SYNOPTIC CLINICAL STUDY REPORT

1.0 TITLE PAGE

Study Title:	A Phase 2/3, Randomized, Open-label Study to Compare Bempegaldesleukin Combined with Pembrolizumab Versus Pembrolizumab Alone in First-Line Treatment of Patients with Metastatic or Recurrent Head and Neck Squamous-Cell Carcinoma with PD-L1 Expressing Tumors (PROPEL-36)
Name of Investigational Product:	Bempegaldesleukin (NKTR-214)
Indication Studied:	Recurrent or metastatic head and neck squamous cell carcinoma
Study Sponsor:	Nektar Therapeutics
Street Address:	455 Mission Bay Boulevard South
City, State Postal Code:	San Francisco, CA 94158
Country:	USA
Protocol Number:	20-214-36
Development Phase of Study:	Phase 2/3
Study Initiation Date (first patient registered):	23 February 2022
Study Completion Date:	16 June 2022
Data Cutoff Date:	16 June 2022
Report Date:	27 July 2022
Report Status:	Final Report
Medical Monitor:	Sohail Chaudhry, MD, PhD
Institution:	Nektar Therapeutics
Address:	455 Mission Bay Boulevard South San Francisco, CA 94158 USA
GCP Compliance Statement:	The Investigators agreed to conduct the study in compliance with the study protocol, with the International Standard of Good Clinical Practice (GCP) procedures, and with the principles of the Declaration of Helsinki (1964) and relevant amendments.

APPROVAL PAGE

A Phase 2/3, Randomized, Open-label Study to Compare Bempegaldesleukin Combined with Pembrolizumab Versus Pembrolizumab Alone in First-Line Treatment of Patients with Metastatic or Recurrent Head and Neck Squamous-Cell Carcinoma with PD-L1 Expressing Tumors (PROPEL-36)

SPONSOR: Nektar Therapeutics
455 Mission Bay Boulevard South
San Francisco, CA 94158
USA

DocuSigned by:
Brian Kotzin
Signer Name: Brian Kotzin
Signing Reason: I approve this document
Signing Time: Aug-05-2022 | 3:35:22 PM PDT
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Brian Kotzin, MD
Senior Vice President, Clinical Development
and Chief Medical Officer

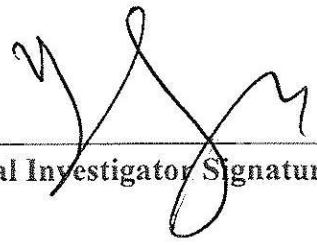
INVESTIGATOR SIGNATURE PAGE

Nektar Therapeutics

Study Title:	A Phase 2/3, Randomized, Open-label Study to Compare Bempegaldesleukin Combined with Pembrolizumab Versus Pembrolizumab Alone in First-Line Treatment of Patients with Metastatic or Recurrent Head and Neck Squamous-Cell Carcinoma with PD-L1 Expressing Tumors (PROPEL-36)
Protocol Number:	20-214-36
Phase of Study:	Phase 2/3
Report Date:	27 July 2022
Study Sponsor:	Nektar Therapeutics 455 Mission Bay Boulevard South San Francisco, CA 94158 USA

PRINCIPAL INVESTIGATOR COMMITMENT:

I, the undersigned Principal Investigator, declare that the study 20-214-36 was conducted in compliance with the protocol and according to the responsibilities outlined in the Code of Federal Regulations (21 CFR § 312) and ICH E6 Good Clinical Practice guidelines (R2) as well as with any and all applicable federal, state and/or local laws and regulations, including the archiving of study-related essential documents.



8/3/2022

Principal Investigator Signature **Date**

Printed Name:	Yungpo B. Su, MD
Affiliation:	Nebraska Methodist Hospital 8303 Dodge Street Omaha, Nebraska 68114-4108

2.0 SYNOPSIS

Name of the Sponsor: Nektar Therapeutics	**Individual Study Table Referring to Part of the Dossier:**	**For National Authority Use Only**
Name of Finished Products: bempegaldesleukin (NKTR-214 drug product); Keytruda®	**Volume:**	
Name of Active Ingredients: bempegaldesleukin (NKTR-214 drug substance) pembrolizumab (anti-programmed cell death protein 1 [anti-PD-1] antibody)	**Page:**	

Title of Study:

A Phase 2/3, Randomized, Open-label Study to Compare Bempegaldesleukin Combined with Pembrolizumab Versus Pembrolizumab Alone in First-Line Treatment of Patients with Metastatic or Recurrent Head and Neck Squamous-Cell Carcinoma with PD-L1 Expressing Tumors (PROPEL-36)

Investigators and Study Centers:

One patient was dosed in this study under Yungpo B. Su, MD at Nebraska Methodist Hospital, Omaha, NE, USA. The study was discontinued on 16 June 2022.

