A Randomized, Double-blind, Placebo-controlled, Single and Multiple Dose Escalation Phase I Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of IMC-003 for Injection in Healthy Postmenopausal Women

NCT07118085

Status	RECRUITING
Phase	Phase 1
Sponsor	ImmuneOnco Biopharmaceuticals (Shanghai) Inc.
Enrollment	56 participants

Key Eligibility Criteria

Inclusion (1)

• (1) The age range for screening is 45 to 75 years (inclusive of the boundary values), and post-menopausal females; (2) Before screening, spontaneous amenorrhea has lasted for at least 12 months, or spontaneous amenorrhea for at least 6 months or amenorrhea caused by hysterectomy with serum FSH level \> 40 IU/L, or bilateral oophorectomy with or without hysterectomy for e 6 weeks; (3) At the time of screening, the weight is e 45 kg and the body mass index (BMI) is within the range of 18.0 to 30.0 kg/m2 (inclusive of the boundary values); (4) Physical examination, vital sign examination, electrocardiogram examination, laboratory tests, etc. are normal (platelet count is greater than the lower limit of the normal value) or judged by the investigator to be abnormal but without clinical significance; (5) Fully understand the trial content, the trial drug, the trial process, etc., can communicate well with the researcher, willing to abide by the trial regulations, and voluntarily participate and sign the informed consent form.

Exclusion (2)

• The subjects must meet any of the following conditions to be eligible for this trial:

• (1) (During the screening period/In the admission interview) They had or currently have clinically significant diseases or abnormalities as determined by the investigators, including but not limited to cardiovascular, respiratory, digestive tract, endocrine, hematological, liver, immune, metabolic, urinary, skin, central nervous system, and chronic kidney diseases, or diseases that the investigators consider to have safety issues or affect the PK evaluation; (2) (During the screening period/In the admission interview) They have active bleeding (such as peptic ulcer, intracranial hemorrhage, skin ecchymosis, nosebleed, gum bleeding) at present; or within the previous 6 months, they have any disease history that may increase the risk of bleeding (such as tumor bleeding, spontaneous hematoma, eye bleeding, hemoptysis, gastrointestinal bleeding or ulcer, hematuria, frequent nosebleeds/gum bleeding, frequent subcutaneous or skin ecchymosis, etc.); (3) (During the screening period/In the admission interview) They have a history of malignant tumors in the past or currently; (4) (During the screening period/In the admission interview) They have a history of thrombosis, cerebral infarction, or myocardial infarction; (5) (During the screening period/In the admission interview) They cannot tolerate venipuncture blood collection or have a history of fainting or hemoversion; (6) (During the screening period/In the admission interview) They have a history of tuberculosis, or they have a severe local or systemic infection within 3 months before screening; (7) (During the screening period/In the admission interview) They have a severe allergic history (such as angioedema, anaphylactic shock), allergic constitution (such as being allergic to pollen, two or more drugs/food), or are known to have previously been allergic to large molecule protein preparations/monoclonal antibodies, known to be allergic to the test drug or its excipients or similar drugs; (8) (During the screening period/In the admission interview) They have used any prescription drugs or herbal medicines within 4 weeks before administration, and used over-the-counter drugs or dietary supplements (including vitamins, calcium supplements, etc.) within 2 weeks; (9) (During the screening period/In the admission interview) They have used drugs that may affect bone metabolism within 6 months before administration, and are expected to use drugs that may affect bone metabolism during this trial. These drugs include but are not limited to the following: estrogen-containing contraceptives, bisphosphonates, fluoride, hormone replacement therapy (such as terbutalone, estrogen, estrogen-like compounds, such as raloxifene), calcitonin, strontium, parathyroid hormone or its derivatives, vitamin D supplements (\>1000 IU/day), calcium supplements, glucocorticoids (except those who used inhaled or other local corticosteroid drugs within 2 weeks before screening), anabolic steroid drugs (such as megestrolone, phenylpropionate nandrolone, hydroxyethyl testosterone, stanazolol, kalicornol, danazol, etc.), calcitriol, etc.; and any drugs that affect platelet function or cause changes in the body's coagulation function; (10) (During the screening period/In the admission interview) They have used teriparatide; (11) (During the screening period/In the admission interview) They have used any drugs that affect platelet count, function, or cause changes in the body's coagulation function within 4 weeks before administration; (12) (During the screening period/In the admission interview)

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They have donated blood or had a blood loss of e 400 mL within 3 months before administration; (13) (During the screening period/In the admission interview) They have undergone major surgery within 3 months before screening or are expected to have major surgery during this trial (including the screening period); (14) (During the screening period/In the admission interview) They are heavy smokers or have a daily smoking amount of e 5 cigarettes within 3 months before administration, or they cannot stop using any tobacco products during the trial; (15) (Screening period / Admission consultation) Alcoholics or those who consumed more than 14 standard units of alcohol per week within 6 months prior to the first administration (1 standard unit contains 17.5 ml or 14 grams of pure alcohol, the alcohol content of different types of beverages is indicated by volume ratio, and the daily alcohol intake is equivalent to 70 ml of 50° liquor or 700 ml of 5° beer), or those who were unwilling to stop drinking alcohol or consuming any alcoholic products during the trial; those with a positive alcohol breath test result; (16) (Screening period / Admission consultation) Those who consumed excessive tea, coffee, and/or caffeinated beverages every day within 3 months prior to screening (more than 8 cups, 1 cup = 250 mL); (17) (Screening period / Admission consultation) Those with a history of drug abuse, or those with positive results from multiple drug screening tests for urine combined screening; (18) (Screening period / Admission consultation) Those who have previously used drugs targeting the same target, including participants in clinical studies of drugs targeting the same target; (19) (Screening period / Admission consultation) Those who participated in any clinical trials of drugs or medical devices within 3 months prior to administration and used the study drugs, vaccines, or devices; (20) Those with positive results for hepatitis B surface antigen, hepatitis C virus antibody, human immunodeficiency virus antibody, or Treponema pallidum specific antibody; (21) (Screening period / Admission consultation) Those cannot guarantee that they will refrain from consuming drugs, foods, or beverages that can induce or inhibit liver metabolic enzymes from 1 week before the trial and throughout the trial period; (22) Other reasons as determined by the investigator that make participation in this trial inappropriate.

Locations (1 total)

Chengdu Xinhua hospital, Chengdu, Sichuan, China

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