Bristol Myers Squibb™

Investigational Trials of CC-99282 in Patients With Relapsed or Refractory Chronic Lymphocytic Leukemia, Small Lymphocytic Lymphoma, and Non-Hodgkin Lymphoma

CC-99282-NHL-001

A Phase 1, Multi-Center, Open-Label Study to Assess the Safety, Pharmacokinetics, and Preliminary Efficacy of an Orally Available Small Molecule, CC-99282, Alone and in Combination With Rituximab in Subjects With Relapsed or Refractory Non-Hodgkin Lymphoma (R/R NHL)[1]

CURRENTLY ENROLLING ACROSS THE US, CANADA, AND EUROPE ***NCT03930953 Phase 1***

PRIMARY ENDPOINTS
Dose-limiting toxicity (DLT), maximum tolerated dose (MTD), and adverse events (AEs)

SELECT SECONDARY ENDPOINTS
Pharmacokinetics, objective response rate (ORR), time to response, duration of response (DoR), progression-free survival (PFS), and overall survival (OS)

KEY ELIGIBILITY CRITERIA

- R/R NHL
- ECOG PS ≤2
- ANC ≥1.5 x 10^9/L without growth factor support for 7 days (14 days if pegfilgrastim)
- Hemoglobin ≥8 g/dL
- Platelets ≥75 x 10^9/L without transfusion for 7 days
- AST/ALT ≤2.5 x ULN
- Serum bilirubin ≤1.5 x ULN
- CrCl ≥60 mL/min

TREATMENT* *Estimated N=100*

Part A: Dose Escalation
CC-99282 monotherapy
Assessment for overall safety and tolerability

Part B: Dose Expansion
- CC-99282 monotherapy *R/R DLBCL*
- CC-99282 monotherapy *R/R NHL*
- CC-99282 + rituximab *R/R DLBCL*
- CC-99282 + rituximab *R/R FL*

FOLLOW-UP
Follow-up for safety (within 28 days after last dose)

Treatment for a maximum of 2 years.

CONTACT: ClinicalTrialDisclosure@bms.com

CC-99282-CLL-001

A Phase 1B, Multicenter, Open-Label Study to Determine the Safety, Pharmacokinetics, and Preliminary Efficacy of CC-99282 in Combination With Obinutuzumab in Subjects With Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma[2]

CURRENTLY ENROLLING ACROSS THE US, CANADA, AND EUROPE ***NCT04434196 Phase 1***

PRIMARY ENDPOINTS
DLT, MTD, and AEs

SECONDARY ENDPOINTS
Pharmacokinetics, ORR, DoR, PFS, and OS

KEY ELIGIBILITY CRITERIA

- Documented diagnosis of R/R CLL/SLL requiring treatment according to iwCLL guidelines and presence of clinically measurable disease
- >2 prior lines of therapy, one of which must have included an approved BTK inhibitor or venetoclax
- ECOG PS ≤2
- ANC ≥1,500 cells/mm^3 or ≥1000 cells/mm^3 if secondary to bone marrow involvement by disease
- Platelet count ≥100,000 cells/mm^3 or ≥50,000 cells/mm^3 if secondary to bone marrow involvement by disease
- AST/ALT <3.0 x ULN
- Serum bilirubin <1.5 x ULN unless due to Gilbert's syndrome
- CrCl ≥60 mL/min

TREATMENT* *Estimated N=50*

Part A: Dose Escalation
CC-99282 orally
+
Obinutuzumab IV

Part B: Dose Expansion
CC-99282 + obinutuzumab

FOLLOW-UP
Follow-up for safety (within 28 days after last dose)

Treatment for a maximum of 2 years.

CONTACT: ClinicalTrialDisclosure@bms.com

The safety and efficacy of CC-99282 and/or its uses are under investigation and have not been established.
There is no guarantee that CC-99282 will receive health authority approval or become commercially available in any country for the uses being investigated.

ALT, alanine aminotransferase; **ANC**, absolute neutrophil count; **AST**, aspartate aminotransferase; **BTK**, Bruton's tyrosine kinase; **BTKi**, BTK inhibitor; **CLL**, chronic lymphocytic leukemia; **CrCl**, creatinine clearance; **DLBCL**, diffuse large B-cell lymphoma; **ECOG PS**, Eastern Cooperative Oncology Group Performance Status; **FL**, follicular lymphoma; **iwCLL**, International Workshop on Chronic Lymphocytic Leukemia; **MCL**, mantle cell lymphoma; **NHL**, non-Hodgkin lymphoma; **PCNSL**, primary central nervous system lymphoma; **R/R**, relapsed/refractory; **SLL**, small lymphocytic lymphoma; **ULN**, upper limit of normal.

1. ClinicalTrials.gov. NCT03930953. Accessed April 29, 2021. **2.** ClinicalTrials.gov. NCT04434196. Accessed April 29, 2021.