CLINICAL TRIAL PROTOCOL

A Phase 1, Open Label, Dose Escalation, Multicenter Study Evaluating the Safety, Pharmacokinetics, and Pharmacodynamics of Oral AUR104 in Patients with Select Relapsed/Refractory Lymphoid Malignancies (VIJAY-1)

Protocol Number	AUR104-101
Clinical Trial Protocol Version	3.0
Version date	04 Jan 2024
Trial Phase	Phase 1
Investigational Product	AUR104 (previously known as XL-114)
Sponsor	**Aurigene Oncology Limited** **(Subsidiary of Dr. Reddy's Laboratories Limited)** 39-40, KIADB Industrial Area, Phase II, Electronic City Hosur Road, Bangalore- 560100, Karnataka, India
US IND Number	167118 (NCT06761586)

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SPONSOR SIGNATURE

Study Title:	A Phase 1, Open Label, Dose Escalation, Multicenter Study Evaluating the Safety, Pharmacokinetics, and Pharmacodynamics of Oral AUR104 in Patients with Select Relapsed/Refractory Lymphoid Malignancies (VIJAY-1)
Protocol Number:	AUR104-101
Final Version and Date	Version 3.0 dated 04 Jan 2024

This study will be conducted in compliance with the clinical trial protocol approved by the Ethics Committee(s) (ECs) / Institutional Review Boards (IRBs) of the respective sites. The study will comply with the International Council for Harmonization (ICH) Good Clinical Practice (GCP) guidelines and current revision of the Declaration of Helsinki. In addition, this study will be conducted in compliance with all local regulatory and ethical requirements, US FDA guidelines and the New Drugs and Clinical Trials Rules, 2019 of the Department of Health and Family Welfare, India. The investigator will be provided with details of any significant or new findings, including adverse events, relating to treatment with the investigational product.

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Dr. Suchit Kumbhare, MBBS, MSCR, MS
Senior Manager - Clinical Development
Aurigene Oncology Limited
(Subsidiary of Dr. Reddy's Laboratories Limited)

Dated

PROTOCOL SIGNATURE PAGE

Study Title: A Phase 1, Open Label, Dose Escalation, Multicenter Study Evaluating the Safety, Pharmacokinetics, and Pharmacodynamics of Oral AUR104 in Patients with Select Relapsed/Refractory Lymphoid Malignancies (VIJAY-1)

I confirm that I have read, and I understand this protocol and other appropriate related documentation, including the Investigator's Brochure for AUR104. I agree that the available nonclinical information on the investigational product is adequate to support the proposed clinical trial. This study will be conducted in compliance with the clinical trial protocol approved by the Ethics Committee (EC) / Institutional Review Board (IRB) overseeing the study at the site. The study will comply with the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines and the current revision of the Declaration of Helsinki and all the local regulatory and ethical requirements. I will also appropriately direct and assist the personnel at the trial site who will be involved in the conduct of the study.

Principal Investigator or Clinical Site Investigator:

Signature Date

Name:	
Title:	
Name of the site:	

1.0 SYNOPSIS

Name of sponsor/company:	**Aurigene Oncology Limited** **(Subsidiary of Dr. Reddy's Laboratories Limited)** 39-40, KIADB Industrial Area, Phase II, Electronic City, Hosur Road, Bangalore- 560100, Karnataka, India
Name of investigational product:	AUR104 (previously known as XL114)
Name of active ingredient:	AUR104 (previously known as XL114)
Title of Trial:	A Phase 1, Open Label, Dose Escalation, Multicenter Study Evaluating the Safety, Pharmacokinetics, and Pharmacodynamics of Oral AUR104 in Patients with Select Relapsed/Refractory Lymphoid Malignancies (VIJAY-1)
Estimated Number of Trial Center(s):	Multicenter Approximately 15-20 sites in Dose Escalation Cohorts
Trial Duration (months):	15-18 months
Phase of development:	1
Objectives:	**Primary** • To assess the safety and tolerability of single-agent AUR104 in patients with relapsed advanced lymphoid malignancies. • To assess the pharmacokinetics (PK) profile of AUR104. **Exploratory** • To explore the pharmacodynamics (PD) effects of AUR104. • Efficacy of AUR104
Methodology:	This is a multicenter, open-label, Phase 1 study of AUR104 in adult patients with select Relapsed/Refractory (R/R) Lymphoid Malignancies. The dose escalation will be conducted in a rule-based manner in patients who do not have any available curative treatment options and have exhausted all effective therapies available locally. The main objective of the study will be to evaluate the safety and tolerability of the study drug AUR104.

