

September 2026

MEDPACE
Clinical Pharmacology

HM-UCN2-101 MAD Cohort 4

Study Inpatient dates:

Sep 28-Oct 03, 2026
Dec 15-19, 2026

Study Outpatient dates:

Oct 07, 14, 21, and 28, 2026
Nov 04, 11, 18, and 25, 2026
Dec 02, 09, and 23, 2026
Jan 20, 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 antidepressants, 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 Labor Day	8	9	10	11	12
13	14	15	16 Screening MRI/DXA Window Closes*	17	18	19
20	21	22	23	24	25	26
27 Begin caffeine, alcohol, tobacco, and strenuous exercise restrictions Begin overnight fast	28 Day -2 Admission	29 Day -1 Inpatient	30 Day 1 Dose			

October 2026

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

November 2026

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Sun	Mon	Tue	Wed	Thu	Fri	Sat
1	2	3 Begin caffeine, alcohol, and tobacco restrictions Begin overnight fast	4 Day 36 OPV	5	6	7
8	9	10 Begin caffeine, alcohol, and tobacco restrictions Begin overnight fast	11 Day 43 OPV	12	13	14
15	16	17 Begin caffeine, alcohol, and tobacco restrictions Begin overnight fast	18 Day 50 OPV	19	20	21
22	23	24 Begin caffeine, alcohol, tobacco, and strenuous exercise restrictions Begin overnight fast	25 Day 57 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 64 OPV	3	4	5
6	7	8 Begin caffeine, alcohol, and tobacco restrictions Begin overnight fast	9 Day 71 OPV Payment 3*	10	11	12
13	14 Begin caffeine, alcohol, tobacco, and strenuous exercise restrictions	15 Day 77 Admission	16 Day 78 Dose	17 Day 79 Inpatient	18 Day 80 Inpatient	19 Day 81 Discharge
20	21 D85 MRI/DXA Window Opens*	22 Begin caffeine, alcohol, tobacco, and strenuous exercise restrictions Begin overnight fast	23 Day 85 OPV	24 D85 MRI/DXA Window Closes*	25 Christmas	26
27	28	29	30	31		

January 2027

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10	11	12	13	14	15	16
17	18	19 Begin caffeine, alcohol, tobacco, and strenuous exercise restrictions Begin overnight fast	20 Day 113 OPV (EOS) Payment 4*	21	22	23
24	25	26	27	28	29	30
31						