References

Citations:

Links:

Available IPD/Information:

Study Results

Participant Flow

Reporting Groups

	Description
PRM-151	PRM-151 (recombinant human serum amyloid P, recombinant human pentraxin 2) PRM-151: PRM-151 2 milligrams (mg) (0.1 mL volume) by subconjunctival injection Days 1 (immediately following trabeculectomy), 2, 3, 5 and 9
Placebo	Placebo Placebo: Placebo solution (0.1 mL volume) by subconjunctival injection Days 1 (immediately following trabeculectomy), 2, 3, 5 and 9

All Study Treatment Days 1-9

	PRM-151	Placebo
Started	62	62
Completed	62	62
Not Completed	0	0

Study Completion

	PRM-151	Placebo
Started	62	62
Completed	60	62
Not Completed	2	0
Physician Decision	1	0

	PRM-151	Placebo
Withdrawal by Subject	1	0

Baseline Characteristics

Baseline Analysis Population Description

All subjects screened and enrolled in study

Reporting Groups

	Description
PRM-151	PRM-151 (recombinant human serum amyloid P, recombinant human pentraxin 2) PRM-151: PRM-151 2 milligrams (mg) (0.1 mL volume) by subconjunctival injection Days 1 (immediately following trabeculectomy), 2, 3, 5 and 9
Placebo	Placebo Placebo: Placebo solution (0.1 mL volume) by subconjunctival injection Days 1 (immediately following trabeculectomy), 2, 3, 5 and 9

Baseline Measures

		PRM-151	Placebo	Total
Overall Number of Participants		62	62	124
Age, Continuous Median (Full Range) Unit of measure: years	Number Analyzed	62 participants	62 participants	124 participants
		65 (35 to 83)	68 (39 to 87)	66 (35 to 87)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	62 participants	62 participants	124 participants
	Female	22 35.48%	32 51.61%	54 43.55%
	Male	40 64.52%	30 48.39%	70 56.45%

		PRM-151	Placebo	Total
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	62 participants	62 participants	124 participants
	American Indian or Alaska Native	0 0%	0 0%	0 0%
	Asian	0 0%	0 0%	0 0%
	Native Hawaiian or Other Pacific Islander	0 0%	0 0%	0 0%
	Black or African American	4 6.45%	3 4.84%	7 5.65%
	White	58 93.55%	59 95.16%	117 94.35%
	More than one race	0 0%	0 0%	0 0%
	Unknown or Not Reported	0 0%	0 0%	0 0%
Ethnicity (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	62 participants	62 participants	124 participants
	Hispanic or Latino	3 4.84%	1 1.61%	4 3.23%
	Not Hispanic or Latino	59 95.16%	61 98.39%	120 96.77%
	Unknown or Not Reported	0 0%	0 0%	0 0%

		PRM-151	Placebo	Total
Region of Enrollment Measure Type: Number Unit of measure: participants	Number Analyzed	62 participants	62 participants	124 participants
Czech Republic		34	39	73
Belgium		5	9	14
Netherlands		4	3	7
United Kingdom		19	11	30

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Safety of Subconjunctival Injection
Measure Description	Number of adverse events (AEs), treatment emergent adverse events (TEAEs), non-ocular TEAEs, Ocular TEAEs, serious adverse events (SAEs), abnormal slit-lamp biomicroscopic findings, and abnormal dilated fundoscopy findings
Time Frame	AEs, slit-lamp, and fundoscopy findings from first injection through end of study; TEAEs from first injection through Day 30

Analysis Population Description

All subjects enrolled in study; all subjects received all study treatment

Reporting Groups

	Description
PRM-151	PRM-151 (recombinant human serum amyloid P, recombinant human pentraxin 2) PRM-151: PRM-151 2 milligrams (mg) (0.1 mL volume) by subconjunctival injection Days 1 (immediately following trabeculectomy), 2, 3, 5 and 9
Placebo	Placebo Placebo: Placebo solution (0.1 mL volume) by subconjunctival injection Days 1 (immediately following trabeculectomy), 2, 3, 5 and 9

Measured Values

	PRM-151	Placebo
Overall Number of Participants Analyzed	62	62

	PRM-151	Placebo
Safety of Subconjunctival Injection Measure Type: Number Unit of measure: Number of occurrences		
Number of AEs	274	220
Number of TEAEs	166	113
Number of Non-ocular TEAEs	16	11
Number of Ocular TEAEs	150	102
Number of SAEs	16	7
Number of abnormal slit-lamp findings	58	108
Number of abnormal optic nerve findings	284	290
Number of abnormal retina findings	18	39
Number of abnormal macula findings	2	4
Number of abnormal choroid findings	0	1

2. Primary Outcome Measure:

Measure Title	Subjects With Safety Related Events or Findings
Measure Description	The number of Subjects with AEs, TEAEs, SAEs, decreased visual acuity, and worsened visual fields
Time Frame	First injection through end of study for AEs, SAEs, visual acuity and visual fields, and from first injection through Day 30 for TEAEs

