1. SYNOPSIS

Name of Sponsor/Company: MEI Pharma, Inc **Name of Finished Product:** Not Applicable **Name of Active Ingredient:** Zandelisib	Individual Study Table Referring to Part of the Dossier Volume: Page:	*(For National Authority Use Only)*

Title of Study:

A Phase 3, Randomized, Open-Label, Controlled, Multicenter Study of Zandelisib (ME-401) in Combination with Rituximab Versus Standard Immunochemotherapy in Patients with Relapsed Indolent Non-Hodgkin's Lymphoma (iNHL) – The COASTAL Study

Principal Investigator: PPD

Investigators and Study Centers:

This study was conducted at 144 centers worldwide.

Publications (reference):

There are no publications based on this study.

Studied Period (years): 19 Months Date first subject enrolled: 13 August 2021 Date last subject completed: 20 March 2023	**Phase of Development:** Phase III

Primary Objective

- To demonstrate that zandelisib in combination with rituximab is superior to standard immunochemotherapy in prolonging progression free survival (PFS) as determined by the Independent Response Review Committee (IRRC) in previously treated subjects with follicular and marginal zone lymphoma

Secondary Objectives

- To compare zandelisib + R to standard immunochemotherapy by overall response rate (ORR) and complete response rate (CRR) as determined by the IRRC
- To compare zandelisib + R to standard immunochemotherapy by overall survival
- Time to next anti-lymphoma treatment
- PFS on next anti-lymphoma treatment
- To evaluate Patient Reported Outcome (PRO) assessment with
    - Follicular Lymphoma Symptom lndex-18
    - PRO with EuroQol 5 Dimension 3 Level
- To evaluate the safety and tolerability of zandelisib in combination with R

Exploratory Objectives

To Evaluate

- [redacted]

CCI [redacted]

Study Design

This was an open label, randomized, two-arm Phase 3 study in subjects with relapsed or refractory follicular lymphoma (FL) or marginal zone lymphoma (MZL) to evaluate efficacy and safety of zandelisib in combination with rituximab in comparison to standard immunochemotherapy (rituximab plus bendamustine [R-B] or R-CHOP). Subjects must have relapsed after at least one previous line of systemic immunochemotherapy. Previous treatments must have included an anti-CD20 monoclonal antibody (mAb) with chemotherapy such as B, CHOP, cyclophosphamide, vincristine, prednisone (CVP), combination of fludarabine, mitoxantrone, dexamethasone (FND), or similar regimens, or an anti-CD20 monoclonal antibody with lenalidomide (L).

Subjects who meet the eligibility criteria will be randomly assigned in a 1:1 ratio to one of the treatment arms:

- Arm 1: R plus zandelisib (R-Z)
- Arm 2: R plus chemotherapy (CHOP or B) [R-chemo])

Subjects were to be stratified based on following criteria:

- Prior treatment regimen: anti-CD20 mAb in combination with non-bendamustine chemotherapy regimen or lenalidomide plus rituximab combination (R-L) vs. anti-CD20 mAb in combination with B
- Number of prior therapies: 1 vs. >1
- Lymphoma histology: FL vs. MZL
- Duration of treatment-free interval from the last lymphoma-directed therapy: ≤24 months vs. >24 months

Study treatment was administered as detailed above. Treatment in either arm was discontinued at any time in case of disease progression or unacceptable toxicity. Before treatment discontinuation due to any reason, including disease progression, it is recommended that the Investigator review the reasons with the Sponsor's medical monitor or designee.

Primary analysis was to be based on assessment of efficacy by an IRRC. Subject management was based on disease response assessment according to investigators.

During the study, continuing review of safety data was performed by the sponsor and an independent Data Monitoring Committee (DMC). The independent DMC regularly reviewed safety and efficacy data from all subjects to assess benefit/risk profile of zandelisib-rituximab therapy and assess if protocol-defined stopping rules were to be triggered. Details of this review was outlined in a separate DMC charter document, including the frequency of meetings of at least once every 3 months, with the first data review meeting occurring when approximately 60 subjects (~30 in each arm) have completed at least 1 cycle of treatment or 6 months after the first subject is dosed, whichever occurs first.

Each subject participation in the study was composed of Screening period, Treatment period, and Follow-up period for efficacy, safety, and survival.

