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Sponsor

Novartis Pharmaceuticals

Generic Drug Name

MHU650

Trial Indication(s)

Macular edema from diabetic macular edema (DME), neovascular age-related macular degeneration (nAMD), or retinal vein occlusion (RVO)

Protocol Number

CMHU650A12101

Protocol Title

A first-in-human, open-label, single ascending dose study to assess safety and tolerability of intravitreal MHU650 in participants with macular edema from diabetic macular edema (DME), neovascular age-related macular degeneration (nAMD), or retinal vein occlusion (RVO)

Clinical Trial Phase

Phase 1

Phase of Drug Development

Phase I

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Study Start/End Dates

Study Start Date: December 10, 2020 (Actual)
Primary Completion Date: May 24, 2022 (Actual)
Study Completion Date: May 24, 2022 (Actual)

Reason for Termination (If applicable)

Not applicable

Study Design/Methodology

This was an open-label, multi-center, FIH study with a single ascending dose (SAD) design that assessed the safety, tolerability and pharmacokinetics (PK) of a single intravitreal (IVT) dose of MHU650 in up to 24 participants with macular edema.

A total of up to 4 cohorts were planned to be enrolled, with an optional additional lower or intermediate cohort of participants.

Centers

United States(6)

Objectives:

Primary: To evaluate the safety and tolerability of a single IVT dose of MHU650 in participants with macular edema.

Secondary: To evaluate the serum pharmacokinetic profile of total MHU650 following a single IVT dose of MHU650 in participants with macular edema.

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Test Product (s), Dose(s), and Mode(s) of Administration

MHU650 30mg powder for solution for intravitreal (IVT) injection with the four doses of 0.25, 0.75, 2.5 or 7.5 mg were investigated in this study. Following safety review of all data from a given cohort, dose escalation to the next dose was performed.

Statistical Methods

Study endpoints were analyzed and presented using descriptive statistics. Continuous variables were summarized with the number of observations, mean, standard deviation, median, minimum, and maximum. Categorical variables were summarized with the number of observations and the numbers and percent from each category.

Study Population: Key Inclusion/Exclusion Criteria

Key Inclusion Criteria:

- Patients with macular edema in at least one eye, including those with focal or diffuse diabetic macular edema (DME), neovascular age-related macular degeneration (nAMD), or retinal vein occlusion (RVO). In the opinion of the investigator, the decrease in vision in the study eye must be due to macular edema.
- Early Treatment Diabetic Retinopathy (ETDRS) letter score in the study eye must equal to or worse than 60 letters (approximately Snellen equivalent of 20/63) but better than 14 letters (20/500) at screening and baseline. The ETDRS score in the non-study eye should be ≥ 60 letters at screening and baseline.
- Sufficiently clear ocular media and adequate pupil dilation to permit fundus photographs of adequate clarity to measure diameters of retinal arteries and veins
- Vital signs as specified in the protocol

Key Exclusion Criteria:

- Concomitant conditions or ocular disorders in the study eye which may, in the opinion of the investigator, confound the interpretation of study results, compromise visual acuity or require medical or surgical intervention during the study period
- High risk and/or/ active proliferative diabetic retinopathy in the study eye, as per investigator assessment at both screening and

baseline.
-Participants with the following conditions in the study eye at screening or baseline must be excluded: structural damage of the fovea, vitreous hemorrhage, retinal detachment, vitreomacular traction, macular hole, retinal arterial occlusion, neovascularization of iris of any cause.
- Laser photocoagulation (macular or panretinal) in the study eye during the 6-month period prior to baseline.
- Patients with type 1or type 2 diabetes who have hemoglobin A1C of ≥ 12 at screening
- Other ocular conditions as specified in the protocol
- Systemic conditions as specified in the protocol

Participant Flow Table

Overall Study

	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg	Total
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg	
Started	3	3	6	9	21
Completed	3	3	6	9	21
Not Completed	0	0	0	0	0

Baseline Characteristics

	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg	Total
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg	
Number of Participants [units: participants]	3	3	6	9	21
Baseline Analysis Population Description					
Age Continuous (units: Years)					

