Appendix 1 Criteria details

Inclusion

The subjects will:

(I) Sign the informed consent form before enrollment;
(II) Be aged 18–75 years old, and be male or female;
(III) Histologically-confirmed squamous cell carcinoma;
(IV) Radiographically and endoscopically confirmed as operable and requiring neoadjuvant treatment, locally advanced esophageal squamous cell carcinoma (ESCC) patients; staging: cT1-3N1-2M0 or cT2-4aN0M0 (stage II/III), according to American Joint Committee on Cancer (AJCC) 8th edition Tumor Node Metastasis (TNM) staging system;
(V) Radiographically and endoscopically confirmed that the patient's tumor is located in the middle and lower esophagus;
(VI) Have an Eastern Cooperative Oncology Group (ECOG) performance score of 0–1;
(VII) No prior chemotherapy, radiotherapy or immunotherapy against any cancers;
(VIII) Have measurable and evaluable lesions according to the RECIST version 1.1 (v1.1);
(IX) R0 resection is expected;
(X) Demonstrate adequate organ function; all screening laboratory tests will be performed within 10 days of treatment initiation;
(XI) Have a negative urine or serum pregnancy within 72 hours before receiving the first dose of study medication if they are a female subject with childbearing potential. If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be required;
(XII) Join the clinical study on a completely voluntary basis, demonstrate good adherence, and cooperate with the follow-up assessments for safety and survival.

Exclusion

The subjects will not:

(I) Have undergone any previous therapy (e.g., an operation, radiotherapy, immunotherapy, or chemotherapy) for esophageal cancer;
(II) Have a history of other anti-PD-1/PD-L1 therapies, or have a known history of an allergy to macromolecular protein preparations or any component of PD-1;
(III) Have a diagnosis of immunodeficiency or have received chronic systemic steroid therapy (in doses >10 mg daily of a prednisone equivalent) or any other form of immunosuppressive therapy within 7 days before the first dose of the study drug;
(IV) Have an active autoimmune disease that required systemic treatment in the past 2 years (e.g., the use of disease modifying agents, corticosteroids, or immunosuppressive drugs);
(V) Patients infected with HIV, or with active hepatitis B or C (HBV DNA ≥104 copies/mL; HCV RNA ≥103 copies/mL);
(VI) Pregnant women or women preparing for pregnancy;
(VII) Patients with known or concurrent bleeding disorders or other uncontrolled diseases who cannot receive surgical treatment;
(VIII) Physical examination or clinical trial findings that could interfere with the results or put the patient at increased risk for treatment complications;
(IX) Patients with comorbidities (chronic pulmonary disease, poorly controlled hypertension, unstable angina, myocardial infarction within 6 months, unstable mental disorders requiring therapy);
(X) Patients who are allergic to study drugs;
(XI) Currently participating in interventional clinical research treatment, or receiving other research drugs or using research instruments within 4 weeks before the first administration;

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(XII) Medical history or evidence of illness that may interfere with the trial results, hinder participants from participating in the entire study, abnormal treatment or laboratory test values, or other situations that the researcher believes are not suitable for enrollment. The researcher believes that there are other potential risks that are not suitable for participation in this study.

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