The study was terminated for business reasons with 82 subjects enrolled and data collection was truncated.

Methodology:

Safety evaluations were conducted at screening, and continuously during the treatment period, and at the safety follow-up visit. During the follow-up period, adverse events (AEs) and serious AEs (SAEs) were reported for up to 30 days after the last dose of study drug. After 30 days post last dose, only SAEs deemed related to study drug were to be reported. For details of methodologies employed refer to the study protocol.

Number of Patients (planned and analyzed):

Originally, it was anticipated that approximately 534 subjects will be randomized into the study; the study was discontinued with 82 subjects enrolled and dosed.

Diagnosis and Main Criteria for Inclusion:

1. Male or female subjects ≥18 years of age, ≥19 years in Korea, or ≥20 years for subjects in Japan and Taiwan, at time of signing informed consent
2. Histologically confirmed diagnosis of CD20 positive iNHL with histological subtype limited to:
   a. FL Gr 1, Gr 2, or Gr 3a
   b. MZL (splenic, nodal, or extra-nodal)

   [Histopathological report confirming diagnosis must be available during screening procedures]
3. Subjects with relapsed or refractory disease who received ≥1 prior lines of therapy that must have included an anti-CD20 antibody in combination with cytotoxic chemotherapy or L, with or without subsequent maintenance therapy. [A line of therapy is defined as following: a minimum of 2 consecutive cycles of immunochemotherapy or R-L, at least 4 doses of anti-CD20 mAb (R) single agent therapy, a minimum of 2 consecutive cycles of therapy with an investigational agent. Maintenance therapy given after an induction treatment (e.g., R maintenance) is considered as the same line of therapy]. [Please see Exclusion Criteria #2 for further clarification]. Relapsed or refractory disease defined as:
   - Relapsed disease: disease progression after a response (complete response [CR] or partial response [PR]) lasting ≥6 months
   - Refractory disease: no response to therapy (no CR or PR) or response lasting <6 months
4. Subjects must have at least one bi-dimensionally measurable nodal lesion with the longest diameter >1.5 cm and/or an extranodal lesion >1.0 cm in the longest diameter (that has not been previously irradiated) according to the Lugano Classification
5. Adequate hematologic parameters at screening unless abnormal values are due to disease per Investigator assessment:
   - Absolute neutrophil count (ANC) $\geq 1.0 \times 10^9$/L ($\geq$1,000/mm^3)
   - Platelet count $\geq 75.0 \times 10^9$/L ($\geq$75,000/mm^3)
   - Hemoglobin ≥9 g/dL
6. Adequate renal and hepatic function per local laboratory reference range at screening as follows:
   - Aspartate aminotransferase (AST)/alanine aminotransferase (ALT) ≤1.5 × upper limit of normal (ULN)
   - Total bilirubin ≤2.0 × ULN or ≤3 × ULN for subjects with Gilbert-Meulengracht syndrome
   - Estimated glomerular filtration rate >50 mL/min using the Cockcroft-Gault equation
7. QT-interval corrected according to Fridericia's formula (QTcF) ≤450 msec; subjects with QTc >450 msec but <480 msec may be enrolled provided the QTc prolongation is due to a right bundle branch block (RBBB), left bundle branch block (LBBB), or pacemaker and is confirmed stable by a cardiologist.

8. Left ventricular ejection fraction (LVEF) ≥45% as measured by echocardiogram (ECHO) or multi-gated acquisition scan. [If LVEF <45% by ECHO, a repeat measurement can be conducted within the screening period.]
9. Subjects must have completed any prior systemic anti-cancer treatment ≥4 weeks (or ≥5 times the half-life [t½] of used therapeutics [including investigational therapy], whichever is longer) or radiation therapy ≥2 weeks before study Day 1 (D1), and ≥3 months before study D1 for high dose therapy with stem cell transplantation, radioimmunotherapy, and CAR T-cell therapy.
10. Eastern Cooperative Oncology Group (ECOG) performance status 0-1
11. Life expectancy of at least 3 months
12. All AEs and laboratory toxicities related to prior therapy must resolve to Gr ≤1 prior to the start of the study therapy (unless otherwise specified in eligibility criteria)
13. For females of childbearing potential, a negative serum human chorionic gonadotropin pregnancy test within 28 days of study D1 and negative result (urine or serum) on study D1
14. Subjects must agree to use appropriate contraception methods during the clinical study
15. Subject is willing and able to comply with all scheduled visits, treatment plans, laboratory tests, and other study procedures.

