CM Pharmaceuticals, Inc.

SITEID

SUBJID Subject ID 044 - 1 ☐☐

Subject Initials ☐☐☐

Eligibility

Inclusion Criteria (all answers must be YES to be included in the trial)	**Yes**	**No**
1 Age 18-45 years, inclusive	☐ 1	☐ 0
2 Willingness to submit to diagnostic machine testing	☐ 1	☐ 0
3 Male or non-pregnant, non-lactating female. Women of reproductive potential must be practicing adequate contraception (e.g., intrauterine device or double barrier device such as a diaphragm or condom plus spermicide). Abstinence is not considered to be an acceptable method of contraception. Additionally, women of reproductive potential must have a negative urine pregnancy at screening and prior to enrollment	☐ 1	☐ 0
4 In good health as determined by medical history and physical examinations	☐ 1	☐ 0
5 Capable of understanding and complying with the protocol and has signed the informed consent document	☐ 1	☐ 0

Exclusion Criteria (all answers must be NO to be included in the trial)	**Yes**	**No**
1 Pregnant or lactating females	☐ 1	☐ 0
2 History of anaphylaxis	☐ 1	☐ 0
3 History or presence of hepatitis	☐ 1	☐ 0

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DOMAIN **Demographics/Medical History**

Demographics					
Sex: SEX	Race: RACE				
☐ 1 Male	☐ 1 Caucasian	☐ 2 Black	☐ 3 Hispanic	☐ 4 Asian	
☐ 2 Female	☐ 5 Other (specify): RACEOTH _____				
Date of Birth: BRTHDTC ____/____/____ (mm dd yy)			Date Informed Consent Signed : RFICDTC ____/____/____ (mm dd yy)		

Pregnancy test		
Result:	☐ 0 Negative	☐ 2 Not applicable

Medical History		
Body System	**Normal**	**Abnormal (describe)**
Neuro	☐ 0	
HEENT	☐ 0	
Heart	☐ 0	
Lungs	☐ 0	
Abdomen	☐ 0	
Musculoskeletal	☐ 0	
Peripheral Vascular	☐ 0	
Skin	☐ 0	
Additional Findings:		

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Physical Examination

	Study Day 1		Study Day 2	
Body System	**Normal**	**Abnormal (describe)**	**Normal**	**Abnormal (describe)**
Neurological	☐ 0		☐ 0	☐ 1 Unchanged from Study Day 1
HEENT	☐ 0		☐ 0	☐ 1 Unchanged from Study Day 1
Heart	☐ 0		☐ 0	☐ 1 Unchanged from Study Day 1
Lungs	☐ 0		☐ 0	☐ 1 Unchanged from Study Day 1
Abdomen	☐ 0		☐ 0	☐ 1 Unchanged from Study Day 1
Musculoskeletal	☐ 0		☐ 0	☐ 1 Unchanged from Study Day 1
Peripheral Vascular	☐ 0		☐ 0	☐ 1 Unchanged from Study Day 1
Skin	☐ 0		☐ 0	☐ 1 Unchanged from Study Day 1
Additional Findings:			☐ 1 Unchanged from Study Day 1	

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Laboratory

	Study Day 1	Study Day 2
Name of Lab		
Lab test	**Result**	**Result**
	☐ 1 Not Done	☐ 1 Not Done
Sodium		
Potassium		
Chloride		
BUN		
Creatinine		
Total Protein		
Albumin		
Direct bilirubin		
Total bilirubin		
ALT/SGPT		
AST/SGOT		
LDH		
WBC		
Neutrophils		
Eosinophils		
Basophils		
Lymphocytes		
Monocytes		
Hct%		
Hgb		
Platelets		
INR		
PT		
PTT		

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VISIT VISITNUM VSDTC
Study Day 1 __ / __ /__
mm dd yy

Evaluations and Dosing

Baseline Vital Signs		VSTEST			
Time (24 Hour)	Temp (°F) VSORRESU	HR (per minute)	RR (per minute)	BP (syst/dia)	O_2 Sat (%)
: VSTPT		VSORRES		/	

Weight	Height	Health Questionnaire Score	
		Pre	Post
_____ . ___ Kg	_____ . ___ inches		

	EPOCH	EPOCH
Cohort	Infusion Period # 1	Infusion Period # 2
ARMCD/TRP01P 1 ☐	EXCAT/ARM ☐ 1 Bottle 1.25 mg/kg	EXCAT/ARM ☐ 1 Bottle 1.25 mg/kg
2 ☐	☐ 2 Bag 0.65 mg/kg	☐ 2 Bag 0.65 mg/kg
	☐ 3 Bag, other 0 . __ __ __	☐ 3 Bag, other 0 . __ __ __
	Amount PROD infused	Amount PROD infused
☐ Other ____	_____ . ____ mg EXDOSU	_____ . ____ mg

