CLINICAL STUDY REPORT

Study title:	A Phase 2 open label study to assess the pharmacodynamic and pharmacokinetic properties of a single subcutaneous injection of RUC-4 in patients with a ST-elevation myocardial infarction presenting to the cardiac catheterization lab with planned primary coronary angioplasty
Name of test drug/investigational product:	RUC-4
Indication(s) studied:	First point of medical contact therapy of ST segment elevation myocardial infarction (STEMI)
Name of the sponsor:	CeleCor Therapeutics, Inc. 1155 Camino Del Mar Suite 481 Del Mar, CA 92014
Protocol identification:	CEL-02
Development phase of study:	2
First Subject Enrolled:	3 June 2020
Last Subject Completed:	4 November 2020
Sponsor reference of the report:	CEL-02
Principal investigator or sponsor's responsible medical officer:	Dr. J.M. Ten Berg St. Antonius Hospital Koekoekslaan 1 3435 CM Nieuwegein (NL)
Date of the report:	28 May 2021

This study was performed in compliance with Good Clinical Practice (GCP), including the archiving of essential documents.

Confidentiality statement
Information contained in this report may be unpublished and therefore is confidential in nature, and may not be used, divulged, published, or otherwise disclosed without the express permission of CeleCor Therapeutics, Inc.

SYNOPSIS

Name of sponsor/company: CeleCor Therapeutics, Inc **Name of finished product:** RUC-4 **Name of active ingredient:** RUC-4	**Individual study table referring to part of the dossier** **Volume:** **Page:**	**(*For National Authority use only*)**
Title of study: A Phase 2 open label study to assess the pharmacodynamic and pharmacokinetic properties of a single subcutaneous injection of RUC-4 in patients with a ST-elevation myocardial infarction presenting to the cardiac catheterization lab with planned primary coronary angioplasty		
Investigator: Dr. J.M. Ten Berg		
Study center: St. Antonius Ziekenhuis Koekoekslaan 1, 3435 CM Nieuwegein, The Netherlands		
Publication (reference): Bor WL, Zheng KL, Tavenier AH, et al. Pharmacokinetics, pharmacodynamics, and tolerability of subcutaneous administration of a novel glycoprotein IIb/IIIa inhibitor, RUC-4, in patients with ST-segment elevation myocardial infarction. EuroIntervention. 2021 May 18:EIJ-D-21-00287. doi: 10.4244/EIJ-D-21-00287. Online ahead of print.		
Studied period (years): Date of first subject enrollment: 3 June 2020 Date of last subject completed: 4 November 2020		**Phase of development:** Phase 2

Objectives:

The primary objective was threefold:

- To assess the pharmacodynamics (PD) properties of a single subcutaneous (SC) injection of RUC-4 in ST-elevation myocardial infarction (STEMI) patients presenting to the cardiac catherization lab (CCL) with planned primary coronary angioplasty
- To assess the pharmacokinetics (PK) properties of a single SC injection of RUC-4 in STEMI patients presenting to the CCL with planned primary coronary angioplasty
- To assess safety and tolerability of RUC-4

The secondary objectives were the following:

- To assess platelet count at select time points before and after RUC-4 administration
- To assess bleeding events (according to [Bleeding Academic Research Consortium] BARC II, III and V criteria for safety assessment and according to International Society on Thrombosis and Haemostasis [ISTH] Major and Thrombolysis in Myocardial Infarction [TIMI] Major for information only) of a single SC injection of RUC-4 at select time points after RUC-4 administration, discharge and at 15-day and at 30-day follow-up
- To assess intraprocedural thrombosis
- To assess the injection site reactions of a single SC injection of RUC-4 at select time points after RUC-4 administration and at 15-day and at 30-day follow-up
- To evaluate any differences in PD or PK within each treatment group (gender, weight, body mass index [BMI], age)

Methodology:

This was an open-label single center Phase 2 study to evaluate the PD, PK, safety and tolerability of a single SC injection of RUC-4 in subjects with STEMI presenting to the CCL with planned primary coronary angioplasty. This study was conducted in subjects with documented STEMI with onset of the cardiac ischemic symptoms within the 6 hours before enrollment and for whom fast revascularization was a major objective for improving prognosis. Subjects were evaluated for study entry in the CCL. If the eligibility criteria were met, witnessed verbal informed consent was obtained and the subject enrolled in the study was assigned to a treatment cohort in sequential order. To each cohort, 8 subjects were planned to be assigned.