Criteria for Exclusion:

1. Histologically confirmed diagnosis of FL Gr 3b or transformed disease
    - For subjects with clinical signs of rapid disease progression (e.g., marked B-symptoms), and laboratory or radiographic indication (e.g., high lactate dehydrogenase level or standardized uptake value by positron emission tomography), a fresh tumor biopsy is recommended to rule out transformed disease
2. Subjects who received both R/O-B and R/O-CHOP (or other anthracycline-containing regimen) as previous lines of therapy, and those who received only single agent anti-CD20 mAb therapy as prior line of treatment
3. Prior therapy with phosphoinositide 3-kinase inhibitors
4. Ongoing or history of drug-induced pneumonitis
5. Known lymphomatous involvement of the central nervous system
6. Seropositive for or active viral infection with hepatitis B virus:
    - HBsAg positive
    - HBsAg negative, anti-HBs positive and/or anti-HBc positive and detectable viral DNA by polymerase chain reaction (PCR)

    [Note: Subjects who are HBsAg negative and viral DNA PCR negative are eligible. These subjects should receive prophylactic therapy for hepatitis as per institutional standards.]
7. Known seropositive for, or active infection with hepatitis C virus.
    - Subjects with positive hepatitis C virus (HCV) antibodies are eligible with negative PCR test for HCV
8. Known seropositive for, or active and uncontrolled infection with human immunodeficiency virus (HIV), or with acquired immunodeficiency syndrome, or currently taking medications for HIV that are contraindicated for concomitant use in this study
9. Known seropositive for, or active infection with human T-cell leukemia virus type 1
10. Any uncontrolled clinically significant illness including, but not limited to, active infections requiring systemic antimicrobial therapy, hypertension, angina, arrhythmias or other uncontrolled cardiovascular condition, pulmonary disease, autoimmune dysfunction, and urinary infection or flow obstruction.
11. Hypersensitivity or other clinically significant reaction to the study drug or its inactive ingredients or other therapy used in the study
12. Major surgical procedure within 4 weeks prior to study D1 (minor surgical procedures, e.g., lymph node biopsy, performed within 1 day or with an overnight stay are allowed)

13. Previous or concurrent cancer that is distinct in primary site or histology from indolent B cell NHL within 3 years before start of study treatment **except for** curatively treated cervical cancer in situ, non-melanoma skin cancer, and superficial bladder tumors (Ta [non-invasive tumor], Tis [carcinoma in situ], and T1 [tumor invades lamina propria]), and asymptomatic localized prostate cancer with no requirement for systemic therapy or requiring only hormonal therapy and with normal prostate-specific antigen values within ≥12 months prior to randomization
14. History of clinically significant cardiovascular abnormalities such as congestive heart failure (New York Heart Association (NYHA) classification ≥ II [NYHA 1994]), myocardial infarction within 6 months of study entry.
15. History of clinically significant gastrointestinal (GI) conditions, particularly:
    - Known GI condition that would interfere with swallowing or the oral absorption or tolerance of study drug
    - Pre-existing malabsorption syndrome or other clinical situation that would affect oral absorption
16. Females who are pregnant; females who plan to breastfeed during study treatment through 90 days after ending treatment
17. Substance abuse, medical, psychological or social conditions that may interfere with the subject's participation in the study or evaluation of the study results.
18. Any illness or medical conditions that are unstable or could jeopardize the safety of the subjects and their compliance in the study. Inability to understand and sign informed consent form.
19. Received a live virus vaccination within 28 days of first dose of study drug, (e.g., yellow fever vaccination)

Test Product, Dose and Mode of Administration, Batch Number:

Zandelisib batch numbers used are available on file.

Chemotherapy drugs and R were sourced commercially and provided by the Sponsor.

Duration of Treatment:

Standard immunochemotherapy (R-B and R-CHOP), designated R-chemo: 6 cycles (approximately 4 to 6 months)

Zandelisib plus R:

- R, 6 cycles (approximately 6 months)
- Zandelisib, 26 cycles of therapy (approximately 24 months)

Study Treatments

Zandelisib capsule was administered in a 28-day cycle, once a day on dosing days at approximately the same time in the morning on an empty stomach on the following schedule:

60 mg daily for the first two cycles of therapy (56 days) followed by once a day for the first 7 days of treatment and 21 days off treatment in every subsequent 28-day cycle, defined as the Intermittent Schedule (IS).