Analysis Population Type: Participants
Mean ± Standard Deviation

	60.0±4.58	64.3±11.85	61.3±7.63	67.0±8.51	64.0±8.26
Sex: Female, Male (units: Participants) Analysis Population Type: Participants Count of Participants (Not Applicable)					
Female	2	1	2	3	8
Male	1	2	4	6	13
Race/Ethnicity, Customized (units: Participants) Analysis Population Type: Participants Count of Participants (Not Applicable)					
White	2	2	6	7	17
Asian	1	1	0	2	4
Japanese	1	0	0	1	2
Vietnamese	0	1	0	0	1
Ethnicity (NIH/OMB) (units: Participants) Analysis Population Type: Participants Count of Participants (Not Applicable)					
Hispanic or Latino	0	2	5	3	10
Not Hispanic or Latino	3	1	1	6	11
Unknown or Not Reported	0	0	0	0	0

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Primary Outcome Result(s)

Overall incidence of adverse events

Description	An adverse event (AE) is any untoward medical occurrence (e.g. any unfavorable and unintended sign [including abnormal laboratory findings], symptom or disease) in a clinical investigation participant after providing written informed consent for participation in the study.
Time Frame	Adverse events were reported from the single dose of study-drug treatment until end of study (Day 60), plus 30 Days for SAE reporting, for a maximum timeframe of 90 days.
Analysis Population Description	Safety analysis set

	MHU650 0.25 mg	**MHU650 0.75 mg**	**MHU650 2.5 mg**	**MHU650 7.5 mg**
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Number of Participants Analyzed [units: participants]	3	3	6	9
Overall incidence of adverse events (units: Participants)	**Count of Participants (%)**	**Count of Participants (%)**	**Count of Participants (%)**	**Count of Participants (%)**
AEs, Subjects with AEs	2 (66.67%)	1 (33.33%)	3 (50%)	4 (44.44%)
AEs of Mild intensity	1 (33.33%)	1 (33.33%)	3 (50%)	3 (33.33%)
AEs of Moderate intensity	1 (33.33%)	0 (%)	0 (%)	1 (11.11%)
AEs of Severe intensity	0 (%)	0 (%)	0 (%)	1 (11.11%)
Study drug-related AEs	1 (33.33%)	0 (%)	0 (%)	1 (11.11%)
Study Procedure-related AEs	1 (33.33%)	0 (%)	2 (33.33%)	1 (11.11%)
Serious AEs	0 (%)	0 (%)	0 (%)	1 (11.11%)

Non-Serious AEs	2 (66.67%)	1 (33.33%)	3 (50%)	4 (44.44%)

Number of participants with ocular adverse events - Study Eye

Description	An adverse event (AE) is any untoward medical occurrence (e.g. any unfavorable and unintended sign [including abnormal laboratory findings], symptom or disease) in a clinical investigation participant after providing written informed consent for participation in the study.
Time Frame	Adverse events were reported from the single dose of study-drug treatment until end of study (Day 60), plus 30 Days for SAE reporting, for a maximum timeframe of 90 days.
Analysis Population Description	Safety analysis set

	MHU650 0.25 mg	**MHU650 0.75 mg**	**MHU650 2.5 mg**	**MHU650 7.5 mg**
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Number of Participants Analyzed [units: participants]	3	3	6	9
Number of participants with ocular adverse events - Study Eye (units: Participants)	**Count of Participants (%)**	**Count of Participants (%)**	**Count of Participants (%)**	**Count of Participants (%)**
Number of subjects with at least one AE	1 (33.33%)	1 (33.33%)	2 (33.33%)	3 (33.33%)
Eye disorders	1 (33.33%)	1 (33.33%)	2 (33.33%)	3 (33.33%)
Choroidal detachment	0 (%)	0 (%)	0 (%)	1 (11.11%)
Conjunctival hemorrhage	1 (33.33%)	0 (%)	2 (33.33%)	2 (22.22%)
Conjunctival hyperaemia	0 (%)	0 (%)	1 (16.67%)	0 (%)
Macular oedema	0 (%)	1 (33.33%)	0 (%)	0 (%)

