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A Multicenter, Multi-Cohort, Phase II Study of Sacituzumab Tirumotecan with or Without Tislelizumab in Patients with Advanced Thyroid Cancer

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Introduction

You are invited to participate in a clinical research study evaluating sacituzumab tirumotecan (SKB264), alone or in combination with tislelizumab, in patients with advanced thyroid cancer.

This study has been approved by the Institutional Ethics Committee of Zhejiang Provincial People's Hospital and plans to enroll approximately 94 participants.

Before deciding whether to participate, it is important that you understand:

- The purpose of the study
- Study procedures
- Potential benefits
- Potential risks
- Your rights and responsibilities

Participation is entirely voluntary.

Why Is This Study Being Conducted?

1. Disease Background and Clinical Challenges

Anaplastic thyroid carcinoma (ATC) is a rare but highly aggressive cancer, accounting for 1–2% of thyroid cancers but 40–50% of thyroid cancer-related deaths.

Median survival is approximately 5 months. Standard chemotherapy response rates are below 20%.

Papillary thyroid carcinoma (PTC) accounts for ~80% of thyroid cancers. However, 25–30% of patients develop recurrent or persistent disease. Many become radioactive iodine refractory (RAI-R), and treatment options are limited.

TROP2 expression is detected in up to 82.5% of PTC cases, suggesting it may be a therapeutic target.

2. Rationale for SKB264 and Immunotherapy Combination

Sacituzumab tirumotecan (SKB264) is a TROP2-directed antibody-drug conjugate (ADC) that delivers a cytotoxic payload directly to tumor cells.

Tislelizumab is a PD-1 immune checkpoint inhibitor.

The combination may provide dual anti-tumor mechanisms:

- Direct tumor cell killing

- Immune microenvironment activation
- Enhanced antigen presentation
- Reversal of immune escape

This strategy has shown promising activity in other solid tumors.

How Many People Will Participate?

Approximately 94 participants.

Who May Participate?

You may be eligible if:

- You are ≥18 years old
- You have advanced thyroid cancer
- You are able to comply with study procedures
- You provide written informed consent

Study Procedures

Screening Period (Day -28 to -1)

- Medical history
- Physical examination
- Laboratory tests
- Imaging studies

Treatment Period

ATC Patients

- Sacituzumab tirumotecan 5 mg/kg IV
- Tislelizumab 200 mg IV
- Day 1, 15, 29 every 6 weeks

PDTC / RAI-Refractory DTC Patients

- Sacituzumab tirumotecan 4 mg/kg IV
- Day 1, 15, 29 every 6 weeks

Dose modification may occur if side effects develop.

Premedication

Before infusion, you will receive medications to reduce allergic reactions, including:

- Antihistamines
- Acetaminophen
- Dexamethasone (first 4 infusions)

Oral hygiene measures are strongly recommended to reduce mucositis risk.

Monitoring

During treatment, you will undergo:

- Vital signs
- Laboratory tests
- ECG
- Echocardiogram
- CT/MRI imaging

Imaging occurs every 6 weeks initially.

Follow-Up

End-of-Treatment Visit

Within 30 days after last dose.

Safety Follow-Up

30 days after last dose.

Survival Follow-Up

Every 3 months via phone.

Biological Sample Collection

Blood and tumor tissue will be collected for:

- Safety testing
- Genomic analysis
- TROP2 testing

Approximately 60 mL blood may be collected at each time point (up to 3 times).

Tumor tissue blocks or slides may be required. If unavailable, biopsy may be needed.

Samples will be stored up to 5 years and then destroyed per regulations.

Reproductive Risk

Animal studies suggest potential embryo-fetal toxicity.

You must use effective contraception:

- During study
- For 6 months after last dose

Acceptable methods include:

- IUD
- Surgical sterilization
- Condoms
- Hormonal contraception

Male participants must avoid sperm donation during this period.

Potential Risks

Sacituzumab Tirumotecan

Very common (>10%):

- Low blood counts
- Anemia
- Elevated liver enzymes
- Nausea/vomiting
- Mucositis
- Alopecia
- Hyperglycemia

Serious but rare:

- Interstitial lung disease
- Severe ocular toxicity
- Severe allergic reactions

Tislelizumab

Common:

- Anemia
- Hyperglycemia
- Fatigue
- Thyroid dysfunction
- Pneumonia

Immune-mediated risks:

- Pneumonitis
- Hepatitis
- Colitis
- Nephritis
- Endocrine disorders

Other Procedure Risks

- Blood draw discomfort
- CT radiation exposure
- MRI anxiety
- Bone scan radiation
- Biopsy bleeding/infection

Potential Benefits

Your cancer may improve or stabilize.

However, benefit is not guaranteed.

Alternatives

Alternative treatments may include:

- Standard chemotherapy
- Targeted therapy
- Immunotherapy
- Supportive care

You may discuss these options with your doctor.

Costs

Study drug SKB264 is provided free.

Tislelizumab:

- 1 cycle free
- Next cycle self-paid (1253 RMB/vial)
- Alternating free/self-pay cycles

Routine medical costs are your responsibility.

Injury Compensation

If you are harmed due to study drug or procedures:

- You will receive medical treatment
- Insurance compensation may apply

Voluntary Participation

Participation is voluntary.

You may withdraw at any time.

Withdrawal will not affect your standard medical care.

Confidentiality

Your personal identity will not be disclosed publicly.

Data may be reviewed by:

- Regulatory authorities

- Ethics committees
- Sponsor representatives

Study information may be posted at:

https://www.clinicaltrials.gov

No identifiable information will be included.

Personal Data Protection Appendix

Your personal data may include:

- Medical history
- Laboratory data
- Genetic testing
- Contact information

You may withdraw consent for future data use, but data already collected may still be used per regulations.

Contact Information

If you have questions:

Principal Investigator:

Minghua Ge, MD

Zhejiang Provincial People’s Hospital

Ethics Committee Contact available upon request.