Rituximab:

- R, 375 mg/m^2 body surface on Day (D)1, D8, D15, and D22 of Cycle (C)1 and then on D1 of C3, C4, C5, and C6 for a total of 8 doses in 6 cycles

R is administered by intravenous infusion according to institutional standards

Dosing of immunochemotherapy (C1-C6):

R-B was administered in a 28-day cycle as follows:

- R, intravenously (IV) 375 mg/m^2 body surface on D1
- B, IV 90 mg/m^2 body surface on D1 and D2

R-CHOP was administered in a 21-day cycle as follows:

- R, IV 375 mg/m^2 body surface on D1
- Cyclophosphamide, IV 750 mg/m^2 body surface on D1
- Doxorubicin, IV 50 mg/m^2 body surface on D1
- Vincristine, IV 1.4 mg/m^2 body surface (maximum dose 2 mg) on D1
- Prednisone, 100 mg daily orally from D1 to D5

The chemotherapy regimen administered in the study had to be different from the one used as prior line of therapy.

- Subjects who received B with anti-CD20 antibody (R or obinutuzumab [O]) as a prior line of therapy were allocated to R-CHOP if randomized to the R-chemotherapy treatment group

Subjects who received CHOP or another chemotherapy regimen, (e.g., CVP), FND, with anti-CD 20 antibody (R or O) or R-L previously, were allocated to R-B if randomized to the R-chemotherapy group.

Reference Therapy, Dose and Mode of Administration, Batch Number:

Immunochemotherapy: R-B or R-CHOP for Cycles 1-6. For details of dose and administration please see Study Treatments section.

Criteria for Evaluation:

AEs were evaluated and recorded using the terminology defined in the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) v5.0.

A TEAE was defined as an AE starting or worsening in CTCAE grade after the first dose until 30 days after the last dose of study drug, or start of new anti-cancer therapy, whichever was earlier.

Death related to disease progression was not considered an AE.

Statistical Methods:

Safety data were summarized as described in the Statistical Analysis Plan and are presented here.

All safety summaries and analyses were based on the Safety Population, defined as all randomized subjects receiving at least 1 dose of any study drug. Safety analyses were performed by actual treatment group. Overall summary of safety included but not limited to the following analyses:

- TEAEs, including severity and possible relationship to study drug and/or study treatment
- Adverse events of special interest (AESI)
- Treatment-emergent SAEs
- Discontinuations from study treatment due to AEs
- Treatment-emergent laboratory toxicities

Clinical laboratory values were graded according to National Cancer Institute Common Terminology Criteria for Adverse Events Version 5.0 for applicable tests.

SAFETY RESULTS:

Demographics of Subjects and Disposition. A total of 82 subjects (41 per arm) were randomized in the study and received study treatment. In the R-chemo arm 31 subjects were assigned to R-B and 10 to R-CHOP (Table 0 and Table 0a).

Subject demographics were similar between the R-Z arm and the R-chemo arm. Median age was 65 years in both arms and the age between 28 to 83 in the R-Z arm and 32 to 76 in the R-chemo arm. Age category was approximately evenly split between subjects <65 years old (48.8%) and those who were 65 years or older (51.2%) and it was the same in the R-Z and the R-chemo arms. The majority of

the subjects were female numbering 49 (59.8%) and 33 (40.2%) were male. In the R-Z arm 24 (58.5%) were female and 17 (41.5%) were male and in the R-chemo arm 25 (61.0%) were female and 16 (39.0%) were male. The majority of the subjects (48.8%) were white, with similar percentages in both arms. ECOG status was 0 in 72% and 1 in 28% of subjects.

Forty-one subjects received study treatment in each arm and discontinued treatment. In the R-Z arm. 41 subjects (100%) were withdrawn from the study when the Sponsor terminated the trial prematurely; in the R-chemo arm 24 subjects (58.5%) completed and 17 (41.5%) were withdrawn from the study.

The majority of discontinuations in both arms of the study were due to termination of study by the sponsor. Among reasons for treatment discontinuations in the R-Z arm 6 subjects were discontinued due to AEs and 7 in each arm of the study discontinued due to disease progression.

