ForPatients
by Roche

Healthy Male SubjectsHealthy Volunteers

A Study in Healthy Male Subjects to Investigate the Comparability of Pharmacokinetics of the Fixed-Dose Combination of Pertuzumab and Trastuzumab Administered Subcutaneously Using a Handheld Syringe or Using the On-Body Delivery System

Trial Status	Trial Runs In	Trial Identifier
Completed	2 Countries	NCT05275010 WP42873

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Randomized, Open-Label, 2-Arm, Parallel Group, Single Dose, Multi-Centre Study in Healthy Male Subjects to Investigate the Comparability of Pharmacokinetics of the Fixed-Dose Combination of Pertuzumab and Trastuzumab Administered Subcutaneously Using a Handheld Syringe or Using the On-Body Delivery System

Trial Summary:

This is a randomized, open-label, 2-arm, parallel-group, single-dose, multi-center study in healthy male subjects to investigate the comparability of the pharmacokinetics of the fixed-dose combination of pertuzumab and trastuzumab administered subcutaneously using the proprietary on-body delivery system or a handheld syringe with hypodermic needle.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT05275010 WP42873
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male	#18 Years & # 45 Years	Accepts Healthy Volunteers

Inclusion Criteria:

- Healthy male subjects age 18-45 years at time of signing Informed Consent Form

- Ability to comply with the study protocol
- Agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agreement to refrain from donating sperm, during the treatment period and for 7 months after the dose of PH FDC SC
- A body mass index (BMI) between 18 and 32 kilograms per metre squared (kg/m2), inclusive
- Intact normal skin without potentially obscuring tattoos, pigmentation, or lesions in the area for intended injection on the thighs
- Baseline LVEF#55% measured by echocardiogram (ECHO)
- No history of hypersensitivity or confirmed, clinically significant and clinically relevant allergic reactions, either spontaneously or following any drug administration
- No history of any clinically significant and clinically relevant cardiac condition
- No history of previous anticancer treatments including pertuzumab, trastuzumab, anthracyclines, or any cardiotoxic drugs
- No apparent family history of clinically significant and clinically relevant hypersensitivity, allergy, and severe cardiac diseases
- No contraindications from detailed medical and surgical history and physical examinations
- No previous enrollment in this study protocol and no concurrent enrollment in any other study protocol

Exclusion Criteria:

- Positive urine test for drugs of abuse as per local standard (for alcohol abuse, positive breath test is also acceptable)
- Positive test result for hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV) 1 or 2, showing: History of exposure to HBV, HCV, or HIV; or Active viral hepatitis infection (HBV or HCV) or HIV infection
- Systolic blood pressure #140 millimetres of mercury (mmHg) or <90 mmHg, or diastolic blood pressure >90 mmHg or <50 mmHg
- Use of prohibited medications including non-prescription medications, nutraceuticals, nutritional supplements or any herbal remedies taken within 10 days or 5 times the elimination half-life (whichever is longer) prior to randomization into the study
- Concomitant subcutaneous, intravenous, or any parenteral drugs within 90 days prior to screening
- Participation in an investigational drug or device study within 90 days or five times the elimination half-life (whichever is longer) prior to screening
- Donation of blood over 500 millilitres (mL) within 3 months prior to enrollment
- Known severe hypersensitivity to plaster, medical adhesive tapes, or bandages
- Known allergy to murine proteins, hyaluronidase, bee, or vespid venom, or any other ingredient in the formulation of rHuPH20 (Hylenex® recombinant [hyaluronidase human injection]) or any other ingredients and excipients in the formulation of PH FDC SC
- Clinically significant abnormalities in laboratory test results (including hepatic and renal panels, CBC, chemistry panel, and urinalysis)
- Clinically relevant electrocardiogram abnormalities at screening or Day -1
- History of any cardiac condition
- Lower extremity edema or pathology (e.g., cellulitis, lymphatic disorder or prior surgery, pre-existing pain syndrome, previous lymph node dissection etc.) that could interfere with any protocol-specified outcome assessment
- Any history of clinically significant and clinically relevant allergies, oncologic, psychiatric, gastrointestinal, renal, hepatic, cardiovascular or pulmonary disease
- Concomitant disease or condition that could interfere with, or for which the treatment might interfere with, the conduct of the study, or that would pose an unacceptable risk to the subject in this study
- Any clinically relevant history of systemic disease (e.g., malignancy, diabetes mellitus, gastrointestinal, renal, hepatic, cardiovascular, rheumatological, or pulmonary disease)
- History of breast cancer or treatment for breast cancer

- Current chronic daily treatment (continuous for >3 months) with corticosteroids (dose #10 mg/day methylprednisolone), excluding inhaled corticosteroids
- Receipt of intravenous antibiotics for infection within 7 days prior to enrollment into the study