Subjects in Cohort 1, 2 and 3 received a single dose of RUC-4 of 0.075 mg/kg, 0.090 mg/kg, or 0.110 mg/kg, respectively, in the CCL before coronary angiography/percutaneous coronary intervention (PCI).

Blood samples for PD assessments, the thrombin-receptor activating peptide (TRAP)- and ADP-induced platelet aggregation assessed by VerifyNow, were collected up to 180 minutes (Cohort 1) or 240 minutes (Cohorts 2 and 3) post RUC-4 administration. Blood samples for the PK analysis of RUC-4 were collected up to 180 minutes post RUC-4 administration. Safety assessments, including adverse events (AEs) recording, clinical laboratory

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measurements, vital signs, bleeding events, injection site reactions, intraprocedural thrombosis and electrocardiogram (ECG) recording were measured up to 72 hours post RUC-4 administration or up to hospital discharge, whichever occurred first. Before hospital discharge, written informed consent was obtained.
A follow-up phone call was conducted at 15 and 30 days after RUC-4 administration.

Number of subjects (planned and analyzed):

	RUC-4			
	0.075 mg/kg	**0.090 mg/kg**	**0.110 mg/kg**	**Total**
Planned	8	8	8	24
Safety Population	8 (100%)	9 (100%)	10 (100%)	27 (100%)
PK Population	8 (100%)	9 (100%)	8 (80%)	25 (92.6%)
PD Population	8 (100%)	8 (88.8%)	8 (80%)	24 (88.8%)

Diagnosis and main criteria for inclusion:

1. Subjects with STEMI, presenting with persistent chest pain (>30 min) and ≥1 mm ST segment elevation in two adjacent electrocardiograph leads, with >6 mm cumulative ST segment deviation, in whom the total duration of symptoms to first intracoronary device deployment (excluding a wire) was anticipated to be within 6 hours
2. Adult males and females 18 years of age or older
3. Females must be non-pregnant, non-lactating, and of non-childbearing potential (postmenopausal or surgically sterilized) by history and review of medical record
4. Weight (by history) of between 52 and 120 kg
5. Written informed consent (following short-form of the informed consent form [ICF] at CCL)

Test product, dose and mode of administration, batch number:
All subjects received a single SC dose of RUC-4 in the CCL before coronary angiography/PCI. Cohorts 1, 2, and 3 received a RUC-4 dose of, respectively, 0.075, 0.090, and 0.110 mg/kg.
Batch numbers: Lot 088I1118

Duration of treatment:
One month (± 7 days) including enrollment into study, dosing and follow-up at 15 and 30 days post RUC-4 administration.

Reference therapy, dose and mode of administration, batch number:
Not applicable.

Criteria for evaluation:
Pharmacokinetics:

Blood concentrations of RUC-4 and metabolite RUC-4-Del-Glycine and RUC-4 concentration derived PK parameters (area under the curve from time zero extrapolated to infinity [$AUC_{0\text{-}inf}$], area under the curve from time zero to time of last quantifiable concentration [$AUC_{0\text{-}last}$], maximum observed blood concentration [C_{max}], terminal phase elimination rate constant [K_{el}], apparent terminal half-life [$t_{1.2}$], time required to reach maximum blood concentration [t_{max}]).

Pharmacodynamics:

VerifyNow tests to assess response to TRAP-, ADP- and TRAP-PAR-4-induced platelet aggregation.

Safety:

Evaluation of treatment-emergent adverse events (TEAEs), treatment-emergent serious adverse events (TESAEs), clinical laboratory parameters, bleeding events, injection site reactions, intraprocedural thrombosis, and ECG recordings.