Summary of adverse events (AEs) is presented in Table 1; a summary of treatment-emergent adverse events (TEAEs) by System Organ Class is presented in Table 9a, by Preferred Term in Table 9b, and a summary of COVID-19 related events is shown in Table 9c.

Overall, 38 (92.7%) subjects reported TEAEs in the R-Z arm and 37 (90.2%) subjects in the R-chemo arm. TEAEs reported with incidence ≥10% in the R-Z arm where diarrhea 15 (36.6%) subjects, COVID-19 related events 11 (26.8%), neutrophil count decreased 10 (24.4%) subjects, constipation 6 (14.6%) subjects, infusion related reaction 6 (14.6%) subjects, and stomatitis 5 (12.2%) subjects.

In the R-chemo arm TEAEs reported at ≥10% were nausea 13 (31.7%) subjects, infusion related reaction 10 (24.4%) subjects, neutrophil count decreased and pyrexia 7 (17.1%) subjects each; COVID-19 related events, constipation, decreased appetite, and vomiting were reported in 6 (14.6%) subjects each. There was 1 treatment-emergent COVID-19 death in the R-chemo arm.

Ten (24.4%) subjects were reported with Gr 4 TEAEs in the R-Z arm and 5 (12.2%) in the R-chemo arm. Gr ≥3 AESIs were reported for 9 (22.0%) subjects in the R-Z arm and 2 (4.9%) subjects in the R-chemo arm. Six (14.6%) subjects discontinued study drug in the R-Z arm and 2 (4.9%) subjects discontinued in the R-chemo arm due to AEs. There was 1 Grade (Gr) 5 TEAE reported in the R-chemo arm: none of the Gr 5 AEs were related to the study drug.

The subject incidence of TEAEs by grade is shown in Table 3 and those deemed related to study drug administration is shown in Table 5c. A Gr 5 treatment emergent COVID-19 infection was reported for 1 subject in the R-chemo arm. In all, 10 Gr 4 TEAEs were reported in the R-Z arm and 5 in the R-chemo arm. Among Gr 4 events, neutrophil count decreased was reported for 6 (14.6%) subjects in the R-Z arm and 3 (7.3%) in the R-chemo arm. Gr 4 AEs of neutropenia, COVID-19 pneumonia, ALT increased, hyponatremia, and Pneumocystis jirovecii pneumonia were reported for 1 subject each in the R-Z arm. In the R-chemo arm, Gr 4 AEs of neutropenia, febrile neutropenia, lymphocyte count decreased, thrombocytopenia, and the white blood count decreased was reported in 1 subject each.

Gr 3 TEAEs were reported for 20 (48.8%) subjects in the R-Z arm and 11 (26.8%) subjects in the R-chemo arm. In the R-Z arm Gr 3 neutrophil count decreased was reported in 3 (7.3%) subjects in the R-Z arm and 2 (4.9%) subjects in the R-chemo arm. White blood cell count decreased, hypokalemia, and pneumocystis jirovecii pneumonia were reported for 2 (4.9%) subjects each in the R-Z arm. Gr 3 anemia was reported for 3 (7.3%) subjects in the R-chemo arm and neutrophil count decreased 2 (4.9) subjects. Other Gr 3 TEAEs were reported in no more than 1 subject each in each arm (Table 3).

Thirty-three (80.5%) subjects in each arm reported TEAEs deemed related to study drug administration. There were no Gr 5 AEs that are related to zandelisib.

In all, 9 Gr 4 TEAEs were reported as related to study drug in the R-Z arm and 4 in the R-chemo arm. Among Gr 4 related events, neutrophil count decreased was reported for 6 (14.6%) subjects in the R-Z arm and 3 (7.3%) in the R-chemo arm. Gr 4 AEs of neutropenia, ALT increased, and Pneumocystis jirovecii pneumonia were reported for 1 subject each in the R-Z arm. In the R-chemo arm, febrile neutropenia, lymphocyte count decreased, and the white blood count decreased was reported in 1 subject each.