Sites that screened or enrolled patients:

- Attikon University General Hospital, Athens, Greece (Professor Amanda Psyrri, MD, PhD)
- Universitätsklinikum Salzburg, Landeskrankenhaus, Salzburg Austria (Richard Greil, Prof. Dr.)
- ASST degli Spedali Civili di Brescia - Spedali Civili di Brescia, Lombardia, Italy (Paolo Bossi, MD)

See Appendix 16.1.4

Publications: none

Study Period:	**Development Phase:**
First patient registered: 23 February 2022 Study completion date: 16 June 2022	2/3

Objectives:

Primary Objectives

- To compare the overall survival (OS) of bempegaldesleukin plus pembrolizumab versus pembrolizumab monotherapy.
- To compare the objective response rate (ORR) of bempegaldesleukin plus pembrolizumab versus pembrolizumab monotherapy.

Secondary Objectives

- To compare progression-free survival (PFS) of bempegaldesleukin plus pembrolizumab versus pembrolizumab monotherapy.
- To compare time to deterioration in global health status/quality of life, pain, and swallowing of bempegaldesleukin plus pembrolizumab versus pembrolizumab monotherapy.
- To compare mean change from baseline in global health status/quality of life of bempegaldesleukin plus pembrolizumab versus pembrolizumab monotherapy.
- To compare the overall safety and tolerability of bempegaldesleukin plus pembrolizumab versus pembrolizumab monotherapy.

Exploratory Objectives

- To compare the complete response rate (CRR) of bempegaldesleukin plus pembrolizumab versus pembrolizumab monotherapy.

- To evaluate duration of response (DOR).
- To evaluate time to response.
- To evaluate changes in health-related quality-of-life assessments from baseline using the EORTC QLQ-C30 and the EORTC QLQ-H&N35.
- To characterize health utilities.
- To evaluate changes from baseline in opioid analgesic use.
- To explore potential biomarkers of efficacy.
- To characterize the pharmacokinetics (PK) of bempegaldesleukin-related molecules and pembrolizumab when administered in combination and pembrolizumab when pembrolizumab is administered as monotherapy.
- To characterize the immunogenicity of bempegaldesleukin and pembrolizumab.

Rationale for the Change in Planned Analyses

On 14 March 2022, Nektar Therapeutics and Bristol Myers Squibb (BMS) reported that their PIVOT-IO-001 study did not meet its primary endpoint of demonstrating an efficacy advantage from addition of bempegaldesleukin to nivolumab therapy in patients with previously untreated inoperable or metastatic melanoma. On 14 April 2022, negative topline results from both PIVOT-09 (renal cell carcinoma) and PIVOT-10 (urothelial cancer) studies were reported. Based on these 3 large negative studies, Nektar Therapeutics and SFJ Pharmaceuticals, Inc. in consultation with the study Independent Data Monitoring Committee (DMC) made the decision to discontinue the PROPEL-36 trial on 21 April 2022 (16.2.4.3). At the time of termination, 1 patient was enrolled and treated in this study, so no summaries are produced; patient-level demographics, disposition and adverse event (AE) listings are provided.

Methodology:

This was planned to be a multicenter, randomized, open-label, Phase 2/3 study to evaluate the efficacy and safety of bempegaldesleukin combined with pembrolizumab compared with pembrolizumab monotherapy in patients with recurrent or metastatic head and neck squamous-cell carcinoma (HNSCC) with positive PD-L1 expression (combined positive score [CPS] ≥ 1).