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Statistical methods:

Endpoints:

The primary study endpoints were the following:

- Inhibition of TRAP-induced platelet aggregation (%) assessed by VerifyNow at baseline, and at 15, 45, 60, 90, 120, 180 and 240 minutes after administration of RUC-4 (the 240 minute timepoint was only applicable if the RUC-4 dose was increased in Cohort 2 and/or 3)
- RUC-4 concentration (ng/mL) versus time profiles (at baseline and at 15, 45, 90, 120 and 180 minutes after administration of RUC-4) and associated PK parameters
- Safety and tolerability parameters at baseline and at hospital discharge

The secondary study endpoints were the following:

- Platelet count (µL) at baseline, and at 15, 45, 90, 120 and 180 minutes after administration of RUC-4 and at hospital discharge
- Bleeding events (according to BARC II, III and V criteria for safety assessment and according to ISTH Major and TIMI Major criteria for information only) at baseline, discharge and at 15-day and at 30-day follow-up
- Intraprocedural thrombosis (assessed by Principal Investigator [PI])
- Injection site reactions at baseline, 1-hour post-PCI, hospital discharge, and at 15-day and at 30-day follow-up
- Inhibition of ADP-induced platelet aggregation (%) assessed by VerifyNow at baseline, and at 15, 45, 60, 90, 120, 180 and 240 minutes after administration of RUC-4 (the 240 minute timepoint was only applicable if the RUC-4 dose was increased in cohort 2 and/or 3)
- Differences in PD or PK among the subjects (gender, weight, BMI, age)

Statistical Analyses:

Pharmacokinetic parameters :descriptive statistics
Pharmacodynamics :descriptive statistics
Safety parameters :descriptive statistics

SUMMARY - CONCLUSIONS

PHARMACOKINETIC RESULTS:

Following a single SC dose of RUC-4, the mean blood concentration-time profiles showed a rapid increase in RUC-4 blood concentration after drug administration, with maximum mean plasma concentrations being reached 15 minutes or 45 minutes post-dose. Thereafter blood concentrations decreased gradually.

For all subjects, the RUC-4-Des-Glycine metabolite blood concentrations were below the limit of quantification (BLQ) at all time points, except for 1 subject in the 0.075 mg/kg group at time point 90 minutes post-dose and 1 subject in the 0.090 mg/kg group at time points 45, 90, and 120 minutes post-dose.

Corrected RUC-4 PK parameters are presented in the table below.

	RUC-4		
Time Point	**0.075 mg/kg (N=8)**	**0.090 mg/kg (N=9)**	**0.110 mg/kg (N=9)**
$AUC_{0\text{-}inf}$ (h*ng/mL)			
Mean (SD)	108.20 (21.75)	161.74 (120.95)	145.82 (51.41)
CV (%)	20.10	74.78	35.25
Geometric Mean[a]	106.27	136.85	139.28
Geometric CV (%)[a]	20.67	61.77	31.51
Median (Q1 - Q3)	105.16 (94.12 - 123.94)	132.70 (111.91 - 156.68)	137.42 (108.33 - 155.06)
Min - Max	76.82 - 142.36	57.28 - 470.20	103.12 - 263.60
N (Nmiss)	8 (0)	9 (0)	9 (0)
$AUC_{0\text{-}last}$ (h*ng/mL)			
Mean (SD)	96.02 (24.30)	152.59 (122.93)	122.57 (40.59)

