

Loncastuximab tesirine in Chinese patients with relapsed or refractory diffuse large B-cell lymphoma: a multicenter, open-label, single-arm, phase II trial

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Supplementary Data to the Manuscript Entitled

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Supplementary methods

Complete eligibility criteria of OL-ADCT-402-001 study

Inclusion Criteria

1. Male or female patients aged 18 years or older who are current residents of mainland China with Chinese ancestry
2. Pathologic diagnosis of DLBCL, as defined by the 2016 WHO classification, to include: DLBCL not otherwise specified, DLBCL transformed from indolent lymphoma, and high-grade B-cell lymphoma, with MYC and BCL2 and/or BCL6 rearrangements
3. Relapsed or refractory disease following two or more multiagent systemic treatment regimens
 - Relapsed disease defined as progression of disease (PD) at least 6 months after having achieved CR or PR with adequate prior anti-DLBCL therapy. Refractory disease defined as failure to achieve CR or PR or experienced PD within 6 months after having achieved CR or PR, after adequate prior anti-DLBCL therapy.
 - Adequate prior anti-DLBCL therapies defined as having received at least 4 cycles of multiagent systemic treatment regimens containing rituximab and anthracycline in 1L therapy and at least 2-cycle treatment regimen in 2L therapy, unless the patients are intolerant or had disease progression during the treatment. If disease progression occurred during the treatment period, then the disease is considered refractory irrespective of the number of treatment cycles received. Patients with transformed DLBCL are eligible if they have received at least two multi-agent systemic anti-lymphoma regimens as defined above, regardless of whether these treatments were given before or after histological transformation.
4. Patients who have received previous CD19-directed therapies must have a biopsy that shows CD19 protein expression after completion of the CD19-directed therapy
5. Measurable disease as defined by the 2014 Lugano Classification
6. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
7. Adequate organ function as defined by screening laboratory values within the following parameters:
 - a) Absolute neutrophil count $\geq 1.0 \times 10^3/\mu\text{L}$ (off growth factors at least 72 h)
 - b) Platelet count $\geq 75 \times 10^3/\mu\text{L}$ without transfusion in the prior 7 days
 - c) Hemoglobin ≥ 80 g/L without transfusion in the prior 7 days

- d) ALT, AST, and GGT $\leq 2.5 \times$ the upper limit of normal (ULN)
- e) Total bilirubin $\leq 1.5 \times$ ULN (patients with known Gilbert's syndrome may have a total bilirubin up to $\leq 3 \times$ ULN)
- f) Blood creatinine $\leq 1.5 \times$ ULN or calculated creatinine clearance ≥ 60 mL/min by the Cockcroft and Gault equation

Note: A laboratory assessment may be repeated a maximum of two times during the Screening period to confirm eligibility.

8. Women of childbearing potential (WOCBP)* must agree to use a highly effective** method of contraception from the time of giving informed consent until at least 9 months after the last dose of loncastuximab tesirine. Men with female partners who are of childbearing potential must agree that they will use a highly effective method of contraception from the time of giving informed consent until at least 6 months after the patient receives his last dose of loncastuximab tesirine

* WOCBP are defined as sexually mature women who have not undergone bilateral tubal ligation, bilateral oophorectomy, or hysterectomy; or who have not been postmenopausal. A postmenopausal state is defined as no menses for 12 months without an alternative medical cause. A high follicle stimulating hormone (FSH) level in the postmenopausal range may be used to confirm a postmenopausal state in women not using hormonal contraception or hormonal replacement therapy. However, in the absence of 12 months of amenorrhea, a single FSH measurement is insufficient.

** Highly effective forms of birth control are methods that achieve a failure rate of less than 1% per year when used consistently and correctly. Highly effective forms of birth control include: hormonal contraceptives associated with inhibition of ovulation (oral, injectable, patch, a vaginal ring or implantable birth control), intrauterine devices and intrauterine hormone releasing systems, male partner sterilization (vasectomy), or total abstinence from heterosexual intercourse, when this is the preferred and usual lifestyle of the patient.

Note: The progesterone-only birth control pills which do not inhibit ovulation, barrier method (e.g., condoms, diaphragm, or cervical cap with or without spermicidal foam, cream, or gel), periodic abstinence (such as calendar, symptothermal, post-ovulation), withdrawal (coitus interruptus), lactational amenorrhea method, and spermicide-only are not considered as highly effective methods of contraception.

Exclusion Criteria

1. Previous treatment with loncastuximab tesirine
2. Known history of hypersensitivity to or positive serum human anti-drug antibody (ADA) to a CD19 antibody
3. Pathologic diagnosis of Burkitt lymphoma
4. Bulky disease, defined as any tumor ≥ 10 cm in longest dimension
5. Active second primary malignancy other than non-melanoma skin cancers, non-metastatic prostate cancer, in situ cervical cancer, ductal or lobular carcinoma in situ of the breast, or other malignancy that the Sponsor's medical monitor and Investigator agree and document should not be exclusionary
6. Autologous stem cell transplant within 30 days prior to start of study drug (Cycle 1 Day 1 [C1D1])
7. Allogeneic stem cell transplant within 60 days prior to start of study drug (C1D1)
8. Active graft-versus-host disease
9. Post-transplant lymphoproliferative disorders
10. Active autoimmune disease, including motor neuropathy considered of autoimmune origin and other central nervous system (CNS) autoimmune disease
11. Seropositive for human immunodeficiency virus (HIV-1 and/or HIV-2 antibodies positive), serologic evidence of chronic hepatitis B virus (HBV) infection and unable or unwilling to receive standard prophylactic antiviral therapy or with detectable HBV viral load, or hepatitis C virus (HCV antibody positive or quantitative HCV RNA results greater than the lower limits of detection of the assay)
12. History of Stevens-Johnson syndrome or toxic epidermal necrolysis
13. Lymphoma with active CNS involvement at the time of screening, including leptomeningeal disease
14. Clinically significant third space fluid accumulation (i.e., ascites requiring drainage or pleural effusion that is either requiring drainage or associated with shortness of breath)
15. Breastfeeding or pregnant
16. Significant medical comorbidities, including but not limited to uncontrolled hypertension (blood pressure $\geq 160/100$ mmHg repeatedly), unstable angina, congestive heart failure (greater than New York Heart Association class II), electrocardiographic evidence of acute ischemia, coronary angioplasty or myocardial infarction within 6 months prior to screening, uncontrolled atrial or

ventricular cardiac arrhythmia, poorly controlled diabetes, severe chronic pulmonary disease, or active infections (including but not limited to tuberculosis)

17. Major surgery, radiotherapy, chemotherapy, or other anti-neoplastic therapy within 14 days prior to start of study drug (C1D1), except shorter if approved by the Sponsor
18. Use of any other experimental medication within 14 days prior to start of study drug (C1D1)
19. Planned live vaccine administration after starting study drug (C1D1)
20. Failure to recover to Grade ≤ 1 (Common Terminology Criteria for Adverse Events version 4.0 [CTCAE v4.0]) from acute non-hematologic toxicity (except Grade ≤ 2 neuropathy or alopecia) due to previous therapy prior to screening
21. Congenital long QT syndrome or a corrected QTcF interval of >480 ms at screening (unless secondary to pacemaker or bundle branch block)
22. Any other significant medical illness, abnormality, or condition that would, in the Investigator's judgment, make the patient inappropriate for study participation or put the patient at risk

Procedures

Lonca was administered as an intravenous (IV) infusion over 30 minutes on Day 1 of each cycle at a dose of 150 $\mu\text{g/kg}$ every 3 weeks (Q3W) for 2 cycles, then at 75 $\mu\text{g/kg}$ Q3W for the subsequent cycles, for up to one year or until disease progression, unacceptable toxicity, or other discontinuation criteria, patients still benefiting at 1 year could continue treatment.

Responses were assessed on PET-CT scans by the investigator as well as by the independent review committee (IRC) based on the 2014 Lugano classification criteria.¹ Adverse events (AEs) were assessed and graded according to the National Cancer Institute–Common Terminology Criteria for Adverse Events (CTCAE), version 4.0. All AEs, including serious AEs (SAEs), were reported from the time of informed consent until 15 weeks after the last dose of the study drug or the start of subsequent new anti-cancer therapy.

Oral dexamethasone premedication as prophylaxis for infusion-related reactions was required unless contraindicated. In addition, spironolactone at standard doses was administered for patients with weight gain greater than 1 kg from day 1 of cycle one (C1D1) with new or worsening edema, and/ or new or worsening pleural effusion. Dose delay (≤ 5 weeks) and dose reduction (≤ 2 times) of loncastuximab tesirine were permitted to manage toxicity.

Imaging with positron-emission tomography (PET)–computed tomography (CT) and or CT was performed at screening; 6 weeks (prior to cycle 3) and 12 weeks (prior to cycle 5) after C1D1, then every 9 weeks until the end of treatment (EOT). During the follow-up period after EOT, for patients who discontinued the study drug for reasons other than disease progression or initiation of other anti-cancer therapy except SCT, imaging was performed approximately every 12 weeks for 1 year, then every 6 months until disease progression or up to 3 years from EOT.

Intensive pharmacokinetic (PK) samples after the first 2 dose administrations were collected in 12 patients and sparse PK samples were collected for all patients. The concentration of loncastuximab tesirine (total antibody) in serum, PBD conjugated antibody, and unconjugated warhead SG3199 were assessed using validated methodology as used in LOTIS-2 study². Anti- loncastuximab tesirine anti-drug antibody (ADA) titers were analyzed by validated bridging ECLIA assay.²

Definition of efficacy endpoints

1. Overall response rate (ORR) was defined as the proportion of patients with a best overall response (BOR) of complete response (CR) or partial response (PR).
2. Duration of response (DOR) was defined as the time from first documented tumor response to disease progression or death.
3. Complete response rate (CRR) was defined as the percentage of treated patients with a BOR of CR
4. Time to response (TTR) was defined as the time from the first dose to the first documented response among patients who achieve either CR or PR as BOR.
5. Relapse-free survival (RFS) was defined as the time from the first documented CR to disease progression or death.
6. Overall survival (OS) was defined as the time between the start of treatment and death from any cause.

Statistical analysis

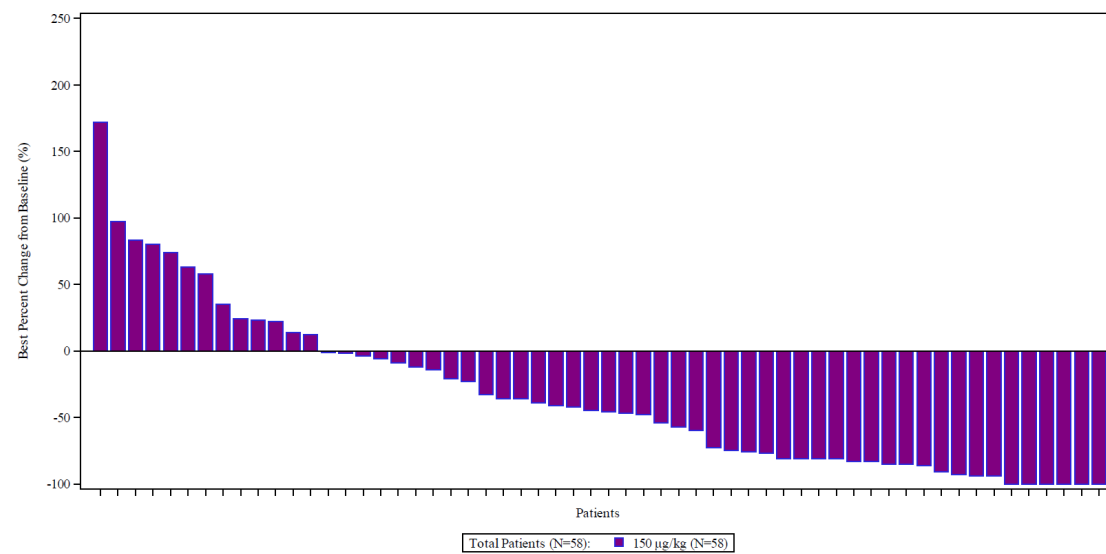
Response rates were reported as the percentage with associated 95% Clopper–Pearson (ie, exact binomial) CIs. Time-to-event endpoints, including DOR, RFS, PFS, and OS, were presented as median survival time estimated using Kaplan–Meier methodology with 95% Greenwood's CIs. Prespecified subgroup analyses of the efficacy variables, ORR, DOR, CRR, RFS, PFS, were performed.

