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:	MCL Elderly III Trattamento con venetoclax in combinazione con l'inibitore di BTK ibrutinib e rituximab vs venetoclax, chemioterapia convenzionale (bendamustina), ibrutinib e rituximab in pazienti con linfoma mantellare non eleggibili a terapia ad alte dosi
Patologia:	Linfoma mantellare DIAGNOSI
Tipo di Studio:	INTERVENTISTICO, RANDOMIZZATO
Fase:	III
Principali criteri di inclusione:	• Inclusion Criteria: • - Histologically confirmed diagnosis of MCL according to WHO classification • - previously untreated stage II-IV (Ann Arbor) • - ≥ 60 years and not suitable for autologous SCT • - At least 1 measurable lesion; in case of bone marrow infiltration only, bone marrow • aspiration and biopsy is mandatory for all staging evaluations. • - ECOG performance status ≤ 2 • The following laboratory values at screening (unless related to MCL): • - Absolute neutrophil count (ANC) ≥ 1000 cells/µL • - Platelets ≥75.000 cells/µL • - Transaminases (AST and ALT) ≤3 x ULN • - Total bilirubin ≤ 2 x ULN unless other reason known (Gilbert-Meulengracht Syndrome) • - Creatinine ≤ 2 mg/dL or eGFR ≥ 50 mL/min • - Written informed consent form according to ICH/EU GCP and national regulations • - Sexually active men with female partners of child-bearing potential potential must • agree to use highly effective contraceptives
Principali criteri di esclusione:	• Exclusion criteria: • - Major surgery within 4 weeks prior to first dose • - Requires anticoagulation with warfarin or equivalent vitamin K antagonists (e.g.

	• phenprocoumon) • - History of stroke or intracranial hemorrhage within 6 months prior to first dose • - Treatment with strong or moderate CYP3A4/5 inhibitors/inducers within 7 days • before first dose and during Venetoclax and Ibrutinib intake • - Any life-threatening illness, medical condition, or organ system dysfunction which, • in the investigator's opinion, could compromise the subject's safety, interfere with • the absorption or metabolism of Ibrutinib capsules, or put the study outcomes at • undue risk • - Vaccinated with live, attenuated vaccines within 4 weeks prior to first dose • - Known CNS involvement of MCL • - Known bleeding disorder (e.g. von Willebrand disease; hemophilia) • - Serious concomitant disease interfering with a regular therapy according to the • study protocol: • - Cardiac (Clinically significant cardiovascular disease such as uncontrolled • or symptomatic arrhythmias, congestive heart failure, or myocardial • infarction within 6 months of Screening, or any Class 3 (moderate) or Class • 4 (severe) cardiac disease as defined by the New York Heart Association • Functional Classification or LVEF below LLN) • - Pulmonary (e.g. chronic lung disease with hypoxemia, e.g. DLCO ≤ 65% • or FEV1 ≤ 65%) • - Endocrinological (e.g. severe, not sufficiently controlled diabetes mellitus) • - Patients with unresolved hepatitis B or C infection or known HIV positive • infection (mandatory test) • - Concomitant or previous malignancies within the last 3 years other than basal cell • skin cancer, Prostate cancer in remission with PSA within normal range or in situ uterine cervix cancer
Sede e contatti	TORINO, MOLINETTE Divisione Universitaria di Ematologia PI: Prof. Simone Ferrero (simone.ferrero@unito.it) Study Coordinator: Irene Scavini (irene.scavini@unito.it)