Bristol Myers Squibb™

Investigational Trials of Iberdomide (CC-220) in Patients With Relapsed or Refractory Lymphomas

CC-220-NHL-001

A Phase 1/2, Multicenter, Open-Label Study to Assess Safety, Pharmacokinetics, and Preliminary Efficacy of Iberdomide (CC-220), Alone and in Combination With an Anti-CD20 Monoclonal Antibody (mAb) in Subjects With Relapsed or Refractory Lymphomas[1,2]

Enrolling — ***NCT04464798 Phase 1/2***

PRIMARY ENDPOINTS
Maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D)

SELECT SECONDARY ENDPOINTS
AEs; pharmacokinetics; ORR, CR, TTR, and DoR, based on 2014 Lugano classification*; PFS; and OS

KEY ELIGIBILITY CRITERIA

- R/R lymphoma
- ECOG PS ≤2
- ANC ≥1.5 x 10^9/L or 1.0 x 10^9/L with bone marrow involvement, without growth factor support for 7d (14d if pegfilgrastim)
- Hemoglobin ≥8 g/dL
- Platelets ≥75 x 10^9/L or ≥50 x 10^9/L with bone marrow involvement, without transfusion for 7d
- AST/ALT ≤2.5 x ULN
- Serum total bilirubin ≤1.5 x ULN (except in cases of Gilbert's syndrome, then ≤3.0 x ULN)
- Estimated CrCl ≥50 mL/min

TREATMENT[†] *Estimated N=152*

Part 1: Dose Escalation		Part 2: Dose Expansion
Cohort A: iberdomide (CC-220) monotherapy *R/R lymphoma*	RP2D →	Cohort D (optional): iberdomide (CC-220) monotherapy *Other lymphoma*
Cohort B: iberdomide (CC-220) + rituximab *B-cell lymphoma*	RP2D →	Cohort E: iberdomide (CC-220) + rituximab *Aggressive B-cell lymphoma* Cohort F: iberdomide (CC-220) + rituximab *FL (1-3a) and MZL*
Cohort C: iberdomide (CC-220) + obinutuzumab *FL (1-3a) and MZL*	RP2D →	Cohort G: iberdomide (CC-220) + obinutuzumab *FL (1-3a) and MZL*

FOLLOW-UP

Safety
28 days after the last dose of iberdomide (CC-220)

Efficacy
Long-term assessments every 6 months for up to 2 years

[†]Up to progressive disease or 12 cycles for patients with FL or MZL, and up to progressive disease or 24 cycles for all other patients with lymphoma.

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CC-220-DLBCL-002

A Phase 1b/2 Randomized, Multicenter, Open-Label Study of Iberdomide (CC-220) in Combination With Polatuzumab Vedotin Plus Rituximab or Tafasitamab or Rituximab Plus Chemotherapy for Subjects With Relapsed or Refractory Aggressive B-Cell Lymphoma[3]

Enrolling soon — ***Phase 1b/2***

PRIMARY ENDPOINTS
Part 1: MTD and RP2D
Part 2: ORR, based on 2014 Lugano classification*

SELECT SECONDARY ENDPOINTS
Part 1: Safety and tolerability, preliminary efficacy, and PK
Part 2: Safety, CR (based on 2014 Lugano classification*), PFS, OS, HRQoL, and PK

KEY ELIGIBILITY CRITERIA

Aggressive BCL according to 2016 WHO classification among the following subtypes:

- DLBCL, NOS (including GCB and ABC types)
- High-grade BCL, with *MYC* and *BCL2* and/or *BCL6* rearrangements
- Primary mediastinal (thymic) large B-cell lymphoma (PMBCL)
- Primary cutaneous DLBCL, leg type
- *ALK*+ large BCL
- EBV+ DLBCL, NOS
- Grade 3b FL

≥2 prior lines of therapy, or ≥1 prior line of therapy and ineligible for ASCT

Previous treatment with CAR-T therapy allowed

ECOG PS ≤2

TREATMENT *Estimated N=252*

Part 1: Dose Escalation			Part 2: Randomized Dose Expansion
Iberdomide (CC-220) + polatuzumab + rituximab	RP2D →	R 2:1 →	Iberdomide (CC-220) + polatuzumab vedotin + rituximab Polatuzumab vedotin + bendamustine + rituximab
Iberdomide (CC-220) + tafasitamab	RP2D →	R 2:1 →	Iberdomide (CC-220) + tafasitamab Tafasitamab + lenalidomide
Iberdomide (CC-220) + rituximab + chemotherapy	RP2D →	R 2:1 →	Iberdomide (CC-220) + rituximab + chemotherapy Rituximab + chemotherapy

FOLLOW-UP

Follow up for adverse events, response assessment, survival, and development of secondary primary malignancies for up to 2 years

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Enrolling soon[4]

A Phase 1B, Open Label, Global, Multicenter, Dose Determination, Randomized Dose Expansion Study to Determine the Maximum Tolerated Dose, Assess the Safety and Tolerability, Pharmacokinetics and Preliminary Efficacy of Iberdomide (CC-220) and CC-99282 in Combination With R-CHOP-21 for Subjects With Previously Untreated, Poor Risk (IPI 3-5), Aggressive B-Cell Lymphoma

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The safety and efficacy of iberdomide (CC-220) and/or its uses are under investigation and have not been established.
There is no guarantee that iberdomide (CC-220) will receive health authority approval or become commercially available in any country for the uses being investigated.

*Recommendations for Initial Evaluation, Staging, and Response Assessment of Hodgkin and Non-Hodgkin Lymphoma.

ABC, activated B-cell; AE, adverse event; ALK, anaplastic lymphoma kinase; ALT, alanine aminotransferase; ANC, absolute neutrophil count; d, days; ASCT, autologous stem cell transplant; AST, aspartate aminotransferase; BCL, B-cell lymphoma; CR, complete response; CrCl, creatinine clearance; DLBCL, diffuse large B-cell lymphoma; DoR, duration of response; EBV, Epstein-Barr virus; ECOG PS, Eastern Cooperative Oncology Group performance status; FL, follicular lymphoma; GCB, germinal center B-cell; HRQoL, health-related quality of life; MZL, marginal zone lymphoma; NOS, not otherwise specified; ORR, objective response rate; OS, overall survival; **PFS**, progression-free survival; **PK**, pharmacokinetics; **R/R**, relapsed/refractory; **TTR**, time to response; **ULN**, upper limit of normal; **WHO**, World Health Organization.

1. ClinicalTrials.gov. NCT04464798. Accessed October 29, 2020. **2.** Bristol-Myers Squibb Company. Data on file (protocol number CC-220-NHL-001). **3.** Bristol-Myers Squibb Company. Data on file (protocol number CC-220-DLBCL-002). **4.** Bristol-Myers Squibb Company. Data on file (protocol number CC-220-DLBCL-001).