Anti-tumor activity and safety data were analyzed with the use of SAS software, version 9.4 (SAS Institute),

and PK data was analyzed with the use of NONMEM version 7.4.

Supplementary Figures

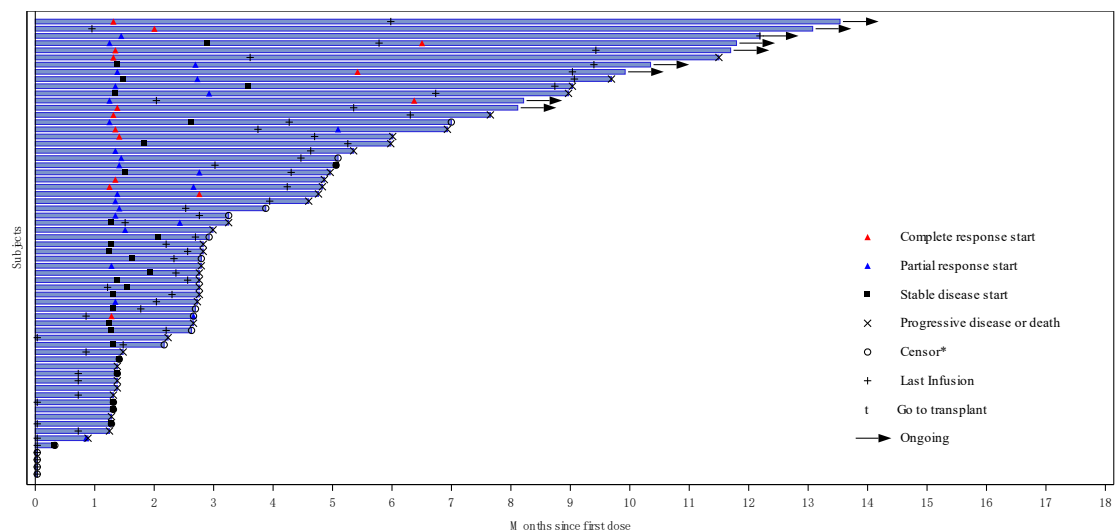
Supplementary Figure S1 Waterfall plot of best percent change from baseline in tumor size, as assessed by independent reviewer (All-Treated Population)



Bars represent individual patients. * Sum of the product of perpendicular diameters in multiple target lesions by independent reviewer is used.

The sum of the product of perpendicular diameters was NE for one patient and was missing for other 5 patients: three patients did not have target lesion; two patients did not have any post baseline assessment.

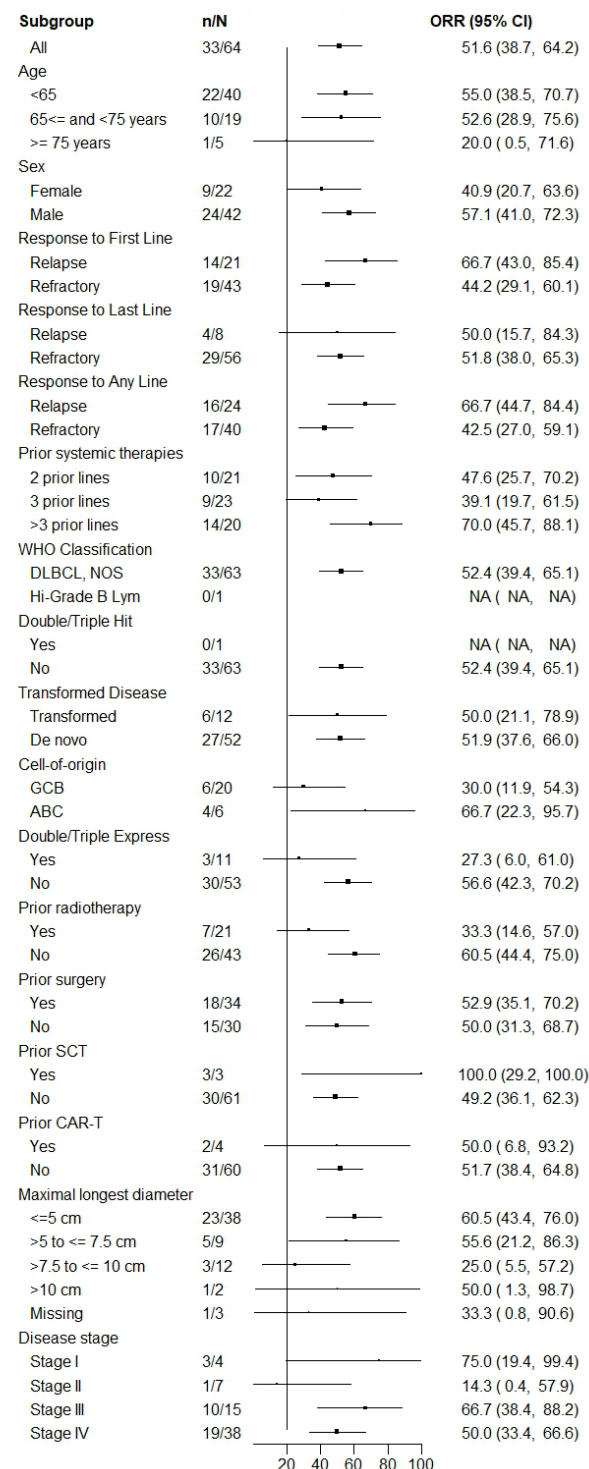
Supplementary Figure S2 Swimmer plot showing timing of response, as assessed by independent reviewer (All-Treated Population)



Each bar represents one patient in the study. Response is determined by independent reviewer

* Only for censored patients who discontinued trial due to reasons other than progression or who went onto a different anticancer treatment other than transplant.

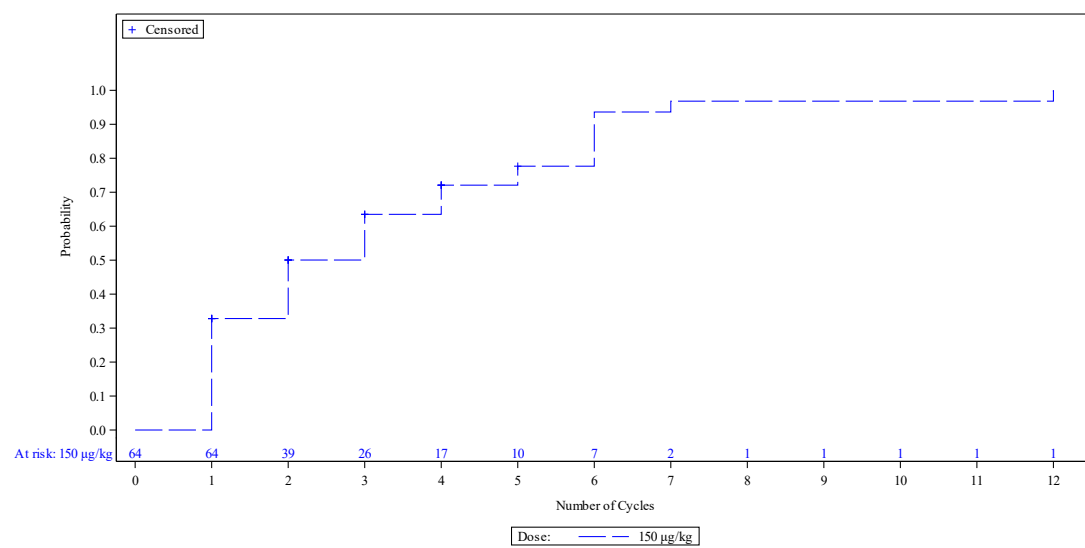
Supplementary Figure S3 Forest Plot of Overall Response Rate by Subgroup, as assessed by independent reviewer (All-Treated Population)



Note: Best overall response (BOR) by independent reviewer. ORR=Overall Response Rate. CI=Confidence Interval.

Note: Relapsed disease was defined as progression of disease (PD) at least 6 months after having achieved complete response (CR) or partial response (PR) with adequate prior anti-DLBCL therapy. Refractory disease was defined as failure to achieve CR or PR or experienced PD within 6 months after achieving CR or PR, after adequate prior anti-DLBCL therapy.

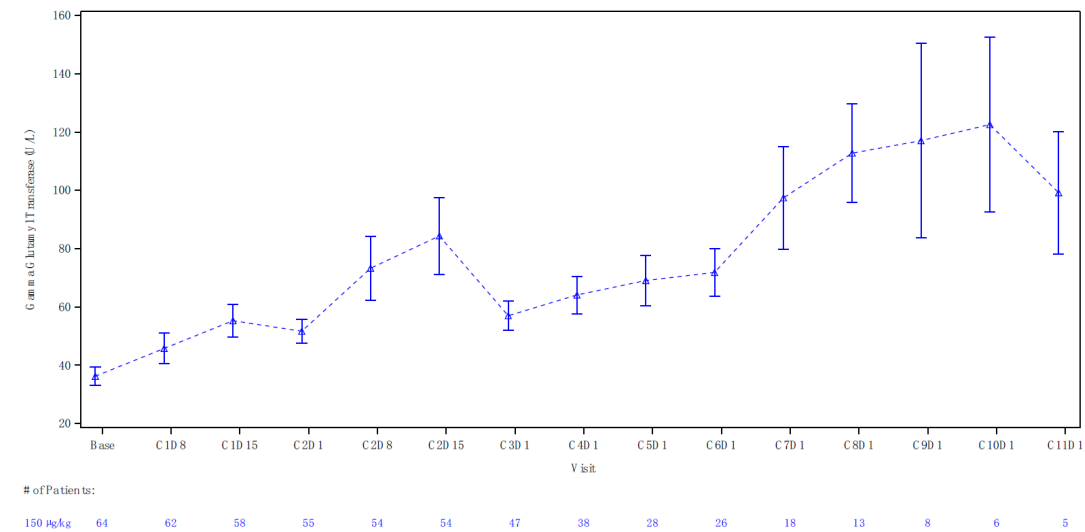
Supplementary Figure S4 Kaplan-Meier Plot of Time to First Adverse Event Leading to Dose Modification Analysis (All-Treated Population)



