

November 2026

MEDPACE

Clinical Pharmacology

HM-UCN2-101 MAD Cohort 5

Study Inpatient dates:

Nov 09-14, 2026
Jan 26-30, 2027

Study Outpatient dates:

Nov 18 and 25, 2026
Dec 02, 09, 16, 23, and 30, 2026
Jan 06, 13, and 20, 2027
Feb 03, 2027
Mar 03, 2027

Instructions / Restrictions:

- Continue to follow birth control requirements outlined in the informed consent. Must not be pregnant, planning to become pregnant, or breastfeeding.
- Abstain from egg donation **during the study** and abstain from sperm donation **during the study and for 90 days after final dose of study drug (Day 78)**.
- Must not have any major surgery **within 6 months prior to Screening**.
- Avoid donation of blood **within 60 days prior to first dose of study drug (Day 1)** and avoid donation of blood or plasma **throughout the study**.
- Must not have a history of drug abuse, positive drug test, or frequent use of marijuana or other THC products **within 1 year prior to Screening**.
- Must not have a history of alcohol abuse **within 1 year prior to Screening** (drinking more than 14 standard units per week).
- Must not smoke more than 10 cigarettes per day (or nicotine equivalent) **at the time of Screening or plan to use during the study**.
- Abstain from smoking and tobacco-containing products **24 hours prior to Admission (Day -2)** and **throughout the study**.
- Abstain from caffeine, alcohol, and tobacco for **24 hours prior to each admission (Days -2 and 77)** and **all outpatient visits (Days 8, 15, 22, 29, 36, 43, 50, 57, 64, 71, 85, and 113)**.
- Abstain from strenuous exercise **24 hours prior to each admission (Days -2 and 77)** and **outpatient visits with blood collection for clinical lab tests (Days 8, 15, 29, 57, 85, and 113)**.
- Must not use any investigational product **within 30 days or 5 half-lives (whichever is longer) prior to Screening**.
- Must not initiate treatment with any new prescription medications **from the time of Screening until the end of study** unless agreed to by the study physician.
- Avoid use of any anti-obesity medications, nutritional supplements or over-the-counter products for weight loss, any product or medication known or suspected to cause weight gain (e.g., tricyclic anti-depressants, atypical antipsychotics, and mood stabilizers), and use of skeletal muscle anabolic agents in any form, such as medications, hormones, over-the-counter products, and nutritional supplements (other than protein) that were labeled as muscle anabolic agents **within 3 months prior to Screening**.
- Avoid initiation of hormone replacement therapy **within 2 months of Screening**.
- Avoid use of any lipid-lowering agents, unless on stable dose for **at least 3 months prior to Screening**.
- Avoid use of any antihypertensive medications, any weight control treatment, e.g., GLP-1 receptor agonist related study (prescribed mono or dual agonist therapies or any GLP-1 receptor agonist mono or combination therapy provided during a clinical study such as triple agonist or other combinations), and use of any vasodilators (including PDE5 inhibitors) **within 3 months prior to Screening**.
- Avoid use of any medications known to affect gastric emptying (including opioids, cannabinoids, prokinetics, antiemetics, and neuromodulators) **within 48 hours prior to Day -1 and Day 80**.
- Fast overnight for **at least 8 hours (no foods or liquids other than water) prior to Admission (Day -2) and all outpatient visits (Days 8, 15, 22, 29, 36, 43, 50, 57, 64, 71, 85, and 113)**.
- Eat a "well-balanced healthy diet" during outpatient periods. Do not start any new diets, supplements, or exercise programs **during the study** and avoid overeating, as well as high sodium or salt intake on the **day before Admission (Days -2 and 77)**.
- Consume an adequate amount of carbohydrates for **at least 3 days prior to Admission (Day -2) and Day 79**.

Reminder: Breath alcohol & urine drug test at each Admission (Days -2 and 77) and all outpatient visits (Days 8, 15, 22, 29, 36, 43, 50, 57, 64, 71, 85, and 113). COVID-19 rapid antigen test at each Admission (Days -2 and 77) only.

***Payment to occur within 48 hours after payment visit day**

***MRI/DXA: A staff member from Cincinnati Children's will contact you with further details.**

Sun	Mon	Tue	Wed	Thu	Fri	Sat
1	2	3	4	5	6	7
8 Begin caffeine, alcohol, tobacco, and strenuous exercise restrictions Begin overnight fast	9 Day -2 Admission	10 Day -1 Inpatient	11 Day 1 Dose	12 Day 2 Inpatient	13 Day 3 Inpatient	14 Day 4 Discharge Payment 1*
15	16	17 Begin caffeine, alcohol, tobacco, and strenuous exercise restrictions Begin overnight fast	18 Day 8 OPV	19	20	21
22	23	24 Begin caffeine, alcohol, tobacco, and strenuous exercise restrictions Begin overnight fast	25 Day 15 OPV	26 Thanksgiving	27	28
29	30					

December 2026

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Sun	Mon	Tue	Wed	Thu	Fri	Sat
		1 Begin caffeine, alcohol, and tobacco restrictions Begin overnight fast	2 Day 22 OPV	3	4	5
6	7	8 Begin caffeine, alcohol, tobacco, and strenuous exercise restrictions Begin overnight fast	9 Day 29 OPV Payment 2*	10	11	12
13	14	15 Begin caffeine, alcohol, and tobacco restrictions Begin overnight fast	16 Day 36 OPV	17	18	19
20	21	22 Begin caffeine, alcohol, and tobacco restrictions Begin overnight fast	23 Day 43 OPV	24	25 Christmas	26
27	28	29 Begin caffeine, alcohol, and tobacco restrictions Begin overnight fast	30 Day 50 OPV	31		

January 2027

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Sun	Mon	Tue	Wed	Thu	Fri	Sat
					1 New Year's Day	2
3	4	5 Begin caffeine, alcohol, tobacco, and strenuous exercise restrictions Begin overnight fast	6 Day 57 OPV	7	8	9
10	11	12 Begin caffeine, alcohol, and tobacco restrictions Begin overnight fast	13 Day 64 OPV	14	15	16
17	18	19 Begin caffeine, alcohol, and tobacco restrictions Begin overnight fast	20 Day 71 OPV Payment 3*	21	22	23
24	25 Begin caffeine, alcohol, tobacco, and strenuous exercise restrictions	26 Day 77 Admission	27 Day 78 Dose	28 Day 79 Inpatient	29 Day 80 Inpatient	30 Day 81 Discharge
31						

February 2027

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Sun	Mon	Tue	Wed	Thu	Fri	Sat
	1 D85 MRI/ DXA Window Opens*	2 Begin caffeine, alcohol, tobacco, and strenuous exercise restrictions Begin overnight fast	3 Day 85 OPV	4	5 D85 MRI/ DXA Window Closes*	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28						

March 2027

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Sun	Mon	Tue	Wed	Thu	Fri	Sat
	1	2 Begin caffeine, alcohol, tobacco, and strenuous exercise restrictions Begin overnight fast	3 Day 113 OPV (EOS) Payment 4*	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			