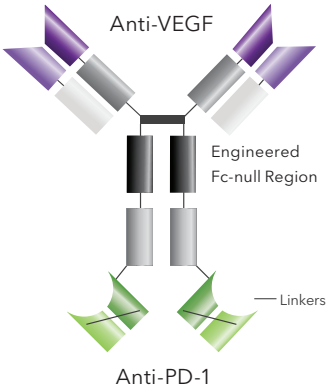
HARMONi-7 Phase 3 Clinical Trial

Phase 3 Study in 1L Metastatic NSCLC with High PD-L1 Expression (NCT06767514)[1]

HARMONi-7

Ivonescimab:

Most Advanced PD-1/VEGF Bispecific Antibody in Clinical Development in the U.S. and EU.* Brings two validated mechanisms in oncology[2-4] into ONE novel tetravalent molecule.



Ivonescimab simultaneously blocks both PD-1 & VEGF

Globally 2,300+ patients have been treated with ivonescimab across Summit and Akeso clinical trials.[5] Summit is actively recruiting approximately 780 patients worldwide for the HARMONi-7 study.

HARMONi-7 STUDY DESIGN

Monotherapy Ivonescimab vs. Pembrolizumab

Key Inclusion
- 1L Metastatic NSCLC High PD-L1 expression
- Without known actionable genomic alterations

Randomization 1:1 (N=780)

Group A: Ivonescimab 20 mg/kg Q3W

Group B: Pembrolizumab 200 mg Q3W

Treatment Until
- Intolerable toxicity, or
- No clinical benefit, or
- 24 months of treatment

Safety and Survival Follow-up

Stratification Factors
- Histology (squamous vs. non-squamous)
- Brain metastases at study entry (present or absent)
- Region (East Asia, North America, or Europe)

Study Endpoints
- Primary endpoints: PFS by IRRC and OS
- Secondary endpoints: ORR, DCR, DOR, safety, PK and immunogenicity

KEY ELIGIBILITY CRITERIA

- Metastatic (Stage IV) NSCLC, PD-1 ≥50%
- ECOG 0 or 1
- Histologically or cytologically confirmed squamous or non-squamous NSCLC. No histologic or cytopathologic evidence of the presence of small cell lung carcinoma
- Patients' tumor must have high PD-L1 expression
- No prior systemic treatment for metastatic NSCLC
- No known actionable genomic alterations in EGFR, ALK, ROS1 or BRAF V600E for which first-line approved therapies are available
- No radiologically documented evidence of major blood vessel invasion, or tumor invading organs, or major blood vessel encasement with narrowing of the vessel or intratumor lung cavitation or necrosis that the investigator determines will pose a significantly increased risk of bleeding
- No symptomatic CNS metastases or CNS metastases with hemorrhagic features or CNS metastases ≥1.5 cm
- No history of bleeding tendencies or coagulopathy and/or clinically significant bleeding symptoms or risk within 4 weeks

Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA).

*There are no known PD-1-based bispecific antibodies approved by the U.S. Food and Drug Administration ("FDA") or the European Medicines Agency ("EMA").

Abbreviations: ALK=anaplastic lymphoma kinase; CNS=central nervous system; DCR=disease control rate; DOR=duration of response; ECOG=eastern cooperative oncology group; EGFR=epidermal growth factor receptor; IRRC=independent radiologic review committee; NSCLC=non-small cell lung cancer; ORR=overall response rate; OS=overall survival; PD-1=programmed cell death protein 1; PD-L1=programmed death-ligand 1; PFS=progression-free survival; PK=pharmacokinetics; Q3W=every 3 weeks; TME=tumor microenvironment; VEGF=vascular endothelial growth factor.

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Cooperative Binding Offers Potential to Drive Synergistic Activity[6-8]

Brings two validated mechanisms in oncology[2-4] into ONE novel tetravalent molecule

Increased Avidity in TME[8*]

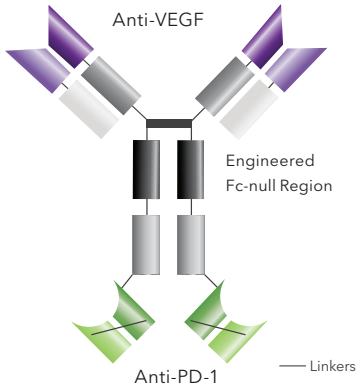
Enhanced Activity of T Cells[8*]

VEGF dimer leads to potential interconnection of ivonescimab molecules, which may increase activity of T Cells