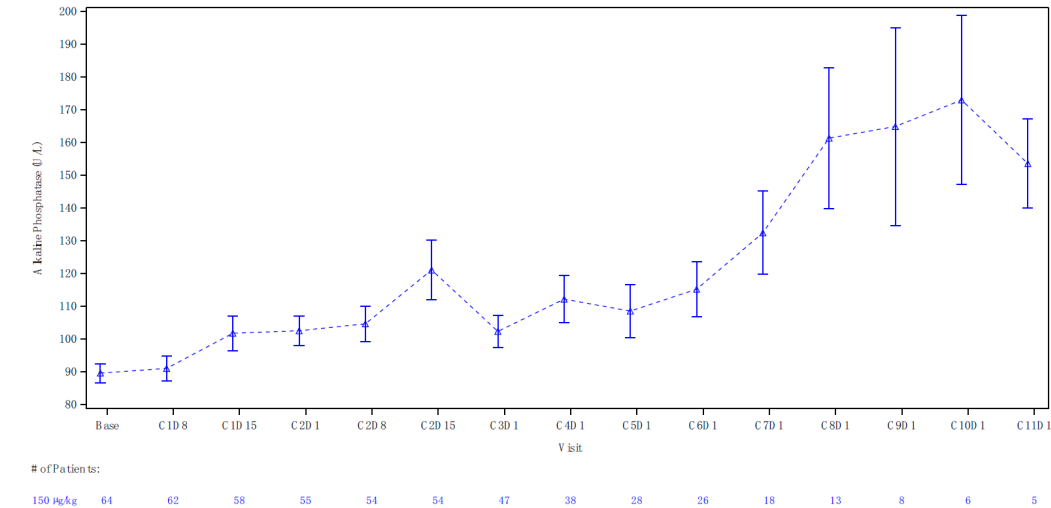
Dose modification includes drug discontinuation, dose delay, and dose reduction.

Supplementary Figure S5 Mean ($\pm$ SE) levels of (A) gamma glutamyltransferase (U/L); (B) alkaline phosphatase (U/L); (C) neutrophils ($\times 10^9/L$); and (D) platelets ($\times 10^9/L$) levels by visit

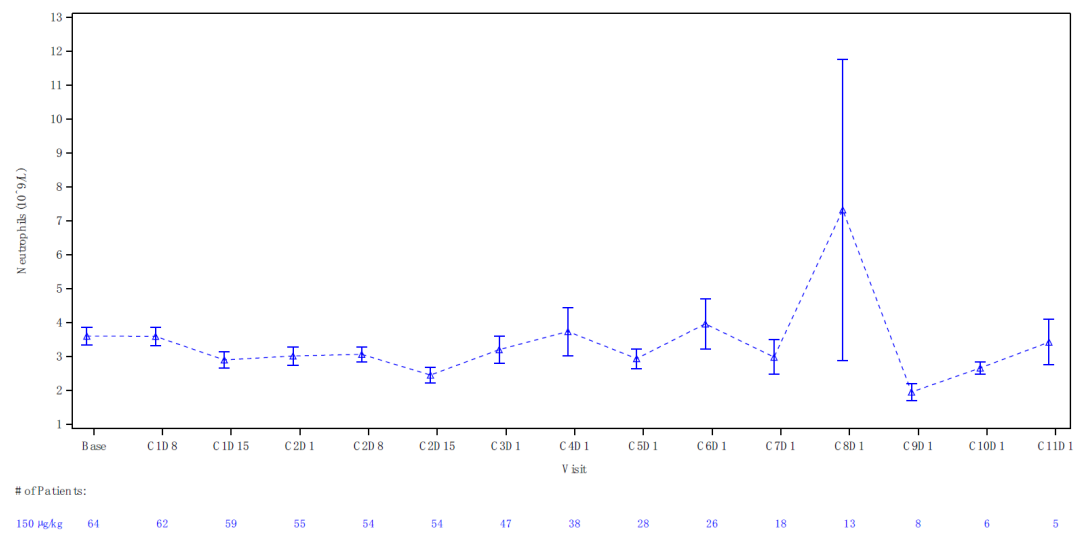
(A)



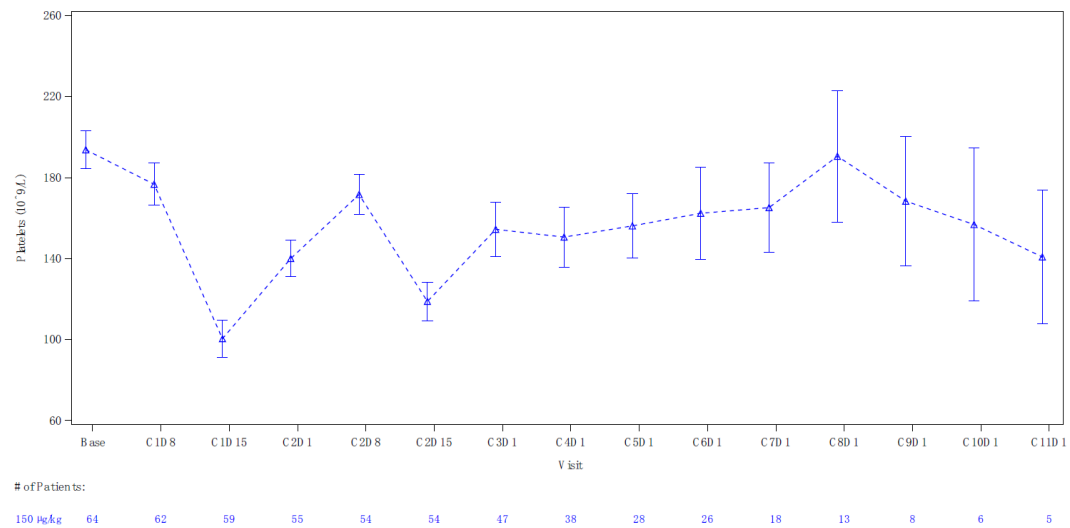
(B)