The study used an adaptive design based on prespecified criteria and an independent, external DMC was to monitor efficacy and safety, approximately twice per year. The first planned interim analysis was to address futility. Enrollment was to pause for approximately 4 months after approximately 200 patients had been randomized, and the first interim analysis was to occur at least one month after the last patient of the Phase 2 portion had been randomized in the study. If the ORR passed the prespecified futility boundary, the Phase 3 portion of the study was to begin with an expected 300 additional patients to be randomized. The second interim analysis was to be conducted when approximately 500 patients had been randomized and about 231 OS events had been observed. At the second interim analysis, if the OS efficacy boundary had been crossed, the trial would have been stopped for efficacy. Otherwise, conditional power was to be calculated to determine the OS event size for final analysis.

Patient randomization was at a 1:1 ratio to receive 1 of 2 treatments:

- Arm A: Bempegaldesleukin plus pembrolizumab every 3 weeks (q3w) for up to 35 cycles (approximately 2 years).
- Arm B: Pembrolizumab monotherapy q3w for up to 35 cycles (approximately 2 years).

Randomization was stratified according to the following factors:

1. Disease status (metastatic vs recurrent only).
2. PD-L1 tumor expression determined by PD-L1 immunohistochemistry (IHC) 22C3 PharmDx (CPS ≥ 20 vs CPS 1-19) at either a local or the central laboratory.

   Note: CPS = the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100; specimen PD-L1 expression: CPS ≥ 1.
3. Human papillomavirus (HPV) status for oropharyngeal cancer determined by p16 IHC (positive vs negative). For patients with cancers of the oral cavity, hypopharynx, and larynx, HPV status was considered HPV negative.

Any patients attaining a complete response could consider stopping study drug if they met criteria for holding therapy. Patients who stopped study drug after receiving 35 cycles (approximately 2 years) for reasons other than disease progression or intolerability, or patients who attained a complete response and stopped study drug would have been eligible for up to 17 cycles (approximately 1 year) of retreatment upon experiencing Investigator-determined radiographic disease progression. The decision to retreat was at the discretion of the Investigator only if the patient met the criteria for retreatment and the trial was ongoing.

After the end of treatment, each patient was to be followed for 90 days after the last dose of all study drug(s) for AE monitoring, including serious AEs (SAEs) and AEs of special interest (AESIs). Patients who discontinued for reasons other than centrally verified disease progression were to have post-treatment follow-up for disease status until disease progression was verified by the central imaging vendor, initiating a non-study cancer treatment, withdrawing consent, or becoming lost to follow-up. All patients were to be followed for OS until death, the patient withdrew consent, the patient was lost to follow-up, or the study was terminated by the Sponsor.

The Sponsor estimated that the study would be fully enrolled within approximately 25 months. Analyses were anticipated at the following times (relative to the first patient's randomization date): approximately 14 months for the first interim analysis, approximately 32 months for the second interim analysis, and approximately 38 to 52 months for the final analysis for OS.

Number of Patients Planned:

Approximately 500 patients (250 per arm).

Number of Patients:

The results in this report pertain to 1 patient, 9066-1001, who received 2 study-drug cycles.
7 patients were screened, 2 patients randomized, 1 patient dosed; 16.2.4.2

Sex: Male

Age: 69

Ethnicity (Race): White, not Hispanic or Latino

16.2.4.1

Diagnosis and Main Criteria for Eligibility (Key Inclusion Criteria):

- Had histologically or cytologically-confirmed recurrent or metastatic HNSCC that was considered incurable by local therapies.
  - No prior systemic therapy for recurrent or metastatic disease. Systemic therapy given as part of multimodal treatment for locally advanced disease was allowed if completed more than 6 months prior to signing consent.
  - The eligible primary tumor locations were oropharynx, oral cavity, hypopharynx, and larynx.
  - Patients could not have a primary tumor site of nasopharynx (any histology) and/or unknown primary.
- Had measurable disease based on RECIST 1.1 as determined by the local site Investigator. Tumor lesions situated in a previously irradiated area were considered measurable if progression had been shown in such lesions since irradiation.
- ECOG Performance Status of 0 or 1.
- Tumor tissue from a core, incisional, or excisional biopsy (fine needle aspirates were not acceptable) to the central laboratory for determination of PD-L1 status (if not determined at local laboratory) and exploratory biomarker analyses. A newly obtained biopsy was strongly preferred, but archival tumor biopsy could have been used and provided.
- The tumor must have had positive PD-L1 expression (ie, CPS $\geq$ 1) as determined with a PD-L1 IHC 22C3 PharmDx diagnostic kit at either a local or central laboratory.
- Patients with oropharyngeal cancer must have had results from testing of HPV status defined as p16 IHC testing using CINtec® p16 Histology assay. For patients with oral cavity, hypopharynx, or larynx cancers, HPV testing by p16 IHC was not required as by convention these tumor locations are assumed to be HPV negative.