Dosing Regimen

[redacted]

an amendment, if deemed appropriate. This will be following an overall assessment of safety, PK, and PD at these three dose cohorts.

Additional patients may be enrolled at any of these dose cohorts to assess non-DLT AEs and/or PK and/or PD in greater detail, if deemed appropriate.

Enrollment plan and Definition of DLT Evaluable

[redacted]

patient will be replaced.

Rules for escalation and de-escalation

- [redacted]

  4 days in each patient.
- Among 6 DLT-evaluable patients in each group, if 0 or 1 patient experiences DLT, then enrollment in the next higher dose

cohort may be started once the data of the previous cohort is reviewed by the SRC and once the SRC has confirmed that the enrolment in new cohort can be started.

- Accrual will be paused after the sixth enrollment unless one or more patients are disqualified or are not eligible for DLT evaluation.
- If 2 or more of 6 patients at a given dose level experience DLT during the first cycle, then maximal tolerated dose would have been exceeded and additional patients may be treated at a lower dose level.
- If 0 or 1 of 6 patients experience DLT at a dose (and the higher dose led to at least 2 DLTs out of 6 patients), then this dose will be declared the maximal tolerated dose (MTD). In other words, MTD is defined as the dose at which ≤1 of 6 patients experience a DLT during Cycle 1 (28 days of dosing), with the next higher dose having at least 2 of 6 patients experiencing a DLT during Cycle 1 (28 days of dosing).
- If ≤ 1 out of the six patients in Cohort 3 experience a DLT, a comprehensive safety, PK, and PD assessment will be conducted to suggest potential new dosing cohorts. If such a recommendation is warranted, an amendment of the protocol will be done and will be shared with regulators.
- [redacted]
- If at any of these Cohorts (Cohort 1, 2 or 3), there is acceptable safety, PK and PD (even without reaching MTD), then also the dose escalation will stop and additional patients (approximately 18 total including the initial 6 in dose escalation) will be enrolled at this cohort in order to assess more safety at this dose.

Method of dosing

Patients will take AUR104 orally with water at approximately the same time on each dosing day. Patients will not eat (but can drink water) for two hours before and one hour after taking the study drug.

	For Cohorts 1 and 2, a total of 4 weeks (28 days) will be considered as one cycle, and Cycle 1 (first 28 days) is considered as the "DLT Evaluation Period." Enrollment day will be considered as Day 1 of Cycle 1 (C1D1). Day 29 of the study will be considered Day 1 of Cycle 2 (C2D1). Accordingly, nomenclature will continue C3D1, C4D1, etc. for Cohorts 1 and 2.  If ≤ 1 out of the six patients in Cohort 3 experience DLT, a comprehensive safety, PK, and PD assessment will be conducted to suggest potential new dosing cohorts. An amendment will subsequently be initiated if deemed appropriate. **Maximum Tolerated Dose** The dose at which no more than one DLT has occurred in six patients and a higher dose has shown two or more DLTs, will be assessed as the "Maximum Tolerated Dose." Backfill cohorts may also be allowed in the trial. The Backfill cohort patients could only be enrolled at a dose level that the SRC has already reviewed, and the dose level has been deemed to be safe by the SRC. Backfill cohort patients may provide "Intensive PK" sampling if required for more PK data of respective dose levels. They might undergo PD sampling and sparse PK as needed. **Part 2 [Single agent AUR104 dose expansion]** Expansion cohorts in any specific lymphoid malignancy will only be started after an amendment.
Number of Patients (Planned):	• ~ 18 patients will participate in the three cohorts during the Dose Escalation Part.