(C)



(D)

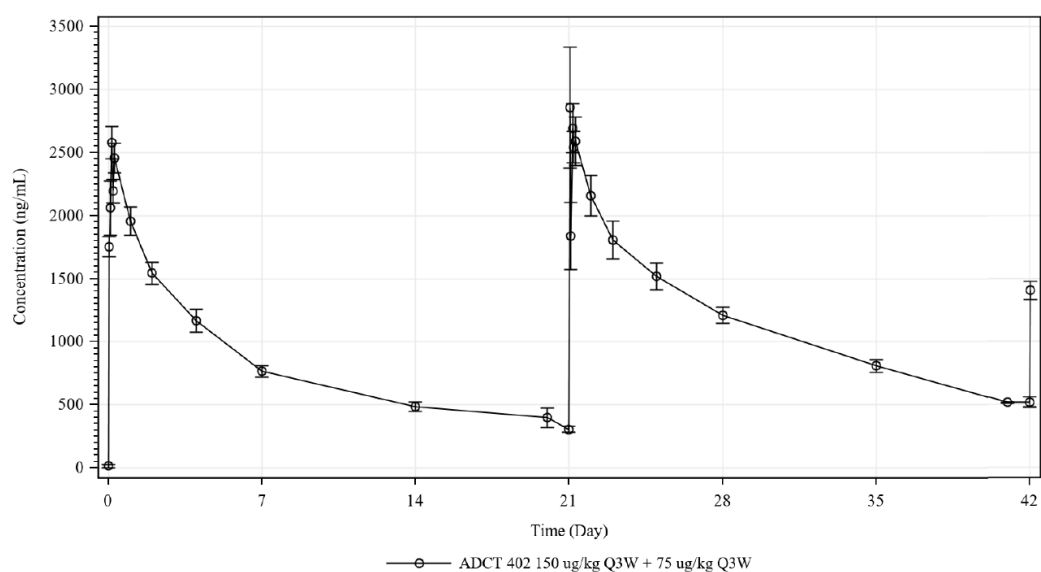


Baseline was defined as the last non-missing value before administration of loncastuximab tesirine.

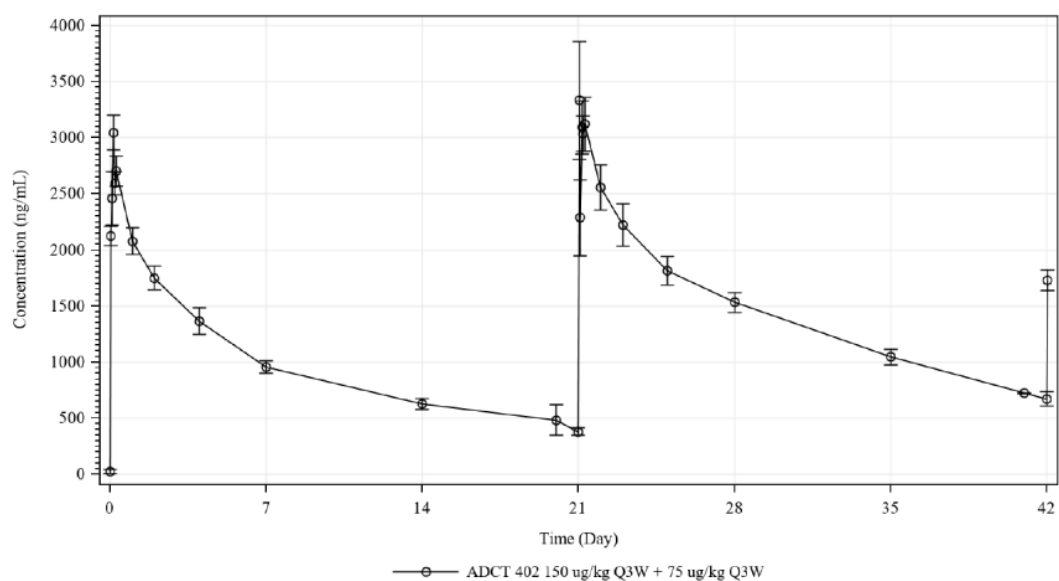
C, cycle; D, day; SE, standard error.

Supplementary Figure S6 Mean ($\pm$ SE) concentration of PBD-conjugated antibody and total antibody in serum vs. time by for patients during cycles 1, 2 and 3

