Nektar Therapeutics

STATISTICAL ANALYSIS PLAN

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, Original

SAP Version: V2.0

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PREPARED BY:

1.0 INTRODUCTION

This document provides an update of the statistical analysis plan for data captured in Nektar Therapeutics Protocol 20-214-36 "A Phase2/3, 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)" Original version dated 14 June 2021.

On March 14, 2022, Nektar Therapeutics reported negative efficacy results in their Phase 3 melanoma study. On April 14th, 2022, negative topline results from both PIVOT-9 (renal cell carcinoma) and PIVOT-10 (urothelial) studies were reported. Based on three negative studies, Nektar Therapeutics made the decision to discontinue the bempegaldesleukin in combination with nivolumab program. As part of this decision, SFJ Pharmaceuticals, Inc. and Nektar Therapeutics, in consultation with the study Independent Data Monitoring Committee, have decided to discontinue the PROPEL-36 trial.

2.0 ANALYSIS PLAN

One patient was enrolled and treated in this study. No summary will be produced, instead, individual patient level listings with the following data will be provided.

Patient disposition, demographics and baseline characteristics will be described using listings of individual patient data. Patient demographics and baseline characteristics will include age, gender, ethnicity, race, geographic region, disease stage, primary tumor location, and disease status (metastatic vs recurrent only), PD-L1 tumor expression (CPS $\geq$ 20 vs CPS 1-19), and HPV status (positive or negative), as applicable.

Prior and concomitant medications and therapies will be described using listings of individual patient data.

Adverse events (AEs) collected in the study will be described using AE listings including AE start and end dates, grade, relatedness to study drug, action taken and AE outcome. Adverse events will be coded by system organ class (SOC) and preferred term (PT) using MedDRA version 24.0. Adverse event severity will be based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Grade (version 5.0). An AE is considered as related to treatment if it is related to any study drug; an AE with a missing relationship will be counted as related to study drug. An AE is considered as leading to treatment discontinuation if it is leading to discontinuation of any study drug. An AE is considered as leading to death if the severity grade is 5 or the outcome is fatal.