	• [redacted] • Additional cohorts beyond Cohort 3 as well as dose expansion cohorts in any specific lymphoid malignancy will be introduced through an amendment. • There may also be enrollment of additional patients for backfill cohorts.
Inclusion Criteria	1. Males and females ≥ 18 years of age. 2. Eastern Cooperative Oncology Group (ECOG) Performance status of 0 or 1. 3. Acceptable bone marrow and organ function at screening as described below: a. ANC ≥ 1000/µL (without WBC growth factor support) b. Platelet count: For patients with CLL ≥ 50,000/µL; For patients with lymphomas ≥ 75,000/µL without bone marrow involvement and ≥ 50,000/µL with bone marrow involvement. These thresholds should be qualified without current transfusion support. c. Hemoglobin ≥ 9 g/dL (Transfusion is allowed to achieve this Hb). d. Total Bilirubin ≤ 1.5 x ULN; (Patients with known Gilbert's syndrome are allowed with a Total Bilirubin ≤ 2.5 x ULN). e. AST (SGOT) ≤ 3 x ULN (≤ 5 × ULN if known liver metastases). f. ALT (SGPT) ≤ 3 x ULN (≤ 5 × ULN if known liver metastases). g. Creatinine clearance (CrCl) ≥ 60 mL/min (either measured or estimated by the Cockcroft-Gault formula). (Cockcroft-Gault formula for estimated creatinine clearance [eCrCl]: eCrCl = [140– Age] × Weight [kg] × [0.85 if Female] / [72 × serum creatinine (mg/dL)]). 4. Ability to swallow and retain oral medications. 5. Histopathological diagnosis of Non-Hodgkin Lymphoma (NHL) or Chronic Lymphocytic Leukemia (CLL) or Hodgkin disease. Note: 5a. The lymphoma should be either in Stage III or IV according to Lugano classification (Cheson et al. 2014) at screening.

	5b. The lymphomas included in this study must fall within one of the following 2017 World Health Organization categories except lymphoma mentioned in Exclusion criterion #5: i. Mature B-cell neoplasms (excluding plasma cell neoplasms, heavy chain disease, and primary central nervous system [CNS] lymphoma). ii. Mature T- and NK-cell neoplasms. iii. Hodgkin lymphomas. 5c. The CLL should be Binet Stage C/Rai stage III or IV, as per the International Workshop on Chronic Lymphocytic Leukemia (iwCLL) guidelines (Halek et al. 2018). 6. In the case of patients who have lymphoid malignancies for which high-dose chemotherapy and autologous stem cell transplantation (HD-ASCT) is considered standard curative therapy, eligibility for this study requires that the subject's disease has relapsed after HD-ASCT, or the subject is not eligible for HD-ASCT, or the subject has refused HD-ASCT. 7. In the case of patients who have lymphoid malignancies for which CAR-T therapy is indicated, eligibility for this study requires that the disease has relapsed after CAR-T, or the patient is not eligible for CAR-T, or the patient has refused CAR-T, or the CAR-T is not available locally. 8. Evidence of measurable disease as per Lugano Criteria for Lymphoma (Cheson et al. 2014) or evidence of measurable disease as per iwCLL Criteria for CLL (Halek et al. 2018). Note: Patients with Small Lymphocytic Lymphoma (SLL) alone or in combination with CLL are allowed. 9. Standard curative measures do not exist, and the patient must have exhausted all effective therapies available locally. At a minimum, the patients must have relapsed or refractory disease to at least 2 prior lines of systemic therapies for NHL or CLL, or Hodgkin's disease. Note: • Any cancer patient with access to any effective therapy locally must not be enrolled.
Exclusion Criteria	1. Systemic anti-cancer therapy, such as chemotherapy, biological therapy, or immunomodulatory drug therapy, received within the past 28 days or 5 half-lives, whichever is longer, from Cycle 1 Day 1 of the study. **Note:** Concomitant use of low-dose prednisone (up to 10 mg/day) is allowed.