Retinal vein occlusion	0 (%)	0 (%)	0 (%)	1 (11.11%)
Serous retinal detachment	0 (%)	0 (%)	0 (%)	1 (11.11%)
Uveitis	0 (%)	0 (%)	0 (%)	1 (11.11%)

Non-ocular adverse events

Description	An adverse event (AE) is any untoward medical occurrence (e.g. any unfavorable and unintended sign [including abnormal laboratory findings], symptom or disease) in a clinical investigation participant after providing written informed consent for participation in the study.
Time Frame	Adverse events were reported from the single dose of study-drug treatment until end of study (Day 60), plus 30 Days for SAE reporting, for a maximum timeframe of 90 days.
Analysis Population Description	Safety analysis set - see Adverse Event Tables for further details

	MHU650 0.25 mg	**MHU650 0.75 mg**	**MHU650 2.5 mg**	**MHU650 7.5 mg**
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Number of Participants Analyzed [units: participants]	3	3	6	9
Non-ocular adverse events (units: Participants)	**Count of Participants (%)**	**Count of Participants (%)**	**Count of Participants (%)**	**Count of Participants (%)**
Number of subjects with at least one AE	2 (66.67%)	0 (%)	1 (16.67%)	1 (11.11%)

Summary of change from baseline in BCVA (number of letters) by dose level and timepoint D2, D29 and EOS - Study Eye

Description	Best Correct Visual Acuity (BCVA) was assessed using Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity testing charts.
Time Frame	Day 1 to Day 60

Analysis Population Description: Safety analysis set

	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Number of Participants Analyzed [units: participants]	3	3	6	9
Summary of change from baseline in BCVA (number of letters) by dose level and timepoint D2, D29 and EOS - Study Eye (units: Number of letters)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Day 2	2.3 ± 4.04	13.7 ± 3.79	7.0 ± 3.74	3.4 ± 7.30
Day 15	7.3 ± 3.06	18.0 ± 11.14	14.2 ± 9.37	5.6 ± 8.89
Day 29	8.3 ± 4.04	20.3 ± 8.02	13.0 ± 10.88	8.6 ± 11.75
EOS / Day 60	7.0 ± 6.56	19.3 ± 11.15	15.5 ± 11.00	6.3 ± 19.31

Summary of change from baseline in Central subfield thickness (CSFT) (µm) in the study eye by dose level and timepoint

Description

Time Frame: Day 1 through Day 60

Analysis Population Description: Safety analysis set

	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg

Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Number of Participants Analyzed [units: participants]	3	3	6	9
Summary of change from baseline in Central subfield thickness (CSFT) (µm) in the study eye by dose level and timepoint (units: µm)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Day 5	-14.9 ± 19.65	-182.0 ± 293.71	-10.2 ± 14.35	-114.7 ± 142.28
Day 15	-27.9 ± 18.05	-178.9 ± 325.27	-21.5 ± 18.62	-115.2 ± 162.82
Day 29	-96.5 ± 85.07	-170.6 ± 252.47	-7.1 ± 51.98	-78.6 ± 93.13
EOS / Day 60	-124.5 ± 141.38	-119.4 ± 134.03	-7.9 ± 40.66	-67.5 ± 120.86

Summary of change from baseline in Intraocular pressure (IOP) (mmHg) in the study eye by dose level and timepoint

Description

Time Frame: Day 1 through Day 60

Analysis Population Description: Safety analysis set. No AEs related to deviations in IOP were reported for any patients in the study.

	MHU650 0.25 mg	**MHU650 0.75 mg**	**MHU650 2.5 mg**	**MHU650 7.5 mg**
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Number of Participants Analyzed [units: participants]	3	3	6	9
Summary of change from baseline in Intraocular pressure (IOP) (mmHg) in the study eye by dose level and timepoint (units: mmHg)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Day 2	-1.0 ± 1.73	-2.0 ± 4.36	-1.0 ± 2.61	-1.2 ± 2.77

Day 5	-0.3 ± 0.58	1.3 ± 5.69	-0.3 ± 2.07	-1.1 ± 2.20
Day 15	-1.3 ± 0.58	-1.3 ± 1.53	0.7 ± 2.66	-1.9 ± 1.54
Day 29	2.0 ± 1.00	-2.0 ± 5.29	-1.3 ± 1.63	-1.2 ± 1.79
Day 43	-1.0 ± 1.00	1.0 ± 2.00	0.0 ± 1.79	-1.0 ± 2.35
EOS / Day 60	0.7 ± 1.15	0.7 ± 3.51	1.7 ± 1.75	-3.2 ± 3.99