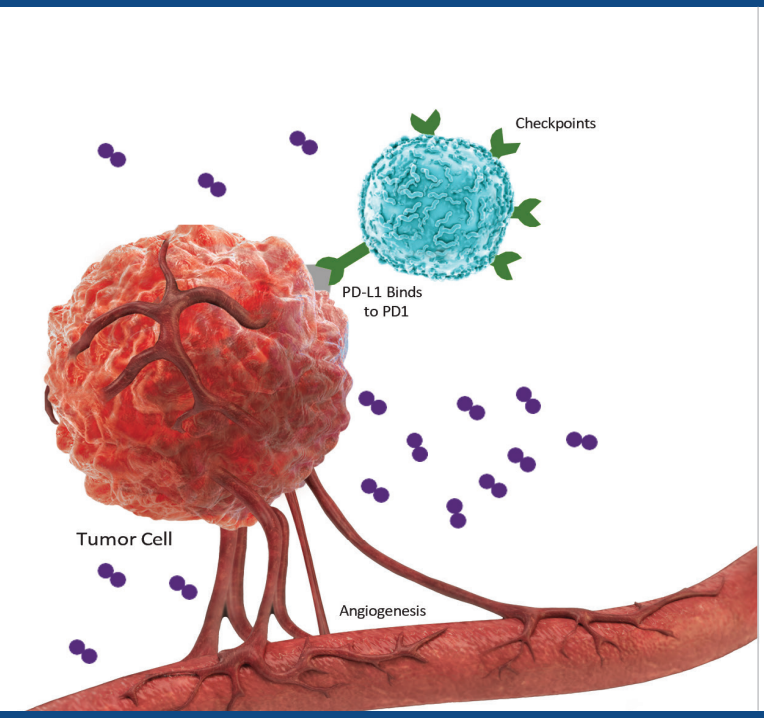
T½ ~10 days[9] and Fc-null region[8]

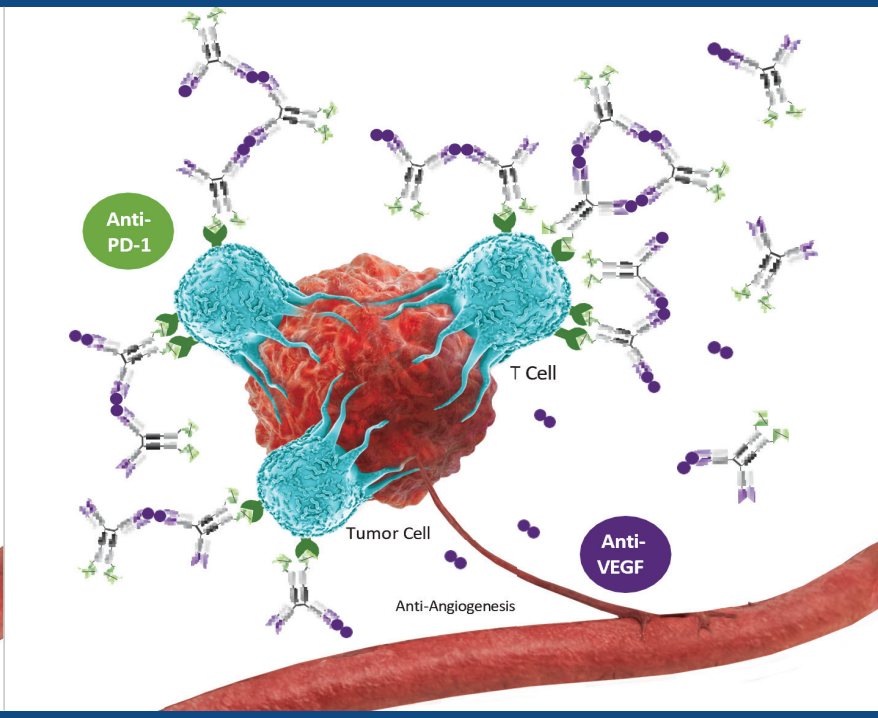
VEGF dimer leads to potential interconnection of ivonescimab molecules, which may increase activity of T Cells

**in vitro*



Tumor Microenvironment	Tumor Microenvironment with Ivonescimab Cooperative Binding





Images for illustrative purposes only

VEGF Dimer PD-1 Receptor in T Cell

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For more information contact medinfo@smmttx.com

1. Clinical Study of Ivonescimab for First-line Treatment of Metastatic NSCLC Patients With High PD-L1 ClinicalTrials.gov identifier: NCT06767514. Updated Jan 10, 2025, Accessed on Jan. 10, 2025.; 2. Manegold C, et al. J Thorac Oncol 2017;12(2):194-207.; 3. Pardoll, D. Nat Rev Cancer 2012;12(4):252-64.; 4. Tamura R, et al. Med Oncol 2020;37(1):2.; 5. Data on File 38. Summit Therapeutics Inc.; 6. Zhao Y. et al., eClinicalMedicine. 2023; 3(62): 102106.; 7. Wang L, et al. J Thorac Oncol. 2024 Mar;19(3):465-475.; 8. Zhong T, et al. iScience. 2024;28(3):111722.; 9. Data on File 39. Summit Therapeutics Inc.

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