different than expected with standard RCHOP. Results from additional patients will be presented at the ICML meeting.

Keywords: diffuse large B-cell lymphoma (DLBCL); lenalidomide; obinutuzumab.

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ONGOING PHASE 1/2 STUDY OF INCB050465, A SELECTIVE PI3Kδ INHIBITOR, FOR THE TREATMENT OF PATIENTS (PTS) WITH RELAPSED/REFRACTORY (R/R) B-CELL MALIGNANCIES (CITADEL-101)

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Introduction: INCB050465 is a potent, selective PI3Kδ inhibitor (≥19,000-fold selectivity for PI3Kδ vs other isoforms), which has demonstrated linear pharmacokinetics (PK) and achieved exposure levels several-fold greater than the IC_{90} for PI3Kδ inhibition at the recommended phase 2 dose (ASH 2016; Abstract 4195). Here, we report emerging safety and efficacy results from pts receiving INCB050465 monotherapy for r/r B-cell malignancies in an ongoing phase 1/2 study (NCT02018861).

Methods: Eligible pts (≥18 y) had ECOG PS ≤2 (≤1 during dose escalation), normal liver and kidney function, and no autologous HSCT within 3 months or allogeneic HSCT within 6 months of screening. The protocol was initiated with a single-pt cohort, treated with oral INCB050465 5 mg QD. Subsequent cohorts used a 3 + 3 design and evaluated doses of 10–45 mg QD. Based on PK/PD, the 20 and 30 mg QD cohorts were expanded. Responses were assessed Q9W using Lugano Classification or International Working Group on Chronic Lymphocytic Lymphoma (CLL) criteria.

Results: As of the data cut-off (Nov 1, 2016), 52 pts were treated (median age, 65 y [range, 30–88]; disease subtypes: diffuse large B-cell lymphoma [DLBCL; *n* = 14], follicular lymphoma [FL; *n* = 10], Hodgkin lymphoma [HL; *n* = 9], marginal zone lymphoma [MZL; *n* = 8], CLL [*n* = 6], mantle cell lymphoma [MCL; *n* = 5]). Approximately 62% of pts had ≥3 prior systemic regimens; 31% had prior HSCT. Median duration of therapy was 3.3 months (range, 0.6–13.4); no DLTs were identified. Approximately 67% of pts discontinued therapy, most commonly for disease progression (31%) and AEs (25%). Approximately 33% of pts had dose interruption; 4% had reduction. Most common nonhematologic AEs (all grade [Gr]; Gr ≥3) were nausea (38%; 0%), diarrhea (31%; 6%), and vomiting (25%; 0%). Gr ≥3 hematologic AEs included neutropenia (21%), lymphopenia (17%), thrombocytopenia (10%), and anemia (4%). Approximately 40% of pts had serious AEs, most frequently colitis, diarrhea, and hypotension (all *n* = 3). A total of 1 pt had Gr 3 pneumonitis; none had *Pneumocystis jirovecii*pneumonia (PJP) or Gr ≥2 elevated transaminase. Objective responses (OR) occurred at all doses (**Table**), except 5 mg QD; 90% of the ORs were observed at the 9-week disease assessment.

Conclusion: INCB050465 demonstrated manageable toxicities with no clinically meaningful transaminitis or PJP. OR rates were generally high and most responses (90%) were observed at the 9-week disease assessment. Different dosing regimens/schedules, long-term safety, and disease-specific cohorts are being evaluated.

	N[a]	Objective Response, n (%)	Complete Response, [b] n	Partial Response, [b] n
NHL	31	19 (61)	10	9
DLBCL	14	5 (36)	3	2
FL	9	7 (78)	2	5
MZL	4	4 (100)	2	2
MCL	4[c]	3 (75)	3	0
CLL	6[c]	2 (33)	0	2
HL	8	1 (13)	0	1

[a]7 pts were not evaluable for response because they had not reached a postbaseline assessment as of the data cutoff date.
[b]Radiologic/metabolic.
[c]1 patient with MCL and 3 with CLL had previously received ibrutinib; among these 4 pts, 1 objective response (partial response in CLL) was observed in this study.

Keywords: B-cell lymphoma; non-Hodgkin lymphoma (NHL); PI3K/AKT/mTOR.

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THE IMMUNOLOGIC DOUBLET OF LENALIDOMIDE PLUS OBINUTUZUMAB IS HIGHLY ACTIVE IN RELAPSED/REFRACTORY FOLLICULAR LYMPHOMA, RESULTS OF A PHASE I/II STUDY

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Introduction: Relapsed follicular lymphoma (FL) remains a challenge and salvage regimens are associated with toxicity and limited control. Clinical outcomes are linked to dynamic changes in the immune microenvironment and novel immune-based approaches such as