(A) Analyte=PBD-conjugated antibody



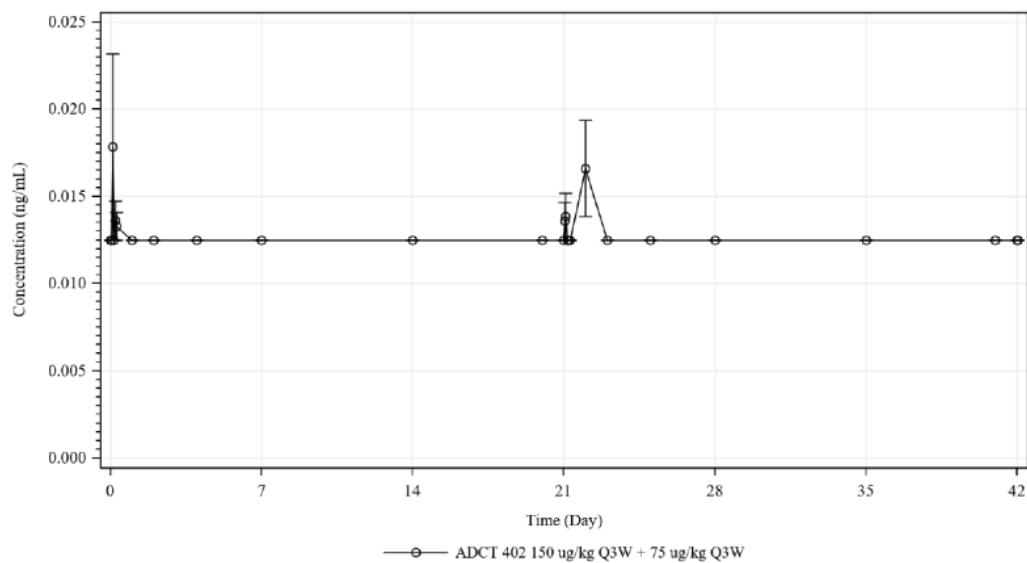
(B) Analyte=total antibody



SE=standard error; kg=kilogram; LOQ=limit of quantification; mL=milliliter; ng=nanogram; Q3W=every three weeks; ug=microgram

Concentrations below the lower limit of quantification are imputed as LLOQ/2

Supplementary Figure S7 Mean ($\pm$ SE) concentration of SG3199 in serum vs. time by for patients during cycles 1, 2 and 3



SE=standard error; kg=kilogram; LOQ=limit of quantification; mL=milliliter; ng=nanogram; Q3W=every three weeks; ug=microgram

Concentrations below the lower limit of quantification are imputed as LLOQ/2

Supplementary Tables

Supplementary Table 1. Overall Response Rate by Investigator Assessment (All-Treated Population)

	All-Treated Population (N=64)
Best Overall Response	
Complete response	14 (21.9)
Partial response	24 (37.5)
Stable disease	11 (17.2)
Not evaluable	5 (7.8)
Progressive disease	10 (15.6)
ORR (CR + PR)	38 (59.4)
95% CI for ORR	(46.4 to 71.5)
95% CI for CR	(12.5 to 34.0)

Data are n (%). Response was assessed by investigator.

ORR=overall response rate, CR=complete response, PR=partial response, CI=confidence interval.

Supplementary Table 2. Overall Response Rate by Independent Reviewer (Per-Protocol Population)

	Per-Protocol Population (N=60)
Best Overall Response	
Complete response	15 (25.0)
Partial response	16 (26.7)
Stable disease	17 (28.3)
Not evaluable	5 (8.3)
Progressive disease	7 (11.7)
ORR (CR + PR)	31 (51.7)
95% CI for ORR	(38.4 to 64.8)

Data are n (%). Response was assessed by central independent review.

CI=confidence interval, CR=complete response, ORR=overall response rate, PR=partial response

Best overall response by independent reviewer. Not evaluable included patients without any scan to the independent reviewer (even clinical progressive disease) or patients whose scan was determined to be not evaluable by the independent reviewer.

Per-Protocol Population included all patients in the All-Treated Population who met the inclusion/exclusion criteria, did not take prohibited concomitant treatments, nor had other protocol deviations which had major impact on efficacy results.

Supplementary Table 3. Maintenance of Response by Independent Review (All-Treated Population)

	All-Treated Population (N=64)
Total number of responders	33
Patients maintaining response at 3 months	24 (72.7)
Patients maintaining response at 6 months	12 (36.4)
Patients maintaining response at 9 months	6 (18.2)
Patients maintaining response at 12 months	Not Reached

Data are n (%). Percentage is calculated using total number of responders as denominator, number of patients at risk at 3, 6, 9 and 12 months as numerator.

Supplementary Table 4. Overall Summary of Treatment-emergent Adverse Events (All-Treated Population)

	All-Treated Population (N=64)
Patients with any TEAE	64 (100)
Patients with any grade 3 or higher TEAE	61 (95.3)
Patients with any TEAE related to loncastuximab tesirine	63 (98.4)
Patients with any grade 3 or higher TEAE related to loncastuximab tesirine	58 (90.6)
Patients with any TEAE leading to loncastuximab tesirine dose delay	47 (73.4)
Patients with any TEAE leading to loncastuximab tesirine dose reduction	10 (15.6)
Patients with any TEAE leading to loncastuximab tesirine withdrawal	11 (17.2)
Patients with any serious TEAE	35 (54.7)
Patients with any serious TEAE related to loncastuximab tesirine	31 (48.4)
Patients with any TEAE with fatal outcome	4 (6.3)
Patients with any fatal TEAE related to loncastuximab tesirine	3 (4.7)
Patients with infusion related reaction	2 (3.1)

Data are n (%). TEAE=treatment-emergent adverse event.

“Related” was classified based on binary causality assessment by the investigator.

Supplementary Table 5. Treatment emergent Adverse Events by Preferred Term (All-Treated Population) in $\geq 10\%$ of patients

Preferred Term	All-Treated Population (N=64)
Patients with any TEAE	64 (100)
Gamma-glutamyltransferase increased	46 (71.9)
Anaemia	45 (70.3)
Platelet count decreased	42 (65.6)
Aspartate aminotransferase increased	41 (64.1)
White blood cell count decreased	41 (64.1)
Neutrophil count decreased	39 (60.9)
Alanine aminotransferase increased	33 (51.6)
Hypokalaemia	24 (37.5)
Blood alkaline phosphatase increased	21 (32.8)
Lymphocyte count decreased	19 (29.7)
Hypoalbuminaemia	18 (28.1)
Hyperuricaemia	17 (26.6)
Neutropenia	16 (25.0)
Blood bilirubin increased	15 (23.4)
Hyperglycaemia	15 (23.4)
Oedema peripheral	15 (23.4)
Blood lactate dehydrogenase increased	13 (20.3)
Leukopenia	13 (20.3)
Pleural effusion	13 (20.3)
Pneumonia	13 (20.3)
Rash	13 (20.3)
Total bile acids increased	12 (18.8)
Upper respiratory tract infection	11 (17.2)
Sinus tachycardia	10 (15.6)
Thrombocytopenia	10 (15.6)
Blood creatinine increased	9 (14.1)
Face oedema	9 (14.1)
Hyperlipidaemia	9 (14.1)
Hyponatraemia	9 (14.1)
Alpha hydroxybutyrate dehydrogenase increased	8 (12.5)
Constipation	8 (12.5)
Hypocalcaemia	8 (12.5)
Malaise	8 (12.5)
Abdominal pain	7 (10.9)
Decreased appetite	7 (10.9)
Nausea	7 (10.9)

Preferred Term	All-Treated Population (N=64)
Pruritus	7 (10.9)
Pyrexia	7 (10.9)

Data are n (%). TEAE=treatment-emergent adverse event.

