abbvie

AbbVie Clinical Pharmacology Research Unit

Information Sheet

www.abbviephase1.com

Grapefruit

Check In Date: Tuesday, 31 May 2022, or Wednesday 01 Jun 2022

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 the study is to assess the safety, tolerability, and pharmacokinetics (the amount of drug absorbed in your bloodstream and how your body handles the drug) of a single intravenous dose of the investigational drug.

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 45 years old.
- Females must be permanently surgically sterile for at least 3 months, or postmenopausal for at least 1 year.
- Average weight for height (BMI 18 to 32 kg).
- Not taking any medications or herbal remedies or supplements.
- No history of clinically significant condition, including any metabolic or endocrine disease, including diabetes and thyroid disease.
- No history of gastrointestinal surgical operations, including removal of the gallbladder.
- No elective surgery from 2 weeks prior to study drug administration or anticipated to be performed through the end of the study.
- No history of seizure disorder, unexplained blackouts, or history of seizure within 6 months.
- No history of congenital/cardiac abnormalities.
- No symptoms of active infection or prior infection requiring hospitalization within 8 weeks before dosing.
- No history of any drug sensitivity or allergy.
- No history of drug or alcohol abuse for 2 years prior to study drug administration.
- Non-user of tobacco for at least 6 months.
- No live vaccines after 4 weeks, or 03 May 2022.
- No drug injection within 5 half-lives of the drug.
- Not treated with any investigational drug within 6 weeks, or 19 April 2022.
- No depot drug injection within 6 weeks, or 19 Apr 2022, prior to study drug administration.
- No blood or blood product donation after 8 weeks, or 05 Apr 2022.
- No other study participation after 6 weeks, or 19 Apr 2022, or 10 half-lives of the drug if known.

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Screenings at ACPRU in Grayslake

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

- May 16, 17, 18, 19, 20, 23, 24, 25 & 26 May 2022.
- **Additional screening dates may be available**.
- Screening appointments are between the hours of 0800 and 1145 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 $ 12,675.00 may be provided if selected and you complete the study.

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

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

CHECK IN: Tuesday, 31 May 2022, or Wednesday, 01 Jun 2022 at scheduled appointment time.

CHECK OUT: Thursday, 09 Jun 2022 or Friday, 10 Jun 2022 at approximately noon.

FOLLOW UP VISIT(S): Day 15, 29, 43, 57, 71, 85, 113 and 141.

(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.