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VISIT

Study Day 1 Vital Signs

Timepoint VSTPT	Time (24 Hour)	HR (per min)	BP (syst/dia)	O_2 Sat (%)
- 5 minutes	:		/	
0 minutes	:		/	
5 minutes	:		/	
10 minutes	:		/	
15 minutes	:		/	
20 minutes	:		/	
25 minutes	:		/	
30 minutes	:		/	
35 minutes	:		/	
40 minutes	:		/	
45 minutes	:		/	
50 minutes	:		/	
55 minutes	:		/	
60 minutes	:		/	
65 minutes	:		/	
70 minutes	:		/	
End of Infusion Period #2	:			
1 hour after Infusion Period #2	:		/	

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Concomitant Medications

☐ 0 None

	Medication	Dose	Unit	Route	Date (mm / dd / yy)	Time (24 Hour)
1					___/___/___	:
2					___/___/___	:
3					___/___/___	:
4					___/___/___	:
5					___/___/___	:
6					___/___/___	:
7					___/___/___	:
8					___/___/___	:
9					___/___/___	:
10					___/___/___	:
11					___/___/___	:
12					___/___/___	:

☐ Check if subsequent pages

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Report all Serious Adverse Events IMMEDIATELY

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DOMAIN **Adverse Events**

☐ 0 None

	Event Description	AETERM		AESTDTC Onset	AEENDTC Resolution	AESEV Severity	AEREL Relationship to PROD	AEACN/AEACNOTH Actions taken (✓ all applicable)
1		Date (mm/dd/yy)		___/___/___	___/___/___	☐ 1 Mild ☐ 2 Moderate ☐ 3 Severe ☐ 4 Life-threatening	☐ 1 Unrelated ☐ 2 Possibly ☐ 3 Probably ☐ 4 Definitely	☐ 0 None ☐ 1 Treatment ☐ 2 PROD stopped ☐ 3 Discontinued trial ☐ 4 SAE Reported
		Time (24 hour)		:	: ☐ 1 Continuing			
2		Date (mm/dd/yy)		___/___/___	___/___/___	☐ 1 Mild ☐ 2 Moderate ☐ 3 Severe ☐ 4 Life-threatening	☐ 1 Unrelated ☐ 2 Possibly ☐ 3 Probably ☐ 4 Definitely	☐ 0 None ☐ 1 Treatment ☐ 2 PROD stopped ☐ 3 Discontinued trial ☐ 4 SAE Reported
		Time (24 hour)		:	: ☐ 1 Continuing			
3		Date (mm/dd/yy)		___/___/___	___/___/___	☐ 1 Mild ☐ 2 Moderate ☐ 3 Severe ☐ 4 Life-threatening	☐ 1 Unrelated ☐ 2 Possibly ☐ 3 Probably ☐ 4 Definitely	☐ 0 None ☐ 1 Treatment ☐ 2 PROD stopped ☐ 3 Discontinued trial ☐ 4 SAE Reported
		Time (24 hour)		:	: ☐ 1 Continuing			
4		Date (mm/dd/yy)		___/___/___	___/___/___	☐ 1 Mild ☐ 2 Moderate ☐ 3 Severe ☐ 4 Life-threatening	☐ 1 Unrelated ☐ 2 Possibly ☐ 3 Probably ☐ 4 Definitely	☐ 0 None ☐ 1 Treatment ☐ 2 PROD stopped ☐ 3 Discontinued trial ☐ 4 SAE Reported
		Time (24 hour)		:	: ☐ 1 Continuing			

Investigator's Signature

Date

☐ 1 Check if subsequent pages

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USUBJID Subject ID 044 - 1 ☐☐

Subject Initials ☐☐☐

VISIT **Study Day 2**

VSDTC __ / __ /__ (mm dd yy)

Study Completion

Study Completion/Termination

Vital Signs (VSTEST)					
Time (VSTPT) (24 Hour)	Temp (°F) (VSORRESU)	HR (per minute)	RR (per minute)	BP (syst/dia)	O_2 Sat (%)
:		(VSORRES)		/	

Did the subject complete the trial ? ☐1 Yes ☐0 No

If No, please complete the following (✓ all applicable)

Reason for discontinuation		Date mm / dd / yy	
☐1	Adverse Event	___/___/___	event:
☐2	Withdrew consent	___/___/___	reason:
☐3	Lost to follow up	___/___/___	reason:
☐4	Right-to-left cardiac shunt	___/___/___	
☐5	Other	___/___/___	specify:

Summary of Protocol Compliance

Was the protocol followed without deviations? ☐1 Yes ☐0 No

If No, please complete the following (✓ all applicable)

Departures		
☐1	Entrance Criteria not met	specify:
☐2	PROD not administered fully	reason:
☐3	Images not obtained	explain:
☐4	Safety data not obtained or not collected at scheduled time point	explain:
☐5	Other	specify: