CLINICAL STUDY REPORT SYNOPSIS

Study Title:	A Phase 1b/2 Study of PF-07901801, A CD47 Blocking Agent, With Tafasitamab and Lenalidomide for Participants With Relapsed/Refractory Diffuse Large B Cell Lymphoma not Eligible for Stem Cell Transplantation
Study Number:	C4971003
Study Phase:	1b/2
Regulatory Agency or Public Disclosure Identifier Number:	NCT #: NCT05626322
Pediatric Investigational Plan Number:	Not Applicable
Study Intervention:	Maplirpacept (PF-07901801)
Indication:	Relapsed/Refractory Diffuse Large B Cell Lymphoma
Study Sponsor:	Pfizer Inc. 66 Hudson Boulevard East New York, NY 10001
Study Initiation Date (FPFV):	04 August 2023
Presentation of data in this CSR synopsis based on: **Study Completion (LPLV) Date:**	01 May 2025
Early Termination Status	This study was terminated by the sponsor on 16 July 2024 due to slow enrollment. The reason for study termination was not due to any safety concerns nor any requests from regulatory authorities.
CSR Version and Report Date:	**Document Version** / **Report Date** Final LPLV CSR CSR Version 1.0 / 19 August 2025
GOOD CLINICAL PRACTICE STATEMENT	

CLINICAL STUDY REPORT SYNOPSIS

This study was conducted in compliance with GCP guidelines and, where applicable, local country regulations relevant to the use of new therapeutic agents in the country/countries of conduct, including the archiving of essential documents.

CLINICAL STUDY REPORT SYNOPSIS

Number of Study Center(s) and Investigator(s):

A list of study centers and investigators involved in this study is provided in Appendix 16.1.4.1.

Publications:

None

Brief Description Of The Trial Design And Methodology:

This was a multicenter, international, Phase 1b/2 study exploring different doses of maplirpacept in combination with tafasitamab and lenalidomide in participants with R/R DLBCL who had completed at least 1 line of systemic treatment (at least 1 containing an anti-CD20 therapy), and who were not candidates for high dose therapy/ASCT.

The Phase 1b was planned to be conducted in approximately 20 participants. The objectives of the Phase 1b were to evaluate the safety, tolerability, PK, and immunogenicity of maplirpacept in combination with standard doses of tafasitamab and lenalidomide, and to select 2 doses to further explore in the randomized Phase 2 portion of the study. The planned 3 dose levels of PF-07901801 to be assessed in Phase 1b were:

- Cohort 1 dose level (DL) 1: 4 mg/kg, Cyele 1 to Cycle 3 once weekly (QW) then ≥Cycle 4 once every 2 weeks (Q2W).
- Cohort 2 DL2: 10 mg/kg, Cycle 1 to Cycle 3 QW then ≥Cycle 4 Q2W.
- Cohort 3 DL3: 18 mg/kg, Cycle 1 to Cycle 3 QW then ≥Cycle 4 Q2W.

An escalation/de-escalation approach guided by mTPI-2 was used in Phase 1b to identify the safety dose of maplirpacept when administered in combination with tafasitamab and lenalidomide. Maplirpacept and tafasitamab treatment was planned to continue until progressive disease (PD), non-tolerable toxicity or death while lenalidomide was planned to be administered for up to 12 cycles.

At the sponsor's discretion, proceeding to Phase 2 would have been determined upon completion of Phase 1b. For the Phase 2 part of the study, approximately 50 participants were planned to be randomized 1:1 into 2 selected fixed doses of maplirpacept in combination with standard doses of tafasitamab and lenalidomide to assess the efficacy and further characterize the safety and tolerability of the combination therapy.

Number of Participants (planned and analyzed):

Table S1. Number of Participants (Planned and Analyzed)

Population	N	Definition
Planned	70	Approximately 70 participants were planned to be enrolled in the study: approximately 20 participants in the Phase 1b and 50 participants in the Phase 2.