Supplementary Table 6. Overall Summary of Treatment-emergent Adverse Events by age Group

Treatment-emergent adverse event	< 65 years (N=40)	≥ 65 - < 75 years(N=19)	≥ 75 years (N=5)	Total (N=64)
Patients with any TEAE	40 (100)	19 (100)	5 (100)	64 (100)
Patients with any grade 3 or higher TEAE	39 (97.5)	19 (100)	3 (60.0)	61 (95.3)
Patients with any TEAE related to loncastuximab tesirine	39 (97.5)	19 (100)	5 (100)	63 (98.4)
Patients with any TEAE leading to loncastuximab tesirine dose delay or reduction	31 (77.5)	15 (78.9)	3 (60.0)	49 (76.6)
Patients with any TEAE leading to loncastuximab tesirine withdrawal	6 (15.0)	5 (26.3)	0	11 (17.2)
Patients with any serious TEAE	20 (50.0)	12 (63.2)	3 (60.0)	35 (54.7)
Patients with any TEAE with fatal outcome	3 (7.5)	1 (5.3)	0	4 (6.3)
Patients with infusion related reaction	2 (5.0)	0	0	2 (3.1)

Data are n (%). TEAE=treatment-emergent adverse event.

Supplementary Table 7. Treatment-emergent- Adverse Events Leading to Loncastuximab Tesirine Dose Delay for ≥5% of Patients (All-Treated Population)

Preferred Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	All Grade
Gamma-glutamyltransferase increased	0	15 (23.4)	6 (9.4)	0	0	21 (32.8)
Platelet count decreased	0	1 (1.6)	5 (7.8)	6 (9.4)	0	12 (18.8)
Neutrophil count decreased	0	1 (1.6)	7 (10.9)	3 (4.7)	0	11 (17.2)
Neutropenia	0	1 (1.6)	4 (6.3)	4 (6.3)	0	9 (14.1)
Anaemia	0	0	7 (10.9)	0	0	7 (10.9)
Leukopenia	0	1 (1.6)	4 (6.3)	2 (3.1)	0	7 (10.9)
White blood cell count decreased	0	1 (1.6)	5 (7.8)	1 (1.6)	0	7 (10.9)
Pneumonia	0	0	6 (9.4)	0	0	6 (9.4)
Hypokalaemia	0	0	4 (6.3)	1 (1.6)	0	5 (7.8)
Thrombocytopenia	0	1 (1.6)	2 (3.1)	1 (1.6)	0	4 (6.3)

Data are n (%).

Supplementary Table 8. Summary of pharmacokinetic parameters during cycles 1, and 2 for patients treated with loncastuximab tesirine 150 µg/kg Q3Wx 2

Cycle 1

Analyte	Cohort (µg/kg)	C _{max} (ng/mL)	AUC _{last} (day*ng/mL)	AUC _{inf} (day*ng/mL)	T _{half} (day)	CL (L/day)	V _{ss} (L)
Conjugate d Antibody	150	2268 (27.2) [64]	15916 (82.9) [63]	16788 (42.0) [25]	8.25 (37.4) [25]	0.464 (46.6) [25]	3.83 (59.7) [25]
Total Antibody	150	2702 (25.5) [64]	18326 (116) [63]	22050 (43.7) [22]	7.72 (42.9) [22]	0.412 (47.1) [22]	3.61 (53.6) [22]
SG3199	150	0.0550 (78.9) [3]	0.00200 (74.8) [3]	-	-	-	-

Cycle 2

Analyte	Cohort (µg/kg)	C _{max} (ng/mL)	AUC _{last} (day*ng/mL)	AUC _{tau} (day*ng/mL)	T _{half} (day)	CL _{ss} (L/day)	V _{ss} (L)	AI
Conjugate d Antibody	150	2746 (57.3) [55]	24268 (49.2) [55]	23780 (42.8) [51]	13.0 (35.5) [48]	0.321 (31.9) [51]	5.46 (33.8) [48]	1.51 (17.3) [48]
Total Antibody	150	3262 (56.2) [55]	29283 (52.1) [55]	29479 (43.9) [49]	12.6 (33.1) [43]	0.303 (32.3) [49]	5.05 (37.0) [43]	1.49 (16.0) [43]
SG3199	150	0.0460 (39.0) [3]	0.00600 (293) [3]	-	-	-	-	-

AI=accumulation index; AUC_{inf}=area under the concentration-time curve from time zero to infinity;
AUC_{last}=area under the concentration-time curve from time zero to last quantifiable concentration;
AUC_{tau}=area under the concentration-time curve from zero to end of dosing interval tau; CL=apparent systemic clearance; C_{max}=maximum concentration; L=liter; mL=milliliter; ng=nanogram; T_{half}=apparent terminal half-life; V_{ss}=apparent volume of distribution at steady-state.

EOI denotes end of infusion; Data were presented in Geometric Mean (CV% GeoMean)[n]; - = Not Calculated; Reliable parameters are based on Rsquare_adj>=0.85 and AUC_%Extrap<=20.

Reference

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