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CV (%)	25.31	80.56	33.12
Geometric Mean[a]	93.39	126.20	117.74
Geometric CV (%)[a]	25.61	66.12	29.37
Median (Q1 - Q3)	96.17 (75.22 - 113.00)	124.03 (99.88 - 141.52)	109.43 (95.25 - 128.28)
Min - Max	66.20 - 133.20	52.43 - 466.61	87.19 - 217.23
N (Nmiss)	8 (0)	9 (0)	9 (0)
C_{max} (ng/mL)			
Mean (SD)	96.69 (26.01)	152.39 (113.98)	135.61 (27.92)
CV (%)	26.90	74.79	20.59
Geometric Mean[a]	93.63	131.04	133.02
Geometric CV (%)[a]	27.70	55.30	21.24
Median (Q1 - Q3)	91.25 (74.50 - 121.50)	123.00 (97.50 - 146.00)	135.00 (119.00 - 148.00)
Min - Max	66.00 - 133.00	82.00 - 448.00	96.50 - 182.00
N (Nmiss)	8 (0)	9 (0)	9 (0)
$t_{1/2}$ (hours)			
Mean (SD)	0.95 (0.54)	0.66 (0.24)	1.21 (0.57)
CV (%)	57.34	35.76	47.24
Geometric Mean[a]	0.85	0.61	1.11
Geometric CV (%)[a]	48.41	45.75	44.03
Median (Q1 - Q3)	0.72 (0.66 - 1.07)	0.71 (0.49 - 0.83)	1.05 (0.79 - 1.40)
Min - Max	0.51 - 2.20	0.26 - 0.95	0.73 - 2.49
N (Nmiss)	8 (0)	9 (0)	9 (0)
t_{max} (hours)			
Mean (SD)	0.25 (0.01)	0.42 (0.25)	0.30 (0.17)
CV (%)	3.04	60.03	56.38
Geometric Mean[a]	0.25	0.36	0.28
Geometric CV (%)[a]	2.99	59.52	39.22
Median (Q1 - Q3)	0.25 (0.25 - 0.26)	0.25 (0.25 - 0.75)	0.25 (0.25 - 0.25)
Min - Max	0.25 - 0.27	0.23 - 0.75	0.22 - 0.75
N (Nmiss)	8 (0)	9 (0)	9 (0)

$AUC_{0\text{-}inf}$: area under the curve from time zero extrapolated to infinity; $AUC_{0\text{-}last}$ = area under the curve from time zero to time of last quantifiable concentration; C_{max} = maximum concentration; CV = coefficient of variation; Max = maximum; Min = minimum; Nmiss = number of subjects with missing data; PK = pharmacokinetic; Q1 = 25th percentile; Q3 = 75th percentile; SD = standard deviation; $t_{1/2}$ = terminal phase elimination half-life; t_{max} = time to maximum concentration

[a] Analysis was performed on log-transformed values. Geometric mean was converted to the original scale by taking the anti-log.

One subject (Subject 01206, 0.090 mg/kg group) showed outlier PK and PD values compared to the PK parameter values of the other subjects in the 0.090 mg/kg group. This subject showed sustained induced platelet aggregation inhibition compared to the other subjects in this group. The $AUC_{0\text{-}inf}$, $AUC_{0\text{-}last}$, and C_{max} of Subject 01206 were approximately 3 times higher than the mean values of the 0.090 mg/kg treatment group (471.8 h*ng/mL, 466.0 h*ng/mL, and 447.5 ng/mL, respectively, compared to mean values of 161.7 h*ng/mL, 152.6 h*ng/mL, and 152.4 ng/mL, respectively). The t_{max} and $t_{1/2}$ of Subject 01206 (0.75 h and 0.42 h, respectively) did fall within the ranges of the treatment group (ranges 0.23 - 0.75 h and 0.26 - 0.95 h, respectively). No obvious explanation has been found for these outlier values.

PHARMACODYNAMIC RESULTS:

RUC-4 antiplatelet effects began rapidly and then diminished over the next 2-3 hours. TRAP-induced platelet aggregation at 15 minutes post-dose was inhibited ≥77% (the value that correlates with ≥80% inhibition of light transmission aggregometry initiated by 20 µM ADP) in 3/8 subjects (37.5%) in the 0.075 mg/kg group, and in 7/8 subjects (87.5%) in the 0.090 mg/kg and 0.110 mg/kg groups. Therefore, it can be suggested that the BED in subjects with STEMI is similar to the BED in healthy subjects and patients with stable CAD on aspirin (~0.075 mg/kg RUC-4 as determined in the previous Phase 1 study [CEL-01]). About 50% inhibition was reached between 90-120 minutes post-dose. This length of time during which there is high-grade platelet function inhibition is shorter than the times when the current αIIbβ3 receptor antagonists are used as approved. This may decrease the risk of hemorrhage.

At 90 minutes post-dose, ≥50% inhibition of TRAP-induced platelet aggregation was observed in approximately 70% of the subjects in total (in 4/8 subjects [50%] in the 0.075 mg/kg group, 6/8 subjects [75%] in the 0.090 mg/kg group, and 7/8 subjects [87.5%] in the 0.110 mg/kg group). The mean inhibition in the treatment groups

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ranged from 48.8% to 60.4%.

