abbvie

AbbVie Clinical Pharmacology Research Unit

Information Sheet

www.abbviephase1.com

Sycamore

There is no confinement in this study. You will be required to come to the ACPRU for at least 5 visits listed below.

Study drug and design:

AbbVie is testing an investigational drug, which is not approved by the Food and Drug Administration (FDA) or any health authority and is not currently available on the market. The objective of this study is to assess the injection site pain and local tolerability between different warm-up times of the autoinjector via subcutaneous administration.

Minimum Subject Selection Criteria:

YOU *may be eligible to take part in this clinical study if you meet the following conditions:*

- Healthy men and women 18 to 55 yrs. old.
- Females must be permanently surgically sterile (bilateral oophorectomy, bilateral salpingectomy, or hysterectomy) or postmenopausal defined as age ≥ 55 years with no menses for 12 or more months without an alternative medical cause.
- Postmenopausal, age 55 years with no menses for 12 months or more months without alternative medical cause and FSH level ≥ 40 IU/L.
- Females of childbearing potential must avoid pregnancy while taking study drug(s) and for at least 140 days after the last dose of study drug & must commit to one of the following methods of birth control.
- Average weight for height (BMI 18 to 30).
- Not taking any medications or herbal remedies or supplements.
- No history of any drug sensitivity or allergy.
- No history of drug or alcohol abuse for 6 months.
- Non-user of tobacco for at least 6 months.
- No blood or blood product donation X 4 weeks
- No other study participation after 30 days or 5 half-lives of drug if known prior to first dose of study drug.

Screenings at ACPRU in Grayslake

Screening dates: *(To find out if you are suitable to take part in this clinical study)*

- October 15, 17, 19, 20, 21, 22, 23, 24, 26, 27, 28 & 29 2020.
- **Additional screening dates may be available**.
- Screening appointments are between the hours of 12:00 or later and take approximately 3 hours.

Stipend:

- **Screening:** $75.00. (No compensation if urine drug/alcohol/cotinine screen is positive or if BMI is out of range.)
- **Study:** Compensation of up to $6,250.00 may be provided if selected and you complete the study.

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Study dates: *(Please note that these dates and times are subject to change)*

Must complete all periods and/or follow up visit(s).

NOTE: You will be required to come to the ACPRU for at least 5 visits listed below:

Screening, Period 1 Day -1, Period 1 Day 1, Period 2 Day 1, Period 3 Day 1

PHONE CALL FOLLOW UP: 30 days and 140 after the last dose of the study drug

(A follow up visit may be required for safety. If this occurs, you will be notified and compensated for your visit time and travel)

(Please note that these dates and times are subject to change)

Please call our recruiting office at 1-800-827-2778 to schedule an appointment.