT04947319), or email PROSPECTstudy@ono-pharma.com.

NOW ENROLLING

The PROSPECT Study

PROSPECT is an open-label, Phase II study evaluating the efficacy, safety, and pharmacokinetics of an investigational oral medicine called tirabrutinib (ONO-4059), a Bruton's tyrosine kinase (BTK) inhibitor, in patients with primary central nervous system lymphoma (PCNSL).

ONO PHARMA USA, INC.

PROSPECT

PROSPECT

This study is actively recruiting. Information about local site coordination is available on clinicaltrials.gov.

To learn more about this study, use the QR code below, visit clinicaltrials.gov (search for NCT04947319), or email PROSPECTstudy@ono-pharma.com.

ONO PHARMA USA, INC.

PROSPECT