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

- Bempegaldesleukin 0.006 mg/kg intravenous (IV) infusion every 3 weeks (q3w):

DP Lot: AP1702B	FG Lot: FG026774	Expiry: 09/2022

- Pembrolizumab 200 mg IV infusion q3w:

DP Lot: 0001235262	FG Lot: FG026885	Expiry: 10/2022

Duration of Treatment:

- Treatment was to be given for 35 cycles (approximately 2 years) following the date of the first dose of study drug/s or until disease progression, death, unacceptable toxicity, symptomatic deterioration, the Investigator decision to discontinue treatment, patient decision to discontinue treatment or withdraw consent, loss to follow-up, or Sponsor decision to terminate the trial.
- Following the Sponsor's decision to end the trial, treatment was discontinued after Patient 9066-1001 received 2 cycles.

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

Pembrolizumab 200 mg IV infusion q3w (N/A)

Criteria for Evaluation:

Efficacy: The primary efficacy measurements were to be OS and ORR by the blinded independent central review (BICR). The key secondary efficacy measurement was to be PFS by BICR.

Safety: Safety was assessed by review of the 1 randomized and treated patient's data (Patient 9066-1001).

Statistical Methods: Per the Statistical Analysis Plan (SAP) v.2.0 (16.1.9), no summary data was produced. Safety data were compiled from listings derived from the case report form (CRF).

Summary and Conclusions:

Patient 9066-1001 had stage IVc metastatic cancer of the oropharynx (16.2.4.1.1), a PD-L1 combined positive score (CPS) of 25 (16.2.4.1.1), positive HPV status (16.2.4.1.1), prior radiation (16.2.4.1.2), no prior surgery (16.2.4.1.3), no prior systematic cancer therapy (16.2.4.1.4), ECOG performance status of 0 (16.2.4.1.5), and was a current smoker (16.2.4.1.7).

Disposition

Patient 9066-1001 was enrolled on 09 March 2022. The first cycle of study drugs (bempegaldesleukin 0.006 mg/kg IV and pembrolizumab 200 mg IV) was administered on 11 March 2022 and the second and last cycle was administered on 01 April 2022 (16.1.6.1, 16.1.6.2). Patient follow-up was completed on 22 April 2022 (16.2.4.1, 16.2.4.4). Patient was offered treatment with pembrolizumab monotherapy as standard of care.

Safety Results

The patient experienced 1 Grade 1 adverse event of cough (16.2.7).Per investigator, cough was assessed as related to pembrolizumab. The company/Sponsor medical assessment attributed causality to the combination of bempegaldesleukin + pembrolizumab (data on file).

Conclusions:

One patient received 2 cycles of the study drugs (bempegaldesleukin 0.006 mg/kg IV and pembrolizumab 200 mg IV) before the bempegaldesleukin program was discontinued and the study was terminated. The patient experienced a Grade 1 AE of cough. No SAEs were reported.

Date of Report:	27 July 2022

3.0 TABLE OF CONTENTS

4.0 LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation or Term	Definition/Explanation
AE	adverse event
AESI	adverse event of special interest
bempegaldesleukin	International Nonproprietary Name (INN) for NKTR-214
BICR	the blinded independent central review
BMS	Bristol Myers Squibb
CFR	Code of Federal Regulations
CPS	combined positive score
CRF	case report form
CRR	complete response rate
CSR	clinical study report
CSV	comma-separated value
DMC	Data Monitoring Committee
DOR	duration of response
ECOG	Eastern Cooperative Oncology Group
EORTC	European Organisation for Research and Treatment of Cancer
GCP	Good Clinical Practice
HGRAC	Human Genetic Resources Administration of China
HNSCC	head and neck squamous-cell carcinoma
HPV	human papillomavirus
IEC	Independent Ethics Committee
IHC	immunohistochemistry
IND	Investigational New Drug Application
IRB	Institutional Review Board
IV	intravenous(ly)
MHRA	Medicines and Healthcare Products Regulatory Agency
N/A	not applicable
NKTR-214	bempegaldesleukin (International Nonproprietary Name)
ORR	objective response rate
OS	overall survival
PD-1	programmed cell death protein 1
PD-L1	programmed cell death ligand 1
PFS	progression-free survival
PK	pharmacokinetics
q3w	every 3 weeks
QLQ-C30	Quality of Life Questionnaire Core 30
QLQ-H&N35	Quality of Life Questionnaire head and neck cancer specific module