	2. Presence of acute or chronic toxicity resulting from prior anti-cancer treatment, except for alopecia or nail changes that have not resolved to Grade ≤ 1, as determined by NCI CTCAE v 5.0 3. Definitive Radiotherapy within the last 21 days of Cycle 1 Day 1 (limited field palliative radiation is allowed and no restrictions during the screening period or during the trial). 4. Use of any investigational agent within 28 days or 5 half-lives (whichever is longer) prior to Cycle 1 Day 1. 5. Patients with Burkitt's lymphoma, Burkitt-like lymphoma, post-transplant lymphoproliferative disease, primary mediastinal large-B cell lymphoma, cutaneous lymphomas, mycosis fungoides (MF), or Sezary syndrome (SS). 6. Known symptomatic or untreated or recently treated (≤ 6 months of screening) central nervous system (CNS) lymphoma. Patients with previously treated (> 6 months of screening) CNS lymphoma and are now stable and asymptomatic, from a CNS perspective, are allowed. 7. Patients with lymphoma requiring immediate cytoreductive therapy. 8. Patients with low-grade or indolent lymphoma not meeting conventional criteria (Jeong SH, 2022) for treatment. 9. Elevated Serum cardiac Troponin I or troponin T > ULN at screening. 10. Serum magnesium and calcium levels > 1.2 x ULN or < 0.8x LLN. 11. Serum Potassium > 1.0x ULN or < 1.0x LLN. Note: Patients experiencing hypokalemia are permitted to undergo treatment to attain normal potassium levels during the screening period. 12. Mean Heart Rate <60 at screening or Cycle 1 Day 1 (to be recorded at least 3 times at least 5 minutes apart) in ECG. 13. Left ventricular ejection fraction (LVEF) < 50% as determined by an echocardiogram (ECHO) or Multigated Acquisition (MUGA) scan. 14. QTcF (Fridericia) interval >450 ms for patients on ECG at screening and/or at Cycle 1 Day 1. 15. Uncontrolled arterial hypertension defined as supine SBP of ≥ 140 mm Hg AND/**OR** supine DBP ≥ 90 mmHg on stable doses of three or lesser different classes of antihypertensive drugs. Notes:

- Patients taking 4 or more classes of antihypertensives are excluded. Diuretics (such as furosemide or spironolactone) are considered as one class of anti-hypertensives.
- The blood pressure has to be recorded 3 times at least 10 minutes apart during Screening and Cycle 1 Day 1 (before dosing) in the supine position. Among these recordings, a single instance of SBP ≥140 mm Hg **or** DBP ≥ 90 mmHg will exclude the patient. Note: A patient excluded on these criteria can be re-screened after optimal BP management.

16. Current or past history of heart failure (NYHA Class 2 or higher)
17. Having a history of moderate to severe cardiovascular disease including unstable angina, myocardial infarction, cerebrovascular accident, or transient ischemic attack (TIA), within 1 year prior to Cycle 1 Day 1.
18. Ongoing cardiac arrhythmias or conduction blocks.
19. History of any ventricular arrhythmia including supraventricular or ventricular premature contractions.
20. Patients on drugs which are sensitive substrates of CYP3A4 and cannot be discontinued at least one week prior to Cycle 1 Day 1.
21. Use of strong CYP3A4 inhibitors or inducers within 2 weeks prior to Cycle 1 Day 1.
22. Concomitant use of any drug which is known to prolong QTc interval or use of such drugs within one week prior to Cycle 1 Day 1.
23. Major surgery ≤ 28 days from Cycle 1 Day 1 (major surgery is defined as a procedure requiring general anesthesia)
24. Active infection requiring systemic therapy.