The whole blood levels of RUC-4 correlated closely with the inhibition from baseline of VerifyNow TRAP-induced platelet function.

The prespecified endpoint was 50% or greater platelet function inhibition (TRAP+PAR-4-induced platelet) at 120 minutes following RUC-4 administration. At 90 minutes post-dose, ≥50% inhibition of TRAP+PAR-4-induced platelet was observed in 2/8 subjects (25%) in the 0.075 mg/kg group, 4/8 subjects (50%) in the 0.090 mg/kg group, and 5/7 subjects (62.5%) in the 0.110 mg/kg group. At 120 minutes post-dose, ≥50% inhibition of TRAP+PAR-4-induced platelet was observed in 2/8 subjects (25%) in the 0.090 mg/kg group and 1/8 subject (12.5%) in the 0.110 mg/kg group.

Subject's gender, weight, BMI, and age and ticagrelor pretreatment time had no relevant effect on the percentage inhibition from baseline of VerifyNow TRAP-induced and TRAP+PAR-4-induced platelet aggregation as measured at 15 and 120 minutes after RUC-4 administration.

After RUC-4 administration, the mean percentage inhibition of ADP-induced platelet aggregation at 15 minutes post-dose was 90.6% in the 0.075 mg/kg group, 94.3% in the 0.090 mg/kg group and 90.9% in the 0.110 mg/kg group. Thereafter, the percentage inhibition from baseline decreased up to 120 minutes post-dose to approximately 65% and remained more or less stable up to 240 minutes post-dose.

SAFETY RESULTS:

In total, 49 TEAEs were experienced by 25 subjects (8 subjects [100%] in the 0.075 mg/kg group, 7 subjects [77.78%] in the 0.090 mg/kg group, and 10 subjects [100%] in the 0.110 mg/kg group). Most TEAEs were assessed by the investigator as Grade 1 or 2 in severity.

The most frequently reported TEAEs were injection site bruising (reported by 11 subjects [40.74%] and vascular access site hematoma (reported in 8 subjects [29.63%]).

In total, 20 treatment related TEAEs were experienced by 17 subjects. These were injection site bruising (reported by 11 subjects [40.74%], all of Grade 1 severity), vascular access site hematoma (reported in 8 subjects [29.63%] and of Grade 1 to 3 severity), and injection site pain (reported by 1 subject [3.7%] and of Grade 1 severity).

Eight (8) subjects (29.63%) experienced one or more TESAEs. The most frequently reported TESAEs were vascular access site hematoma and cardiac failure (each reported in 2 subjects [7.41%]). All TESAEs were considered not related to the study drug, except for the 2 events of vascular access site hematoma. The 2 events of vascular access site hematoma, one experienced in the 0.075 mg/kg group and one in the 0.110 mg/kg group, were assessed as Grade 3. Both events occurred during the PCI procedure and were most probably caused by a vascular wall injury that occurred during the PCI procedure.

No subjects withdrew from the study or died during the study due to a TEAE.

Seventeen subjects (63.0%) had one or more bleeding events during the study. Most bleeding events were injection site bruising (reported by 11 subjects [40.7%]), and vascular access site hematoma (reported by 8 subjects [29.6%]).

One subject (11.1%) in the 0.090 mg/kg group experienced an injection site reaction (mild tenderness), which started 6 days after study drug administration.

None of the subjects experienced intraprocedural thrombosis or developed thrombocytopenia. Platelet counts were decreased on average by 3% at 1 hour post-dose and by 9% and 8% at 24 and 72 hours post-dose, respectively. Since none of the subjects developed thrombocytopenia, these changes are not considered clinically relevant.

There were no clinically relevant changes noted with respect to clinical laboratory evaluations and ECGs.

Overall, a single SC dose of RUC-4 in doses from 0.075 to 0.110 mg/kg administered to subjects with STEMI

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presenting to the CCL with planned primary coronary angioplasty was generally safe and well-tolerated.