Secondary Outcome Result(s)

Pharmacokinetics of single dose of MHU650 - Tmax - Mean

Description	Assess serum PK profile of MHU650 by Tmax (if feasibile)
Time Frame	Days 1, 2, 5, 15, 29, 43 and 60
Analysis Population Description	PK analysis set

	MHU650 0.25 mg	**MHU650 0.75 mg**	**MHU650 2.5 mg**	**MHU650 7.5 mg**
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Number of Participants Analyzed [units: participants]	0	0	6	9
Pharmacokinetics of single dose of MHU650 - Tmax - Mean (units: hour)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
			12.5 ± 11.1	68.9 ± 40.1

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Pharmacokinetics of single dose of MHU650 - Tmax - Geo-Mean

Description	Assess serum PK profile of MHU650 by Tmax (if feasibile)
Time Frame	Days 1, 2, 5, 15, 29, 43 and 60
Analysis Population Description	PK analysis set

	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Number of Participants Analyzed [units: participants]	0	0	0	9
Pharmacokinetics of single dose of MHU650 - Tmax - Geo-Mean (units: hour)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
				49.9 (151.6%)

Pharmacokinetics of single dose of MHU650 - Cmax - Mean

Description	Assess serum PK profile of MHU650 by Cmax (if feasibile)
Time Frame	Days 1, 2, 5, 15, 29, 43 and 60
Analysis Population Description	PK analysis set

	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Number of Participants Analyzed [units: participants]	0	0	6	9

Pharmacokinetics of single dose of MHU650 - Cmax - Mean (units: ng/mL)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
			46.4 ± 37.3	122 ± 65.9

Pharmacokinetics of single dose of MHU650 - Cmax - Geo-Mean

Description	Assess serum PK profile of MHU650 by Cmax (if feasibile)
Time Frame	Days 1, 2, 5, 15, 29, 43 and 60
Analysis Population Description	PK analysis set

	MHU650 0.25 mg	**MHU650 0.75 mg**	**MHU650 2.5 mg**	**MHU650 7.5 mg**
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Number of Participants Analyzed [units: participants]	0	0	0	9
Pharmacokinetics of single dose of MHU650 - Cmax - Geo-Mean (units: ng/mL)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
				104 (74.9%)

Pharmacokinetics of single dose of MHU650 - AUClast - Mean

Description	Assess serum PK profile of MHU650 by AUClast (if feasibile)
Time Frame	Days 1, 2, 5, 15, 29, 43 and 60
Analysis Population Description	PK analysis set

	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Number of Participants Analyzed [units: participants]	0	0	5	9
Pharmacokinetics of single dose of MHU650 - AUClast - Mean (units: h*ng/mL)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
			3500 ± 2870	20000 ± 11100

Pharmacokinetics of single dose of MHU650 - AUClast - Geo-Mean

Description: Assess serum PK profile of MHU650 by AUClast (if feasibile)

Time Frame: Days 1, 2, 5, 15, 29, 43 and 60

Analysis Population Description: PK analysis set

	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Number of Participants Analyzed [units: participants]	0	0	5	9
Pharmacokinetics of single dose of MHU650 - AUClast - Geo-Mean (units: h*ng/mL)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
			2800 (81.6%)	14700 (138.5%)

Pharmacokinetics of single dose of MHU650 - AUCinf

Description: Assess serum PK profile of MHU650 by AUCinf (if feasibile)

Time Frame	Days 1, 2, 5, 15, 29, 43 and 60
Analysis Population Description	PK analysis set - There were an insufficient number of quantifiable timepoints to permit an estimation of the AUCinf.

