AOU Città della Salute e della Scienza di Torino – PO Molinette

Protocolli di Ricerca Clinica in ambito oncologico:

Disordini linfoproliferativi AOU CDSS

Divisione Universitaria di Ematologia (Prof. Benedetto Bruno)

Divisione Ospedaliera di Ematologia (Dott. Freilone Roberto)

Titolo:	ONO-4059-17 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
Patologia:	Primary Central Nervous System Lymphoma RECIDIVA
Tipo di Studio:	interventistico, randomizzato
Fase:	III
Principali criteri di inclusione:	• Participants aged ≥18 years on the day of consenting to the study • Pathology report confirming the diagnosis of B-cell PCNSL • Relapsed or refractory B-cell PCNSL with at least 1 prior HD-MTX–based therapy for • PCNSL • One or more bi-dimensionally measurable brain lesions with a minimum diameter • ≥1 cm × ≥1 cm in gadolinium-enhanced MRI based on local read performed within 14 days before starting study drug • Eastern Cooperative Oncology Group Performance Status of 0, 1, or 2 at Screening
Principali criteri di esclusione:	• Isolated intraocular PCNSL or spinal PCNSL with no brain lesions • Participants who have contraindications to MRI or use of MRI contrast • Participants with non-B cell PCNSL • Participants with systemic presence of lymphoma • Prior nitrosoureas (eg, carmustine) within 42 days, cytarabine and cytotoxic therapies other than procarbazine and methotrexate within 28 days, procarbazine within 21 days,

	• methotrexate within 14 days before starting study drug • Prior non-cytotoxic investigational drugs (including bispecific antibodies) within 14 days or 5 half-lives, whichever is shorter, before starting study drug Prior investigational cytotoxic drugs within 28 days or 5 half-lives, whichever is shorter, before starting study drug • Prior autologous stem cell transplant or CAR-T cell therapy within 1 month and allogeneic • stem cell transplant within 6 months before starting study drug • Prior radiotherapy within 14 days before starting study drug • Prior major invasive surgery within 28 days before starting study drug, or minor invasive • surgery within 7 days before starting study drug • Prior Bruton's tyrosine kinase inhibitor treatment • Refractory to temozolomide with or without rituximab containing regimens (eg, methotrexate-temozolomide-rituximab) in the last PCNSL treatment
Sede e contatti	TORINO, MOLINETTE Divisione Universitaria di Ematologia PI: Prof.ssa Federica Cavallo (f.cavallo@unito.it) Study Coordinator: Irene Scavini (irene.scavini@unito.it)