Alkermes' Nemvaleukin Clinical Program

Nemavleukin alfa (nemvaleukin) is Alkermes' novel, investigational engineered interleukin-2 (IL-2) variant immunotherapy, which is being evaluated as a potential treatment for cancer. The clinical development program is comprised of clinical trials evaluating intravenous and subcutaneous dosing of nemvaleukin as monotherapy and in combination with the anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with advanced solid tumors.

PHASE 1/2

ARTISTRY 1

Evaluating safety, IV RP2D, and ORR; assessing as monotherapy and in combination with pembrolizumab.

Cancer/Tumor Type: Advanced solid tumors that have progressed after treatment with established approved therapies or are intolerant to established therapies.

Administration: **Region:** NCT02799095

ARTISTRY 2

Evaluating safety, SC RP2D, and ORR; assessing as monotherapy and in combination with pembrolizumab.

Cancer/Tumor Type: Advanced solid tumors that have progressed after at least one line of treatment.

Administration: **Region:** NCT03861793

PHASE 2

ARTISTRY 3

Evaluating clinical and immunologic activity of nemvaleukin with less frequent IV dosing schedule, as monotherapy and in combination with pembrolizumab, and impact on TME.

Cancer/Tumor Type: Advanced solid tumors with at least 1 accessible lesion; pre-treated with 1-3 FDA-approved targeted therapies.

Administration: **Region:** NCT04592653

ION 01

Evaluating ORR; assessing in combination with pembrolizumab.

Cancer/Tumor Type: Head and neck squamous cell cancer previously treated with anti-PD-(L)1 therapy.

Administration: **Region:** NCT04144517

PHASE 2/3

Potential Registrational

ARTISTRY 6

Evaluating efficacy, safety and tolerability; assessing as monotherapy.

Cancer/Tumor Type: Advanced cutaneous and mucosal melanoma: unresectable and/or metastatic, previously treated with anti-PD-L1 +/- anti-CTLA-4 therapy.

In August 2021, the U.S. FDA granted nemvaleukin both Orphan Drug Designation and Fast Track Designation for the treatment of mucosal melanoma.

Administration: **Region:** NCT04830124

ARTISTRY 7

Evaluating efficacy, safety and tolerability; assessing monotherapy and in combination with pembrolizumab, compared to investigator choice chemotherapy.

Cancer/Tumor Type: Platinum-resistant ovarian cancer.

In October 2021, the U.S. FDA granted nemvaleukin Fast Track Designation for the treatment of platinum-resistant ovarian cancer.

Administration: **Region:** NCT05092360

Administration: Subcutaneous injection; Intravenous infusion; Active, not recruiting; Recruiting

Region: Global; USA

IV: Intravenous **SC:** Subcutaneous

RP2D: Recommend phase 2 dose **ORR:** Overall response rate **TME:** Tumor microenvironment

ION-01 in collaboration with Fred Hutchinson Cancer Research Center

ARTISTRY 7 in collaboration with Merck. Partnership with the GOG Foundation and ENGOT to conduct the study

Alkermes®