Related Gr 3 TEAEs were reported for 16 (39.0%) subjects in the R-Z arm and 10 (24.4%) subjects in the R-chemo arm. In the R-Z arm Gr 3 related neutrophil count decreased was reported in 3 (7.3%) subjects in the R-Z arm and 2 (4.9%) subjects in the R- chemo arm. Related Gr ≥3 white blood cell count decreased was reported for 2 (4.9%) subjects in the R-Z arm and Gr 3 anemia for 2 (4.9%) subjects in the R-chemo arm. Other Gr 3 related TEAEs were reported in no more than 1 subject each in each arm (Table 5c).

A summary of ≥Gr 3 infections is shown in Table 7.1. There were 7 (17.1%) subjects with at least 1 Gr ≥3 infection reported in the R-Z arm and 2 (4.9%) subjects in the R-chemo arm. In the R-Z arm the infections consisted of 3 subjects with Pneumocystis jirovecii infection, 2 each with pneumonia and COVID-19 pneumonia, and 1 each with cytomegaloviral pneumonia and tooth infection. In the R-chemo arm there was 1 Gr ≥3 COVID-19 infections and 1 Gr ≥3 respiratory tract infection.

Incidence of SAEs by grade is shown in Table 4. In total, 14 (34.1%) and 8 (19.5%) subjects reported SAEs in the R-Z and R-chemo arms, respectively. Gr 5 SAEs of COVID-19 or COVID-19 pneumonia were reported in 1 subject each in the R-Z arm and R chemo arm. Gr 4 SAEs were reported in 2 subjects (4.9%) in the R-Z arm (neutrophil count decreased and pneumocystis jirovecii pneumonia) and in 1 (2.4%) subject in the R-chemo arm (febrile neutropenia). Gr 3 SAEs were reported for 9 (22.0%) in the R-Z arm and 6 (14.6%) subjects in the R-chemo arm. Among Gr 3 SAEs in the R-Z arm pneumocystis jirovecii pneumonia and pneumonia were reported for 2 (4.9%) subjects each in the R-Z arm. Other Gr 3 SAES were reported in no more than 1 subject each in each arm (Table 4).

Subject incidence of G ≥3 AESIs is presented in Table 2 and a summary of AESIs by maximum grade is presented in Table 2a. In all, 8 (19.5%) subjects in the R-Z and 2 (4.9%) subjects in the R-chemo arm reported treatment-emergent AESIs. There were no Gr 5 AESIs reported. Gr 4 AESIs were reported in 2 (4.9%) subjects in the R-Z arm, 1 Pneumocystis jirovecii pneumonia and 1 ALT increased. In the R-Z arm the most frequently reported Gr 3 AESI were lung infection/ pneumonia in 4 (9.8%) subjects. Gr 3 AESIs were reported in 2 (4.9%) subjects in the R-chemo arm and were related to cutaneous reactions/rash and mucositis. Other Gr 3 AESIs were reported in no more than 1 subject each in each treatment arm (Table 2a).

AEs leading to discontinuation of study drug are presented in Table 5a and those deemed related to study drug administration are presented in Table5b. In the R-Z arm 6 subjects (14.6%) discontinued treatment due to AEs. The AEs were in 1 subject each: ALT increased, AST increased, hepatic function abnormal, infusion related reaction, Pneumocystis jirovecii pneumonia, pneumonitis, and rash. In the R-chemo arm 2 (4.9%) subjects discontinued study drug; 1 subject due to ejection fraction decreased and 1 due to lung neoplasm (not related).

Summary of laboratory toxicities Grade ≥3 is shown in Table 10. The most frequently reported Gr ≥3 laboratory toxicities were hematologic toxicities in both arms. Absolute neutrophil count decreased was reported in 11 (26.8%) subjects in both R-Z arm and the R chemo arm. White blood cell count decreased was reported in 3 (7.3%) subjects in the R-Z arm and 9 (22.0%) subjects in the R-chemo arm; lymphocyte count decreased was reported for 2 (4.9%) subjects in the R-Z arm and 22 (53.7%) subjects in the R-chemo arm.

SUMMARY – CONCLUSIONS

Overall, there were more discontinuations due to AEs in the R-Z arm. Gr ≥3 AESIs were more prevalent in the R-Z arm than the R-chemo arm. Incidence of lung infections including COVID-19, cytomegaloviral, and Pneumocystis jirovecii infection was higher in the R-Z arm. Due to premature termination of the study for business reasons and the limited number of subjects that were treated, it is not possible to define a definitive safety and risk/benefit profile for zandelisib in combination with rituximab.

Date of the Report: 28-April-2023