CLINICAL STUDY REPORT SYNOPSIS

Table S1. Number of Participants (Planned and Analyzed)

Enrolled	6	"Enrolled" means a participant's, or their legally authorized representative's, agreement to participate in a clinical study following completion of the informed consent process and assignment to study treatment.
Safety Analysis Set	6	All enrolled participants who received at least 1 dose of study treatment.
DLT Evaluate Set	5	All enrolled participants who received at least 1 dose of the study treatment in the Phase 1b of the study and either experience DLT(s) or complete the DLT observation period without DLT. Participants without DLTs who received less than 80% of the planned dose of maplirpacept or less than 75% of the planned dose of any component of the tafasitamab and lenalidomide regimen in the DLT observation period were not evaluable for DLTs. The DLT observation period was 28 days following C1D1.
PK Analysis Set	5	The PK analysis set included all participants in the safety analysis set who have at least 1 post-dose concentration measurement.
Immunogenicity Analysis Set	5	All participants in the safety analysis set who had at least 1 sample tested for ADA.

Abbreviations: ADA = anti-drug antibodies; C1D1 = Cycle 1 Day 1; DLT = dose-limiting toxicity; LLOQ = lower limit of quantitation; PK = pharmacokinetic(s).

Diagnosis and Main Criteria for Inclusion and Exclusion:

This study enrolled adult participants (≥18 years of age) with histologically confirmed measurable R/R DLBCL not eligible for stem cell transplantation.

Study Intervention:

Study interventions were administered in 28-day cycles. Lenalidomide was administered up to Cycle 12 while maplirpacept and tafasitamab were administered until PD, non-tolerable toxicity, or death.

- Maplirpacept was administered by intravenous (IV) infusion weekly for the first three cycles and then every two weeks for Cycle 4 and beyond. Participants received different dose levels as per assigned cohort.
- Tafasitamab was administered 12 mg/kg IV on Days 1, 4, 8, 15 and 22 in Cycle 1, weekly for Cycle 2 and 3 and then every 2 weeks for Cycle 4 and beyond.
- Lenalidomide was administered 25 mg by mouth (PO) daily on Days 1 through 21 of each 28-day cycle for up to 12 cycles.

Premedications were not required for maplirpacept but were to be administered per institutional guidelines at the investigator's discretion and/or if a prior infusion related reaction (IRR) had been experienced.

The manufacturing lot numbers for the study intervention(s) dispensed in this study are provided in Table S2.

CLINICAL STUDY REPORT SYNOPSIS

Table S2. Study Intervention(s) Administered

Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength / Potency	Dosage Form
Lenalidomide (Zelvina) 10 mg Capsules	B15781P1	22-AE-00609	10 mg	Commercial product
Lenalidomide (Zelvina) 10 mg Capsules	C17645P3	23-AE-00807	10 mg	Commercial product
Lenalidomide (Zelvina) 10 mg Capsules	C18388P1	23-AE-01059	10 mg	Commercial product
Lenalidomide (Zelvina) 15 mg Capsules	B15882P1	22-AE-00608	15 mg	Commercial product
Lenalidomide (Zelvina) 15 mg Capsules	C17373P1	23-AE-00806	15 mg	Commercial product
Lenalidomide (Zelvina) 15 mg Capsules	C18641P3	23-AE-01060	15 mg	Commercial product
Lenalidomide (Zelvina) 2.5 mg Capsule	B16598P1	22-AE-00611	2.5 mg	Commercial product
Lenalidomide (Zelvina) 2.5 mg Capsule	B16598P1	23-AE-00808	2.5 mg	Commercial product
Lenalidomide (Zelvina) 2.5 mg Capsule	C18382P7	23-AE-01057	2.5 mg	Commercial product
Lenalidomide (Zelvina) 20 mg Capsule	B15367P2	22-AE-00607	20 mg	Commercial product
Lenalidomide (Zelvina) 20 mg Capsule	B16486P1	22-AE-00802	20 mg	Commercial product
Lenalidomide (Zelvina) 20 mg Capsule	C18377P6	23-AE-01061	20 mg	Commercial product
Lenalidomide (Zelvina) 25 mg Capsule	B15368P1	22-AE-00600	25 mg	Commercial product
Lenalidomide (Zelvina) 25 mg Capsule	C17354P5	22-AE-00803	25 mg	Commercial product
Lenalidomide (Zelvina) 25 mg Capsule	D19144P2	23-AE-01062	25 mg	Commercial product
Lenalidomide (Zelvina) 5 mg Capsules	B15522P5	22-AE-00610	5 mg	Commercial product
Lenalidomide (Zelvina) 5 mg Capsules	B16465P4	22-AE-00804	5 mg	Commercial product
Lenalidomide (Zelvina) 5 mg Capsules	C18387P1	23-AE-01058	5 mg	Commercial product
PF-07901801 (TTI-622) Sol Inj 10 mg/mL [DS P1,US]	3-FIN-3973	22-DP-01063	10 mg	Solution
PF-07901801 (TTI-622) Solution for Injection, 10 mg/mL [DS P2, Global]	3-FIN-3975	22-DP-01238	10 mg	Solution
Tafasitamab-cxix (Monjuvi) 200 mg/vial powder for solution for injection, for intravenous use	C20036A	22-AE-00635	200 mg	Commercial drug product
Tafasitamab-cxix (Monjuvi) 200 mg/vial powder for solution for injection, for intravenous use	C22057	22-AE-00760	200 mg	Commercial drug product
Tafasitamab-cxix (Monjuvi) 200 mg/vial powder for solution for injection, for intravenous use	C22057	22-AE-00760	200 mg	Commercial drug product
Tafasitamab-cxix (Monjuvi) 200 mg/vial powder for solution for injection, for intravenous use	C23211	23-AE-01166	200 mg	Commercial drug product

CLINICAL STUDY REPORT SYNOPSIS

Global Substantial Modifications

Table S3. Global Substantial Modifications

Date of Protocol Amendment	Amendment
09 December 2024	A business decision was made by Pfizer to terminate the C4971003 study. The reason for study termination was not due to any safety concerns or requests from regulatory authorities. As a result of this decision, Phase 1b was to be discontinued after the last participant last visit and Phase 2 of the study would not be initiated.

Global Interruptions and re-starts

Not applicable.

Endpoints And Statistical Methods:

CLINICAL STUDY REPORT SYNOPSIS

Table S4. Objectives, Endpoints, and Statistical Methods for Phase 1b

Objectives	Endpoints	Analysis Type	Analysis Population	Data Inclusion and Rules for Handling Intercurrent Events and Missing Data	Analysis Model
Primary	**Primary:**				
To assess DLTs, safety and tolerability of maplirpacept in combination with tafasitamab and lenalidomide in adult participants with R/R DLBCL in order to select up to 2 doses of maplirpacept for further evaluation in Phase 2 of the study.	DLTs during the DLT observation period (28 days following C1D1).	Primary safety analysis	DLT evaluable set	All enrolled participants who received at least 1 dose of the study treatment in the Phase 1b of the study and either experience DLT(s) or complete the DLT observation period without DLT. Participants without DLTs who received less than 80% of the planned dose of maplirpacept or less than 75% of the planned dose of any component of the tafasitamab and lenalidomide regimen in the DLT observation period were not evaluable for DLTs. The DLT observation period was 28 days following C1D1.	Descriptive statistics
Secondary	**Secondary:**				
To evaluate the overall safety profile of the combination.	AEs as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), timing, seriousness, and relationship to study treatment.	Secondary safety analysis	Safety analysis set	All enrolled participants who received at least 1 dose of study treatment.	Descriptive statistics
	Laboratory abnormalities as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), and timing.				
To evaluate the anti-tumor activity of maplirpacept in	OR, DoR, CR, DoCR, and PFS per Lugano Response	Efficacy analysis	Efficacy analysis	All data from the start date until the first documentation of PD, death, or start of new anticancer	Descriptive statistics, Kaplan-Meier method, and

CLINICAL STUDY REPORT SYNOPSIS

Table S4. Objectives, Endpoints, and Statistical Methods for Phase 1b

Objectives	Endpoints	Analysis Type	Analysis Population	Data Inclusion and Rules for Handling Intercurrent Events and Missing Data	Analysis Model
combination with tafasitamab and lenalidomide.	Classification Criteria 2014 as assessed by the investigator.			therapy. All data collected after an intercurrent event of subsequent anticancer therapy were excluded. All response assessments regardless of gaps in disease assessments were considered.	per Lugano 2014 response criteria
To evaluate the PK of maplirpacept.	Pre- and post-dose concentration of maplirpacept.	PK analysis	PK analysis	All participants in the safety analysis set who had at least 1 post-dose concentration measurement.	Descriptive statistics
To evaluate immunogenicity of maplirpacept.	ADAs and NAbs against maplirpacept.	Immunogenicity analysis	Immunogenicity analysis	All participants in the safety analysis set who had at least 1 sample tested for ADA.	Descriptive statistics

Abbreviations: ADA = anti-drug antibodies; AE = adverse event; C1D1 = Cycle 1 Day 1; CTCAE = Common Terminology Criteria for Adverse Events; CR = complete response; DLBCL = diffuse large B cell lymphoma; DoCR = duration of complete response; DoR = duration of response; Nab = neutralizing antibodies; NCI = National Cancer Institute; PFS = progression-free survival; PK = pharmacokinetic(s); OR = objective response; R/R = relapsed-refractory; PD = progressive disease.

CLINICAL STUDY REPORT SYNOPSIS

SUMMARY OF RESULTS:

Participant Disposition

All 6 participants, including 3 participants, 2 participants, and 1 participant from 4 mg/kg, 10 mg/kg, and 18 mg/kg maplirpacept combination treatment cohorts, received maplirpacept, tafasitamab, and lenalidomide combination treatments.

All (6 [100%]) participants discontinued maplirpacept and tafasitamab. The most common reasons for discontinuation of maplirpacept and tafasitamab were death and progressive disease (each reported in 2 [33.3%] participants).

- Discontinuation due to death was reported in 2 participants in 4 mg/kg maplirpacept combination treatment cohort.

- Discontinuation due to progressive disease was reported in 1 participant each in 10 mg/kg maplirpacept combination treatment cohort and 18 mg/kg maplirpacept combination treatment cohort.

Three (50%) participants discontinued lenalidomide. The most common reason for discontinuation of lenalidomide was progressive disease (2 [33.3%] participants), reported 1 each in 10 mg/kg and 18 mg/kg maplirpacept combination treatment cohorts).

A total of 2 (33.3%) participants entered the follow-up phase of whom 1 (16.7%) participant completed follow-up. The other participant discontinued from follow-up due to study termination by sponsor.

Demographic and Other Baseline Characteristics:

- A total of 3 (50.0%) participants were males. The mean (SD) age was 60.3 (14.92) years. Most participants (4 [66.7%]) were white.

- The majority of participants had Eastern Cooperative Oncology Group (ECOG) performance status 0 (3 [50%] participants) or 1 (2 [33.3%] participants) at baseline.

- 5 (83.3%) participants had diffuse large B-cell lymphoma and 1 (16.7%) participant (10 mg/kg maplirpacept combination treatment cohort) had Grade 3B follicular lymphoma at baseline.

- At initial diagnosis, 3 (50.0%) participants were at Stage IV and 1 (16.7%) participant each was at Stage I, Stage II, Stage III; At current stage, 3 (50.0%) participants were at Stage II, 1 (16.7%) participant was at Stage I and 2 (33.3%) participants were at Stage IV.

- The median (range) time since initial histopathological diagnosis was 19.7 (7.6, 196.9) months.

- 4 (66.7%) participants had complete response to first line of prior anti-cancer therapy and the most recently administered prior anti-cancer therapy.

CLINICAL STUDY REPORT SYNOPSIS

Exposure:

Overall, the median (range) duration of treatment for maplirpacept, tafasitamab, and lenalidomide was 37.0 (6.0, 62.0) weeks, 37.0 (6.0, 62.0) weeks, and 35.2 (7.0, 47.9) weeks, respectively. Of note, the median (range) duration of treatment for the one participant enrolled in 18 mg/kg maplirpacept combination treatment cohort was 6.0 (6.0, 6.0) weeks, 6.0 (6.0, 6.0) weeks, and 7.0 (7.0, 7.0) weeks for maplirpacept, tafasitamab, and lenalidomide, respectively. This was due to progressive disease leading to discontinuation.

The mean (SD) relative dose intensity for maplirpacept, tafasitamab, and lenalidomide was 86.6% (9.78%), 87.3% (9.04%), and 72.2% (38.44%), respectively.

Summary of Efficacy/Immunogenicity/PK/Safety Results

Table S5. Study C4971003 Safety/Efficacy/PK/Immunogenicity Results

Endpoints	Results
Primary:	
DLTs during the DLT observation period (28 days following C1D1).	There was no DLT event reported in the 5 DLT-evaluable participants in Phase 1b.
Secondary:	
AEs as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), timing, seriousness, and relationship to study treatment.	All 6 (100%) participants experienced all-causality TEAE and TEAE related to any study intervention. 3 (50.0%) participants who received 4 mg/kg maplirpacept in combination with tafasitamab and lenalidomide experienced all-causality treatment-emergent SAEs, of whom 1 (16.7%) had an SAE of Leukemia related to lenalidomide, leading to death. None of the SAEs were assessed as related to maplirpacept or tafasitamab. • 4 treatment-emergent SAEs (2 episodes of Acute kidney injury, Urinary tract obstruction, Leukemia of which only Leukemia was assessed as treatment-related) were reported in a single participant in the 4 mg/kg maplirpacept combination treatment cohort. This participant had an SAE of Leukemia leading to death, which was assessed as related to lenalidomide by the investigator. • 3 treatment-emergent SAEs (Appendicitis, Pneumonia, Sepsis), assessed as not related to study interventions, were reported in another single participant in the 4 mg/kg maplirpacept combination treatment cohort. This participant had cardiac arrest leading to death, which occurred outside the on-treatment period (28 days of last treatment). • In addition, 1 participant in the 4 mg/kg maplirpacept combination treatment cohort had a treatment-emergent SAE of Sepsis, which was assessed as not related to the study interventions.