	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Number of Participants Analyzed [units: participants]	0	0	0	0
Pharmacokinetics of single dose of MHU650 - AUCinf (units:)	()	()	()	()

Pharmacokinetics of single dose of MHU650 - T1/2

Description	Assess serum PK profile of MHU650 by T1/2 (if feasibile)
Time Frame	Days 1, 2, 5, 15, 29, 43 and 60
Analysis Population Description	PK analysis set - There were an insufficient number of quantifiable timepoints to permit an estimation of the systemic half-life of MHU650

	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg
Number of Participants Analyzed [units: participants]	0	0	0	0
Pharmacokinetics of single dose of MHU650 - T1/2 (units:)	()	()	()	()

Summary of Safety

Safety Results

Time Frame	Adverse events were reported from the single dose of study-drug treatment until end of study (Day 60), plus 30 Days for SAE reporting, for a maximum timeframe of 90 days.
Source Vocabulary for Table Default	MedDRA (25.0)
Collection Approach for Table Default	Systematic Assessment

All-Cause Mortality

	MHU650 0.25 mg N = 3	**MHU650 0.75 mg N = 3**	**MHU650 2.5 mg N = 6**	**MHU650 7.5 mg N = 9**	**Total N = 21**
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg	Total
Total Number Affected	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Total Number At Risk	3	3	6	9	21

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Serious Adverse Events

Time Frame	Adverse events were reported from the single dose of study-drug treatment until end of study (Day 60), plus 30 Days for SAE reporting, for a maximum timeframe of 90 days.
Source Vocabulary for Table Default	MedDRA (25.0)
Collection Approach for Table Default	Systematic Assessment

	MHU650 0.25 mg N = 3	**MHU650 0.75 mg N = 3**	**MHU650 2.5 mg N = 6**	**MHU650 7.5 mg N = 9**	**Total N = 21**
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg	Total
Total # Affected by any Serious Adverse Event	0 (0%)	0 (0%)	0 (0%)	1 (11.11%)	1 (4.76%)
Total # at Risk by any Serious Adverse Event	3	3	6	9	21
Eye disorders					
Choroidal detachment	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (4.76%)
Serous retinal detachment	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (4.76%)
Uveitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (4.76%)

Other (Not Including Serious) Adverse Events

Time Frame	Adverse events were reported from the single dose of study-drug treatment until end of study (Day 60), plus 30 Days for SAE reporting, for a maximum timeframe of 90 days.
Source Vocabulary for Table Default	MedDRA (25.0)
Collection Approach for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	0%

	MHU650 0.25 mg N = 3	**MHU650 0.75 mg N = 3**	**MHU650 2.5 mg N = 6**	**MHU650 7.5 mg N = 9**	**Total N = 21**
Arm/Group Description	MHU650 0.25 mg	MHU650 0.75 mg	MHU650 2.5 mg	MHU650 7.5 mg	Total
Total # Affected by any Other Adverse Event	2 (66.67%)	1 (33.33%)	3 (50.00%)	4 (44.44%)	10 (47.62%)
Total # at Risk by any Other Adverse Event	3	3	6	9	21
Eye disorders					
Conjunctival haemorrhage	1 (33.33%)	0 (0.00%)	2 (33.33%)	2 (22.22%)	5 (23.81%)
Conjunctival hyperaemia	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (4.76%)
Dry eye	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (4.76%)
Macular oedema	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	1 (4.76%)
Retinal vein occlusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (4.76%)
Gastrointestinal disorders					
Nausea	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	1 (4.76%)

Immune system disorders					
Contrast media allergy	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)
Infections and infestations					
Upper respiratory tract infection	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)
Renal and urinary disorders					
Haematuria	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (4.76%)
Respiratory, thoracic and mediastinal disorders					
Cough	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.76%)

Other Relevant Findings

Not applicable

Conclusion:

Safety and tolerability data, including Best corrected visual acuity (BCVA), macular thickness by Spectral Domain Optical Coherence Tomography (SD-OCT), Intraocular pressure (IOP), vital signs, Electrocardiogram (ECG) and safety laboratory tests, showed that a single Intravitreal (IVT) at all doses (0.25 to 7.5 mg) of MHU650 was overall safe and well tolerated in participants with macular edema from diabetic macular edema (DME), neovascular age-related macular degeneration (nAMD), or retinal vein occlusion (RVO).

Date of Clinical Trial Report

4 Apr 2023