Note: Prophylactic use of antibiotics is allowed. Any infection detected during the screening period, which is resolved adequately according to the investigator before Cycle 1 Day 1, is allowed.

25. Known to be human immunodeficiency virus (HIV) positive or have an acquired immunodeficiency syndrome-related illness.
26. Known active or chronic hepatitis B (HBsAg +ve) or hepatitis C infection (HCV antibody +ve).
27. Patient expected to require any other form of antineoplastic therapy or targeted therapy while in the study.
28. Uncontrolled intercurrent illness including, but not limited to, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, active peptic ulcer disease or significant gastritis, active bleeding diatheses, presence of any major medical illness (e.g., renal, hepatic, hematologic,

	gastrointestinal, endocrine, pulmonary, or psychiatric illness/social situations or clinically significant laboratory / ECG abnormalities at screening, any or a combination of illnesses, which, in the opinion of the PI, may either put the patient at risk because of participation in the study or influence the results or the patient's ability to participate in the study 29. Current swab-positive or suspected (under investigation) Covid-19 infection or fever and other signs or symptoms suggestive of Covid-19 infection with recent contact of the person(s) with confirmed Covid-19 infection, at screening or Cycle 1 Day 1. 30. History of another primary malignancy within 5 years prior to starting the study drug, except for adequately treated basal or squamous cell carcinoma of the skin or cancer of the cervix in situ or cured early-stage (Stage 1 or 2) prostate cancer. 31. Positive pregnancy test for women of childbearing potential (WOCBP) at the screening or enrolment visit 32. Lactating women or WOCBP who are neither surgically sterilized nor willing to use reliable contraceptive methods (hormonal contraceptive, IUD, or any double combination of male or female condom, spermicidal gel, diaphragm, sponge, cervical cap).
Test Product, Dose, and Mode of Administration:	[redacted]
Reference Therapy:	None
Duration of Treatment:	Each treatment cycle will be 28 days in length for Cohort 1 and Cohort 2. [redacted] Patients who are deriving clinical benefit (defined as not meeting criteria for progressive disease by Lugano Criteria for NHL/Hodgkin lymphoma (Cheson et al. 2014) or iwCLL criteria for CLL (Halek et al. 2018) may continue to receive AUR104 until either progressive disease or intolerable toxicity occurs.
Endpoints:	**Primary Endpoints:** • First cycle DLT • Safety and tolerability of AUR104 as measured by NCI CTCAE v 5.0. • PK parameters including but not limited to $AUC_{(0-12)}$, $AUC_{(0-}$

$_{24)}$, AUC_{0-t}, C_{max}, C_{min}, T_{max}, MRT, and t½.

Dose-Limiting Toxicities (DLTs)

DLT assessment will occur in the initial 28 days (Cycle 1) of treatment for Cohorts 1 and 2. In the case of Cohort 3, DLT evaluation will be done in 32 days which includes the initial 4 days of the ramp-up phase. Safety and tolerability will be assessed by the incidence and severity of adverse events as determined by NCI Common Terminology Criteria for Adverse Events (NCI CTCAE v 5.0). A Safety Review Committee (SRC) comprised of the Medical Monitor(s), Principal Investigators, and Sponsor representatives will review safety information and decide upon dose escalation and further patient enrollment.

A DLT is defined as any of the following toxicities occurring during Cycle 1 during Part 1 (Single agent Dose Escalation Part) unless clearly or incontrovertibly related to the underlying malignancy, any other co-morbidities or concomitant medications or extraneous causes:

The DLTs include:

- Decrease in Left Ventricular Ejection Fraction (LVEF) to < 50% **AND** an absolute drop in LVEF by > 10%.
  (Note: Both need to be fulfilled to be called a DLT)
- Grade 3 or higher Left Ventricular Systolic Dysfunction.
- Asymptomatic Systolic BP ≥160 mmHg **AND/OR** Diastolic BP ≥100 mmHg, persisting for 3 days despite optimal medical management.
- Symptomatic Systolic BP ≥160 mmHg **AND/OR** Diastolic BP ≥100 mmHg, regardless of duration.
- Grade 4 hypertension.
- Myocardial Infarction, new onset angina, Transient Ischemic Attack (TIA), or Stroke.
- Asymptomatic Grade 3 or higher QTc prolongation (Average QTcF > 500 ms. and/or >60 ms. change from baseline).
- Grade 2 or higher QTc prolongation (Average QTcF: 481- 500 ms.) with cardiovascular symptoms suggestive of arrhythmia, such as palpitation, shortness of breath, chest pain, etc.