CLINICAL STUDY REPORT SYNOPSIS

Table S5. Study C4971003 Safety/Efficacy/PK/Immunogenicity Results

Endpoints	Results
	4 (66.7%) participants experienced all-causality TEAEs with Grade ≥3 (100.0% in 4 mg/kg combination treatment cohort, and 50.0% in 10 mg/kg combination treatment cohort), of whom 2 (33.3%) had treatment-related TEAEs with Grade ≥3. Grade 3-4 TEAEs related to maplirpacept were reported in 2 patients and included Neutrophil count decreased (N=2), Platelet count decreased (N=1), and Aneamia (N=1). The most common (≥50%) all-causality TEAEs by PT were Diarrhoea (4 [66.7%] participants), Neutrophil count decreased (4 [66.7%] participants), Nausea (3 [50.0%] participants), and Platelet count decreased (3 [50.0%] participants). The most common (≥50%) TEAEs related to any treatment by PT were Neutrophil count decreased (4 [66.7%] participants), Nausea (3 [50.0%] participants), and Platelet count decreased (3 [50.0%] participants). The most common (≥50%) TEAEs related to maplirpacept by PT were Neutrophil count decreased (4 [66.7%] participants) and Platelet count decreased (3 [50%] participants). No participant experienced TEAEs leading to discontinuation of maplirpacept, lenalidomide, or tafasitamab. 3 (50.0%) participants experienced treatment-related TEAEs leading to dose reduction of lenalidomide (66.7% in 4 mg/kg combination treatment cohort, and 50.0% in 10 mg/kg combination treatment cohort). No TEAEs leading to dose reduction of maplirpacept or tafasitamab were reported. 3 (50.0%) participants each experienced TEAEs leading to dose interruptions of maplirpacept, tafasitamab, and/or lenalidomide; 1 (16.7%), 2 (33.3%), and 2 (33.3%) participants had treatment-related TEAEs leading to dose interruptions of maplirpacept, tafasitamab, lenalidomide, respectively.
Laboratory abnormalities as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), and timing.	Hematology • Hematology results worsening to Grade 3: Anemia of 1 (16.7%) participant (4 mg/kg maplirpacept combination treatment cohort) worsened from Grade 2 to Grade 3, Leukocytosis of 1 (16.7%) participant (4 mg/kg maplirpacept combination treatment cohort) worsened from Grade 0 to Grade 3, lymphocyte count decreased of 1 (16.7%) participant (4 mg/kg maplirpacept combination treatment cohort) worsened from Grade 0 to Grade 3 and another 1 (16.7%) participant (10 mg/kg maplirpacept combination treatment cohort) worsened from Grade 1 to Grade 3, Neutrophil count decreased of 3 (50%) participants worsened from Grade 0 to Grade 3 (including 2 participants from 4 mg/kg maplirpacept combination treatment cohort and 1 participant from 10 mg/kg maplirpacept combination treatment cohort).

CLINICAL STUDY REPORT SYNOPSIS

Table S5. Study C4971003 Safety/Efficacy/PK/Immunogenicity Results

Endpoints	Results
	• Hematology results worsening to Grade 4: Neutrophil count decreased of 1 (16.7%) participant (4 mg/kg maplirpacept combination treatment cohort) worsened from Grade 0 to Grade 4, Platelet count decreased of 1 (16.7%) participant (10 mg/kg maplirpacept combination treatment cohort) worsened from Grade 0 to Grade 4 and of another 1 (16.7%) participant (4 mg/kg maplirpacept combination treatment cohort) worsened from Grade 1 to Grade 4, White blood cell decreased of 1 (16.7%) participant (4 mg/kg maplirpacept combination treatment cohort) worsened from Grade 0 to Grade 4. Chemistry • Chemistry results worsening to Grade 3: Creatinine increased of 1 (16.7%) participant (4 mg/kg maplirpacept combination cohort) worsened from Grade 0 to Grade 3, Hypoalbuminemia of 1 (16.7%) participant (4 mg/kg maplirpacept combination cohort) worsened from Grade 1 to Grade 3. • No participant had Grade 4 chemistry results. Liver Function Tests • No participant had ALT or AST ≥3 × ULN. • 1 (16.7%) participant (4 mg/kg maplirpacept combination treatment cohort) had TBILI ≥2 × ULN. • No participant had concurrent ALT ≥3 × ULN and TBILI ≥2 × ULN
OR, DoR, CR, DoCR, and PFS per Lugano Response Classification Criteria 2014 as assessed by the investigator.	Overall, 4 (66.7%) participants achieved objective response (CR or PR), including 2 participants each from 4 mg/kg and 10 mg/kg maplirpacept combination treatment cohorts, with an ORR of 66.7% (95% CI: 24.1%, 94.0%). Among the 4 participants who achieved objective response, all 4 (66.7%) participants achieved CR. The CRR was 66.7% (95% CI: 24.1%, 94.0%) Among the 4 responders, 3 (75%) participants lost their response due to progressive disease (1 participant in 10 mg/kg maplirpacept combination treatment cohort) or death (2 participants in 4 mg/kg maplirpacept combination treatment cohort); 1 participant in 10 mg/kg maplirpacept combination treatment cohort was ongoing without an event at the time of the analysis. Kaplan-Meier estimates of median (95% CI) time to an event (duration of response or duration of complete response) was 11.9 (3.3, NE) months. Four (66.7%) participants had PFS events, including 2 (33.3%) participants with progressive disease (1 each from 10 mg/kg and 18 mg/kg maplirpacept combination treatment cohorts) and 2 (66.7%)