Abbreviation or Term	Definition/Explanation
RECIST	Response Evaluation Criteria in Solid Tumors
SAE	serious adverse event
SAP	statistical analysis plan
SIDC	Czech Republic State Institute for Drug Control

9.6 DATA QUALITY ASSURANCE

A risk-based approach to management, monitoring and oversight of the study was implemented, including proactive risk management, addressing areas of project risk in a prospective manner to allow for planning and prevention of negative risk, while taking advantage of pre-identified positive opportunities for improvement of project objectives.

Essential documents will be retained until at least 2 years after the withdrawal of the Investigational New Drug Application (IND) have elapsed (US sites) or until at least 2 years since the formal discontinuation of clinical development of the investigational product (sites outside the US).

These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the Sponsor. It is the responsibility of the Sponsor to inform the Investigator/institution when these documents no longer need to be retained.

16.0 APPENDICES

Due to the early termination of this study with only 1 dosed patient and as defined in the SAP, this synoptic clinical study report provides no summarizations and the following appendices:

16.1 Study Information

16.1.1 Protocol and Protocol Amendments

The Original Protocol 20-214-36 dated 14 June 2021, had 3 country-specific amendments:

Protocol 20-214-36/Amendment 0.1-UK (13 Dec 2021). In response to comments from the Medicines and Healthcare Products Regulatory Agency (MHRA), the amendment contained recommendations for use of alternatives to hormonal contraception.

Protocol 20-214-36/Amendment 0.2-Czech-Republic (24 Feb 2022). Following Czech Republic State Institute for Drug Control (SIDC) comments:

- Removed the option for a second course of ≤17 additional cycles of study treatment for patients who had Investigator-determined radiographic disease progression after having completed or stopped treatment following a confirmed complete response
- Removed possibility of continued monotherapy treatment with bempegaldesleukin following discontinuation of pembrolizumab for patients on doublet therapy.
- Clarified that live attenuated vaccines were not allowed for 90 days after the last dose of study drug

Protocol 20-214-36/Amendment 0.3-China (24 Feb 2022). To meet expectations of the Human Genetic Resources Administration of China (HGRAC) regarding samples obtained for exploratory objectives, elevated pharmacokinetics and immunogenicity characterizations from exploratory to secondary objectives and removed an objective to explore potential biomarkers of efficacy, adding a secondary objective to characterize prognostic biomarkers of efficacy.

16.1.2 Sample Case Report Form

20-214-36 Sample Case Report Form

16.1.3 List of Independent Ethics Committee (IECs) or Institutional Review Boards (IRBs) and Representative Written Information for Patient and Sample Consent Forms

Site No	Investigator Name	IRB/IEC Name	IRB/IEC Address	Chairperson	Country
1542	Prof. Dr. Richard Greil	Ethikkommission für das Bundesland Salzburg	Sebastian-Stief-Gasse 2, 5020 Salzburg	Dr. Alexander Hönel	AUT
2540	Dr. Paolo Bossi	Comitato Etico di Brescia	c/o Segreteria Tecnico Scientifica - ASST Spedali Civili di Brescia, Piazzale Spedali Civili, 1, Lombardia 25123, Italy	Prof. Sandra Sigala	ITA
3002	Professor Amanda Psyrri	National Ethics Committee (NEC)	284 Mesogeion Avenue Athens, Cholargos 15562, Greece	Theofilos Kolettis	GRE
9066	Yungpo B. Su, MD	Nebraska Methodist Hospital Institutional Review Board	8303 Dodge Street Omaha Nebraska, 68114-4108 United States	Dr. Aru Panwar	US

20-214-36 (35-Cycle First Course) Informed Consent Form Version 3.0 (dated 23 December 2021)