Note: If the QTcF interval exceeds 480 ms. at any timepoint, the ECG will be repeated twice, and the average reading will be recorded.

- Grade 3 or higher Sinus Bradycardia.
- Grade 2 or higher Atrial Fibrillation.
- Grade 2 or higher Atrial Flutter.
- Grade 2 or higher Ventricular Arrhythmia.

	• Grade 2 or higher Atrio-Ventricular Block. • Asymptomatic elevation of Cardiac Troponin I and/or Cardiac Troponin T ≥ 1.2 x ULN confirmed by two separate readings. • Grade 2 or higher Rhabdomyolysis. • Grade 2 or higher CPK elevation (2.5-5 x ULN) with Grade 2 or higher muscle weakness, myalgia, or myopathy. • Asymptomatic Grade 3 or higher CPK elevation (> 5.0 x ULN). • Febrile neutropenia as per NCI CTCAE v 5.0 - ANC < 1000 /µL with a single temperature of >38.3 degrees C (101 degrees F) or a sustained temperature of ≥ 38 degrees C (100.4 degrees F) for more than one hour • Grade 4 neutropenia (ANC < 500/µL). • Grade 3 neutropenia (ANC < 1000 - 500/µL) without fever, lasting at least for 7 days. • Grade 4 thrombocytopenia (< 25,000/µL). • Grade 3 thrombocytopenia (platelet count < 50000-25000/µL) associated with Grade 2 or higher bleeding. • Grade 4 anemia (life-threatening and/or with a need for urgent interventions) not due to underlying disease. • Positive for Hy's law (AST or ALT ≥ 3 x ULN with concomitant Total Bilirubin≥ 2 x ULN, without findings of cholestasis on radiological scans and no other reasons for increase in AST/ALT and bilirubin, such as viral hepatitis or acute liver disease or another drug which can clearly result into these findings). • Any other Grade 3 or higher clinically significant toxicity (except alopecia or nail changes), per NCI CTCAE v 5.0, which is considered as "not clearly or incontrovertibly related to the underlying malignancy, any other co-morbidities or concomitant medications or extraneous causes" by the investigator/SRC. (Asymptomatic Grade 3 electrolyte abnormalities are excluded from DLT definition if these abnormalities resolve to Grade 1 or less within 72 hours). • Any other AE, apart from the aforementioned DLTs, (not clearly or incontrovertibly related to the underlying malignancy, any other co-morbidities or concomitant medications or extraneous causes) that leads to either discontinuation of the study drug or leading to < 75% compliance during 1st cycle (i.e. < 21 out of 28 day of dosing in Cycle 1 in Cohorts 1 and 2 and < 21 out of last 28 day of dosing in Cycle 1 in Cohort 3)

- Any other toxicity which, in the judgment of the Safety Review Committee (SRC), is determined to be a DLT.

Exploratory Endpoints:

- PD biomarkers.
- Efficacy assessments of overall response rates (ORR), duration of response (DOR), Progression Free Survival (PFS), etc., as measured by Lugano Criteria for NHL/ Hodgkin's lymphoma (Cheson et al. 2014) or iwCLL criteria for CLL (Halek et al. 2018).

Early termination or Interruption Criteria

This study may be prematurely terminated, if in the opinion of the Sponsor there is sufficiently reasonable cause. In the event of such action, written notification documenting the reason for the study termination will be provided to each Investigator and the regulators.