CONCLUSION:

Following a single SC dose of RUC-4, the mean RUC-4 blood concentration increased rapidly, with a median t_{max} of RUC-4 of 0.25 hours for the RUC-4 0.075, 0.090 and 0.110 mg/kg doses. The mean $t_{1/2}$ ranged from 0.66 to 1.21 hours. Blood concentrations of metabolite RUC-4-Des-Glycine were BLQ in the vast majority of the subjects.

The whole blood levels of RUC-4 correlated closely with the inhibition from baseline of VerifyNow TRAP-induced platelet function.

In subjects with STEMI, a single SC dose of RUC-4 ranging from 0.075 to 0.110 mg/kg produced a dose dependent response of maximal platelet function inhibition within 15 minutes and returned to baseline within approximately 120 minutes. At 15 minutes post-dose, TRAP-induced platelet aggregation was inhibited for ≥77% in 3/8 subjects (37.5%) in the 0.075 mg/kg group, and in 7/8 subjects (87.5%) in the 0.090 mg/kg and 0.110 mg/kg groups. The mean inhibition in the treatment groups ranged from 77.5% to 91.7%.

Platelet inhibition declined after 15 minutes post-dose, reaching 50% platelet inhibition between 90 and 120 minutes post-dose. At 90 minutes post-dose, ≥50% inhibition of TRAP-induced platelet aggregation was observed in approximately 70% of the subjects in total (in 4/8 subjects [50%] in the 0.075 mg/kg group, 6/8 subjects [75%] in the 0.090 mg/kg group, and 7/8 subjects [87.5%] in the 0.110 mg/kg group). The mean inhibition in the treatment groups ranged from 48.8% to 60.4%.

At 15 minutes post-dose, TRAP+PAR-4-induced platelet aggregation was inhibited for ≥77% in 7/8 subject (87.5%) in the 0.075 mg/kg group, and in all subjects (100%) in the 0.090 mg/kg and 0.110 mg/kg groups. The mean inhibition in the treatment groups ranged from 86.0% to 93.0%.

At 90 minutes post-dose, ≥50% inhibition of TRAP+PAR-4-induced platelet aggregation was observed in approximately 45% of the subjects (in 2/8 subjects [25%] in the 0.075 mg/kg group, 4/8 subjects [50%] in the 0.090 mg/kg group, and 5/8 subjects [62.5%] in the 0.110 mg/kg group). The mean inhibition in the treatment groups ranged from 41.7% to 56.4%.

Subject's gender, weight, BMI, age, and ticagrelor pretreatment time had no relevant effect on the percentage inhibition from baseline of VerifyNow TRAP-induced and TRAP+PAR-4-induced platelet aggregation as measured at 15 and 120 minutes after RUC-4 administration.

After RUC-4 administration, the mean percentage inhibition of ADP-induced platelet function at 15 minutes post-dose was 90.6% in the 0.075 mg/kg group, 94.3% in the 0.090 mg/kg group and 90.9% in the 0.110 mg/kg group. Thereafter, the percentage inhibition from baseline decreased through 120 minutes post-dose to approximately 65% and remained more or less stable up to 240 minutes post-dose. The latter inhibition reflected the effect of ticagrelor since the effect of RUC-4 was minimal at that time as judged by the TRAP-based assays. The inability of ticagrelor to inhibit the TRAP+PAR-4 assay at 240 minutes, when it was at or near its peak effect, contrasts sharply with the profound impact of RUC-4 on this assay at 15 minutes, demonstrating the greater impact of RUC-4 on inhibiting platelet function.

The majority of bleeding and injection site bruising events were Grade 1 or 2 in severity. Two TESAEs with BARC 3a and 3b bleeding were judged to be probably related to RUC-4, but definitely related to the PCI as a result of wire- or catheter-induced arterial injury. It is not possible to definitely assess the contribution of RUC-4 to the bleeding since the arterial injury and the concomitant administration of heparin, aspirin, and ticagrelor also contributed.

Overall, a single SC dose of RUC-4 in doses from 0.075 to 0.110 mg/kg administered to subjects with STEMI presenting to the CCL with planned primary coronary angioplasty produced consistent high-grade inhibition of platelet function within 15 minutes and was generally safe and well-tolerated. Importantly, thrombocytopenia did not occur in STEMI patients following a single SC dose of RUC-4.

Date of the report:
28 May 2021