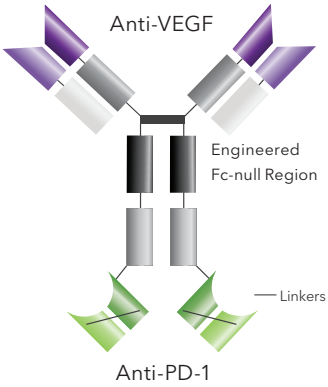
HARMONi-7 Phase 3 Clinical Study

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

HARMONi-7

Ivonescimab:

PD-1/VEGF Bispecific Antibody being studied in phase 3 NSCLC study.
Brings two validated mechanisms in oncology[2-4] into ONE novel tetravalent molecule.



Ivonescimab simultaneously blocks both PD-1 & VEGF

Globally 4,000+ 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

Key Inclusion

- Untreated Stage IV NSCLC with high tumor PD-L1 expression (TPS≥50% or TC≥50%) and without actionable mutations
- Histologically or cytologically confirmed squamous or non-squamous NSCLC

Key Exclusions

- Any prior therapy for NSCLC in the metastatic setting
- Symptomatic CNS metastases
- Tumor invades major blood vessels or organ
- Active autoimmune disease

R 1:1

N~780

- Ivonescimab 20 mg/kg Q3W
- Pembrolizumab 200 mg Q3W

Treatment Until

- Intolerable toxicity
- Disease progression
- 24 months

Safety and Survival Follow-up

Endpoints

Primary
- PFS by IRRC per RECIST v1.1
- OS

Secondary
- ORR, DCR, DOR, safety, PK and immunogenicity

Stratification Factors

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

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).

Abbreviations: 1L=first-line; 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 radiology 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; R=randomization; RECIST=response evaluation criteria in solid tumors; Q3W=every 3 weeks; TC=tumor cells; TME=tumor microenvironment; TPS=tumor proportion score; 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

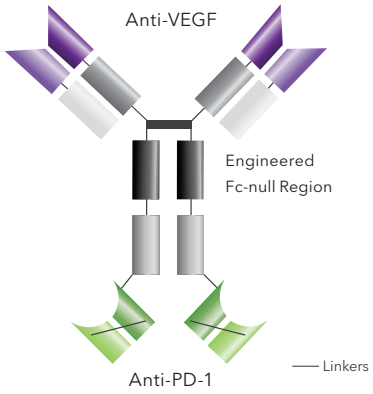
Dual Blocking of PD-1 & VEGF[8]

Increased Avidity in TME

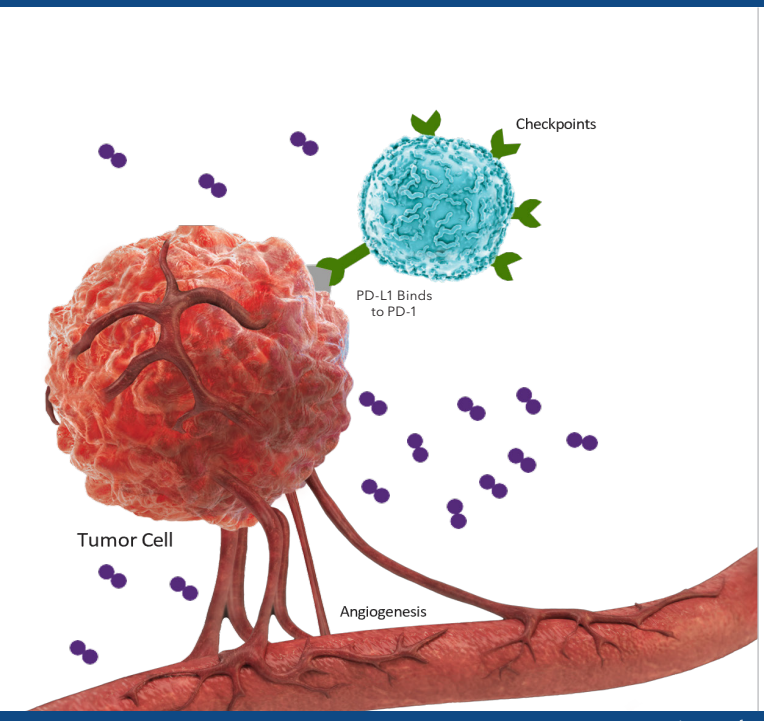
VEGF-A efficiently enhances the binding affinity to PD-1 by several fold[8] *(in vitro)*

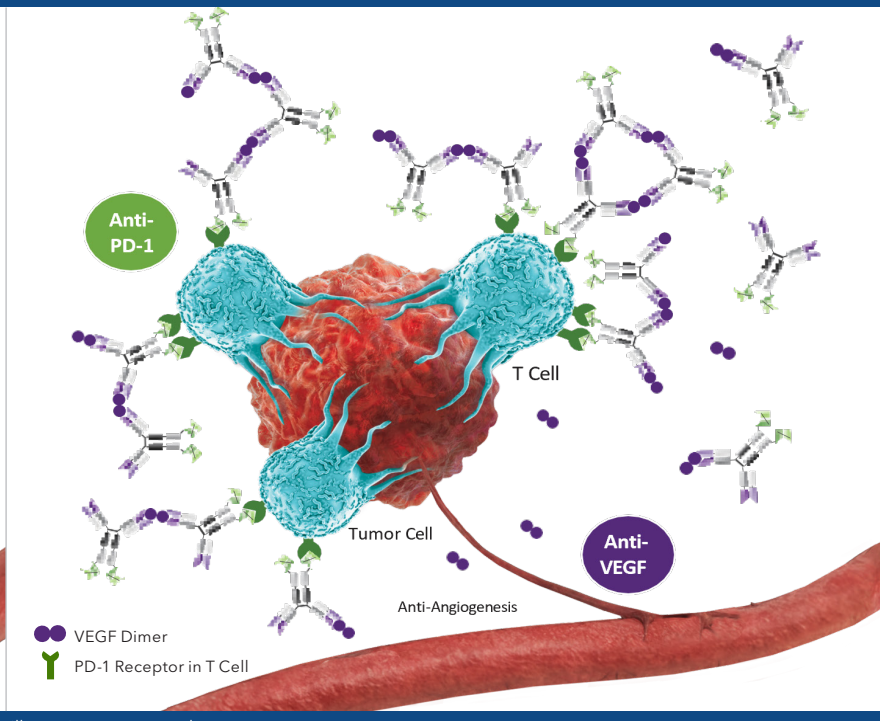
Enhanced Activity of T Cells

VEGF dimer leads to potential interconnection of ivonescimab molecules, which may increase activity of T Cells[8] (*in vitro)*



Tumor Microenvironment	Tumor Microenvironment with Ivonescimab Cooperative Binding





Images for illustrative purposes only

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For more information contact medinfo@smmttx.com

HARMONi-7

Summit therapeutics

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1. Clinical Study of Ivonescimab for First-line Treatment of Metastatic NSCLC Patients With High PD-L1 ClinicalTrials.gov identifier: NCT06767514. Updated Feb 24, 2026, Accessed on April 17, 2026.; 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. Summit Press Release (March 27, 2026). Available at: https://www.smmttx.com/press-releases/.; 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. 2025; 28(3):111722.

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