The study will be terminated if any of the following circumstances occurs:

- Occurrence of two DLTs at any dose level, without adequate PK exposure where de-escalation is not meaningful for further drug development.
- Determination of unexpected, significant, or unacceptable risk to subjects.
- Slow recruitment.
- Plans to modify, suspend, or discontinue the development of the study treatment.
- Decisions of regulatory authorities or IRB/IEC.

Enrolment in the study will be interrupted and engagement with regulators will immediately occur, if any of the following events (irrespective of the cycle) occur **at any time (during or beyond the DLT evaluation period**):

- Any case of life-threatening or fatal cardiovascular toxicity, e.g., malignant hypertension, unstable angina, myocardial infarction, stroke, TIA (transient ischemic attack), ventricular arrhythmia, etc.
- Any case of life-threatening or fatal rhabdomyolysis
- Any other case of life-threatening or fatal event, which is not clearly or incontrovertibly related to the underlying

	malignancy, any other co-morbidities or concomitant medications or extraneous causes. • [redacted] In addition to above "Interruption Criterion" for the study, if there are non-life threatening cardiovascular / muscular DLT equivalents in patients, in the post- DLT period, then dosing in those patients will be stopped and all the safety data will be thoroughly evaluated as a whole. If such non-life threatening DLT equivalents (for cardiovascular and/or muscular toxicity) are occurring in more than 20% of patients at any specific dose or across dosages, then a report will be prepared and presented to the agency, for discussion if the study should be stopped or continued. If a DLT or DLT equivalent (cardiovascular and/or muscular toxicities) AEs are observed in over 30% of patients at a particular dose level or across multiple doses over any treatment duration, then the enrollment in the study will be halted. A comprehensive safety report will be prepared and presented to regulators to guide the decision-making process for the next steps for the trial.
Statistical Analysis:	**General:** Descriptive statistics will be used. **Safety Analyses:** Safety observations and measurements include drug exposure, AEs, safety laboratory tests, vital signs, physical examinations, ECGs, echocardiograms, cardiac biomarkers, muscle biomarkers, and ECOG performance status. Adverse events will be coded using the Medical Dictionary for Regulatory Activities (MedDRA™) dictionary. The number and percentages of patients experiencing AEs will be tabulated by system organ class (SOC), preferred term, maximum severity, and relationship to AUR104. The severity of AEs will be graded according to the NCI CTCAE v 5.0. Summaries of the number of patients with dose reductions/interruptions, SAEs, AEs resulting in trial discontinuation, and deaths will be presented by dose, tumor type, and overall. Laboratory parameters will be summarized using descriptive statistics by post-dosing shifts in NCI CTCAE toxicity grade relative to baseline and data listings of clinically significant abnormalities. Vital signs and ECG data will be summarized by changes from baseline values using descriptive statistics (number of patients, mean, median, standard deviation, minimum, and maximum), and physical examination abnormalities and ECOG performance status will be

	summarized using frequencies and percentages. **Efficacy Analyses:** Patients will be assessed by radiological scans by Lugano Criteria for NHL/ Hodgkin's lymphoma (Cheson et al. 2014) or iwCLL criteria for CLL (Halek et al. 2018). Objective tumor response rates (ORR), duration of response (DOR), time to objective tumor response, time to progression (TTP), and progression free survival (PFS) will be presented. Additionally, tumor lesion measurements and changes from baseline will be summarized by cycle, tumor type, and dose. Tumor markers will also be summarized by cycles. **Pharmacokinetic Analyses:** Individual plasma PK parameters, including but not limited to $AUC_{(0-12)}$, $AUC_{(0-24)}$, AUC_{0-t}, C_{max}, T_{max}, Mean Residence Time (MRT), and t½, will be estimated using appropriate compartmental or non-compartmental models. Summaries of PK parameters will be presented by dose groups and tumor histology. ***Exploratory Biomarkers:*** Summaries of PD biomarkers will be presented by dose groups.