20-214-36 (17-Cycle Second Course) Informed Consent Form Version 3.0 (dated 23 December 2021)

16.1.4 List of Investigators

Investigator/ Site with Randomized Dosed Patient 9066-1001

Country	Site	Principal Investigator Name	Address	Sub-Investigator Name	Start Date
US	9066	Yungpo B. Su, MD	Nebraska Methodist Hospital 8303 Dodge Street Omaha Nebraska, 68114-4108 United States	Joel Michalski, MD Robert Langdon, Jr., MD James Schwarz	25-Oct-21 28-Oct-21 30-Dec-21

Investigator/Sites with Screened Patients

Country	Site	Principal Investigator Name	Address	Sub-Investigator Name	Start Date
AUT	1542	Prof. Dr. Richard Greil	Universitätsklinikum Salzburg, Landeskrankenhaus, Universitätsklinik für Innere Medizin IIIder Paracelsus Medizinische Privatuniversitat (PMU), Muellner Hauptstrasse 48, Salzburg 5020, Austria	Lukas Weiss Florian Huemer Thomas Melchardt	29-Mar-22 29-Mar-22 29-Mar-22
ITA	2540	Dr. Paolo Bossi	U.O Oncologia Medica, ASST degli Spedali Civili di Brescia – P.le Spedali Civili 1, Brescia, Lombardia 25123, Italy	Dr. Luigi Lorini, MD Dr. Vittorio Ferrari, MD Antonella Turla	1-Feb-22 1-Feb-22 1-Feb-22
GRE	3002*	Professor Amanda Psyrri	Attikon University General Hospital of Athens 2nd Propaedeutic Internal Medicine Department Nathional and Kapodistrian University of Athens Medical School 1 Rimini Street, Chaidari, Athens 12462, Greece	Ioannis Kotsantis Anastasios Pantazopoulos	11-Feb-22 11-Feb-22
	*Includes enrolled, not dosed, Patient 3002-1003				

16.1.5 Signatures of Principal or Coordinating Investigator(s) or Sponsor's Responsible Medical Officer

See Approval Page.

16.1.6 Listing of Patients Receiving Test Drugs/Investigational Products from Specific Batches, Where More Than One Batch Was Used

See Synopsis for batch numbers.

16.1.6.1 Bempegaldesleukin Administration

16.1.6.2 Pembrolizumab Administration

16.1.7 Randomization Scheme and Codes

Not applicable.

16.1.8 Audit Certificates

No audits were performed.

16.1.9 Documentation of Statistical Methods

20-214-36 Statistical Analysis Plan Version 2.0 (dated 06 May 2022).

16.1.10 Documentation of Inter-Laboratory Standardization Methods and Quality Assurance

Clinical laboratory certifications and reference ranges are located in the Trial Master File.

16.1.11 Publications Based on the Study

None.

16.1.12 Important Publications Referenced in the Report

Not applicable.

16.2 Patient Data Listings

16.2.1 Discontinued Patients

Not applicable.

16.2.2 Protocol Deviations

None.

16.2.3 Patients Excluded from the Efficacy Analysis

Not applicable.

16.2.4 Demographic Data

16.2.4.1 Demographics

16.2.4.1.1 Cancer History

16.2.4.1.2 Prior Radiation

16.2.4.1.3 Prior Surgery

16.2.4.1.4 Prior Systematic Cancer History

16.2.4.1.5 ECOG Performance Status

16.2.4.1.6 Medical History

16.2.4.1.7 Smoking History

16.2.4.2 Enrollment

16.2.4.3 End of Study Status

16.2.4.4 Safety Follow-up

16.2.5 Compliance and/or Drug Concentration Data

Not applicable.

16.2.6 Individual Efficacy Response Data

Not applicable.

16.2.7 Adverse Event Listings

16.2.8 Laboratory Measurements and Vital Signs

16.2.8.1 Target Lesion Screening Scans

16.2.8.2 Non-Target Lesion Screening Scans

16.2.8.3 Vital Signs–Screening

16.2.8.4 Serial Vital Signs

16.3 Case Report Forms

Due to study termination and bempegaldesleukin clinical program discontinuation, patient CRFs are not included in this CSR.

There were no deaths, SAEs, or withdrawals due to AEs.

16.4 Individual Patient Data Listings

See Section 16.2.