CLINICAL STUDY REPORT SYNOPSIS

Table S5. Study C4971003 Safety/Efficacy/PK/Immunogenicity Results

Endpoints	Results
	died (in 4 mg/kg maplirpacept combination treatment cohort). The median PFS was 11.4 (95% CI: 5.6, NE) months.
Pre- and post-dose concentration of maplirpacept.	The fold increase in exposure from 4 mg/kg to 10 mg/kg was greater than 2.5-fold based on the geometric mean of serum concentrations at time points of interest (Cycle 1 Day 1 EOI), Cycle 1 Day 8 pre-dose, Cycle 2 Day 1 EOI, Cycle 4 Day 1 pre-dose, Cycle 7 Day 1 pre-dose). In general, steady-state is reached by Cycle 3 Day 1. One participant in the 10 mg/kg maplirpacept combination treatment cohort did not receive a Cycle 3 Day 22 dose, and their Cycle 4 Day 1 trough concentration decreased substantially. Lastly, maplirpacept trough concentrations decreased starting Cycle 5, coinciding with the reduced frequency of dosing (QW in Cycle 1-3, and Q2W thereafter).
ADAs and NAbs against maplirpacept.	Of the 5 participants with at least 1 ADA result, no participant had post-treatment positive ADA or NAb.

Abbreviations: ADA = antidrug antibodies; C1D1 = Cycle 1 Day 1; CR = complete response; CRR = complete response rate; CTCAE = Common Terminology Criteria for Adverse Events; DLT = dose limiting toxicity; DoCR = duration of complete response; DoR = duration of response; EOC = end of infusion; EOI = end of infusion; Nab = neutralizing antibodies; NCI = national cancer institute; OR = objective response; PFS = progression-free survival; PR = partial response; PT = preferred term; TEAE = treatment emergent adverse event; SAE = serious adverse event.

CONCLUSIONS:

Efficacy:

- Although no conclusions can be drawn considering the small sample size (N=6) and three different maplirpacept dose levels explored, all 4 responders achieved complete response, with an estimated ORR of 66.7% (95% CI: 24.1%, 94.0%), a median DoR of 11.9 (3.3, NE) months, and a median PFS of 11.4 (95% CI: 5.6, NE) months.

Safety:

- Acknowledging the limitation of the small sample size, maplirpacept in combination with tafasitamab and lenalidomide was generally tolerable. No DLTs were reported in the 5 DLT-evaluable participants in Phase 1b. Gastrointestinal and hematological toxicities including diarrhea, nausea, neutropenia and thrombocytopenia were the most common events. Treatment-emergent adverse events related to maplirpacept by the investigators were mostly moderate in severity although Grade 3-4 hematological toxicities were also reported. No participant experienced TEAEs leading to permanent discontinuation. No clinically significant trends or changes in the laboratory data were observed. Overall, no new safety signal was identified.

CLINICAL STUDY REPORT SYNOPSIS

PK:

- The increase in maplirpacept serum concentrations from 4 mg/kg to 10 mg/kg was greater than 2.5-fold.
- Maplirpacept reached steady-state by Cycle 3 Day 1 (8 weeks after the first dose).

Immunogenicity:

- No participants were tested ADA or NAb positive at baseline or post study intervention.