

AbbVie Clinical Pharmacology Research Unit
 Information Sheet
 www.abbviephase1.com

Check In:
Sunday, November 01, Monday, November 02, or Tuesday, November 03
Thimbleberry

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 determine safety, tolerability, and pharmacokinetics (the amount of drug absorbed into your blood stream and how your body handles the drug) through 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 between 18 & 55 yrs. of age inclusive at the time of Screening.
- ◆ Average weight for height (\geq BMI 18 to 29.9 kg/m²).
- ◆ Postmenopausal, age \leq 55 years with no menses for 12 or more months without an alternative medical cause AND a follicle stimulating hormone (FSH) level $>$ 40 IU/L.
- ◆ Permanently surgically sterile (bilateral oophorectomy, bilateral salpingectomy, or hysterectomy)
- ◆ Not taking any medications or herbal remedies or supplements.
- ◆ No history of any drug sensitivity or allergy.
- ◆ No vaccination within 4 weeks prior to the first dose of study drug.
- ◆ No history of drug or alcohol abuse x 6 months
- ◆ Non-user of tobacco x 6 months.
- ◆ No drug by injection within 30 days or within a period defined by 5 half-lives, whichever is longer, prior to study drug administration.
- ◆ No blood or blood product donation x 8 weeks. Note: not listed in the I/E criteria.
- ◆ No other study participation after 30 days or 5 half-lives of drug (whichever is longer) prior to the 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 26, 27, 28 & 29 2020.
- ◆ **Additional screening dates may be available.**
- ◆ Screening appointments are between the hours of 08:00 and 11:00 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 \$6,800.00 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).

CHECK IN: Sunday, November 01, Monday, November 02, or Tuesday, November 03 at scheduled appointment time

CHECK OUT: Tuesday, November 10, Wednesday, November 11, or Thursday, November 12 at approximately noon.

FOLLOW UP VISIT(S): Day 11, 15, Day 18, Day 30, Day 45, Day 60 by scheduled appointment time.

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

Check In: Sunday, Nov 01, 2020			
Check Out: Tuesday, Nov 10, 2020			
Study Day		Follow Up Date	
	Day	Date	Time
DD	11	Nov. 14, 2020	08:00
DD	15	Nov. 18, 2020	08:00
DD	18	Nov. 22, 2020	08:00
DD	30	Dec. 03, 2020	08:00
DD	45	Dec. 20, 2020	08:00
DD	60	Jan. 04, 2020	08:00
*Days you need to be fasting			
Check In: Monday, Nov 02, 2020			
Check Out: Wednesday, Nov 11, 2020			
Study Day		Follow Up Date	
	Day	Date	Time
DD	11	Nov. 15, 2020	08:00
DD	15	Nov. 19, 2020	08:00
DD	18	Nov. 23, 2020	08:00
DD	30	Dec. 04, 2020	08:00
DD	45	Dec. 21, 2020	08:00
DD	60	Jan. 05, 2020	08:00
*Days you need to be fasting			
Check In: Tuesday, Nov 03, 2020			
Check Out: Thursday, Nov 12, 2020			
Study Day		Follow Up Date	
	Day	Date	Time
DD	11	Nov. 16, 2020	08:00
DD	15	Nov. 20, 2020	08:00

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DD	18	Nov. 24, 2020	08:00
DD	30	Dec. 05, 2020	08:00
DD	45	Dec. 22, 2020	08:00
DD	60	Jan. 06, 2020	08:00
*Days you need to be fasting			

If you need more information or to schedule a screening appointment, please call our recruiting office at (800) 827-2778.