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
PRM-151	PRM-151 (recombinant human serum amyloid P, recombinant human pentraxin 2) PRM-151: PRM-151 2 milligrams (mg) (0.1 mL volume) by subconjunctival injection Days 1 (immediately following trabeculectomy), 2, 3, 5 and 9

	Description
Placebo	Placebo Placebo: Placebo solution (0.1 mL volume) by subconjunctival injection Days 1 (immediately following trabeculectomy), 2, 3, 5 and 9

Measured Values

	PRM-151	Placebo
Overall Number of Participants Analyzed	62	62
Subjects With Safety Related Events or Findings Measure Type: Number Unit of measure: participants		
Subjects with at least 1 AE	46	47
Subjects with at least 1 Treatment Emergent AE	44	41
Subjects with at least 1 SAE	9	6
Subjects with decreased visual acuity	0	0
Subjects with worsened visual field	5	5

3. Other Pre-specified Outcome Measure:

Measure Title	Successful Intra-ocular Pressure (IOP) Control
Measure Description	Exploratory efficacy outcome measure. Successful IOP control defined as IOP between 6 and 18 mm Hg or 25% reduction from pre-surgical IOP
Time Frame	Day 120

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
PRM-151	PRM-151 (recombinant human serum amyloid P, recombinant human pentraxin 2) PRM-151: PRM-151 2 milligrams (mg) (0.1 mL volume) by subconjunctival injection Days 1 (immediately following trabeculectomy), 2, 3, 5 and 9

	Description
Placebo	Placebo Placebo: Placebo solution (0.1 mL volume) by subconjunctival injection Days 1 (immediately following trabeculectomy), 2, 3, 5 and 9

Measured Values

	PRM-151	Placebo
Overall Number of Participants Analyzed	62	62
Successful Intra-ocular Pressure (IOP) Control Measure Type: Number Unit of measure: participants	36	46

4. Other Pre-specified Outcome Measure:

Measure Title	Bleb Scarring
Measure Description	Exploratory Efficacy Outcome measure: Bleb scarring is graded on a scale from 0-3. 0= none to minimal scarring, 1= mild, 2= moderate, 3= severe scarring.
Time Frame	Day 120

Analysis Population Description

Number of subjects who had assessment of bleb scarring on Day 120

Reporting Groups

	Description
PRM-151	PRM-151 (recombinant human serum amyloid P, recombinant human pentraxin 2) PRM-151: PRM-151 2 milligrams (mg) (0.1 mL volume) by subconjunctival injection Days 1 (immediately following trabeculectomy), 2, 3, 5 and 9
Placebo	Placebo Placebo: Placebo solution (0.1 mL volume) by subconjunctival injection Days 1 (immediately following trabeculectomy), 2, 3, 5 and 9

Measured Values

	PRM-151	Placebo
Overall Number of Participants Analyzed	46	54

	PRM-151	Placebo
Bleb Scarring Mean (Standard Deviation) Unit of measure: units on a scale	1.29 (0.663)	1.30 (0.633)

Reported Adverse Events

Time Frame	SAEs are reported for all subjects from first study treatment injection through end of study (51 weeks). Treatment emergent adverse events are reported as defined in the protocol for all subjects from first study treatment injection through Day 30.
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
PRM-151	PRM-151 (recombinant human serum amyloid P, recombinant human pentraxin 2) PRM-151: PRM-151 2 milligrams (mg) (0.1 mL volume) by subconjunctival injection Days 1 (immediately following trabeculectomy), 2, 3, 5 and 9
Placebo	Placebo Placebo: Placebo solution (0.1 mL volume) by subconjunctival injection Days 1 (immediately following trabeculectomy), 2, 3, 5 and 9

All-Cause Mortality

	PRM-151	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total All-Cause Mortality	/	/

Serious Adverse Events

	PRM-151	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	9/62 (14.52%)	6/62 (9.68%)
Cardiac disorders		

	PRM-151	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Myocardial infarction †	1/62 (1.61%)	0/62 (0%)
Eye disorders		
Choroidal detachment †	1/62 (1.61%)	0/62 (0%)
Choroidal effusion †	0/62 (0%)	1/62 (1.61%)
Flat Anterior Chamber of Eye †	1/62 (1.61%)	0/62 (0%)
Glaucoma †	1/62 (1.61%)	1/62 (1.61%)
Retinal vein occlusion †	1/62 (1.61%)	0/62 (0%)
Gastrointestinal disorders		
Abdominal pain †	1/62 (1.61%)	0/62 (0%)
Pancreatitis †	1/62 (1.61%)	0/62 (0%)
Vomiting †	1/62 (1.61%)	0/62 (0%)
Investigations		
Intraocular pressure increased †	2/62 (3.23%)	4/62 (6.45%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Chronic Lymphocytic Leukaemia †	1/62 (1.61%)	0/62 (0%)
Rectosigmoid cancer recurrent †	0/62 (0%)	1/62 (1.61%)
Nervous system disorders		
Cerebrovascular disorder †	1/62 (1.61%)	0/62 (0%)
Visual field defect †	1/62 (1.61%)	0/62 (0%)
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease †	1/62 (1.61%)	0/62 (0%)

† Indicates events were collected by systematic assessment.

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	PRM-151	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	44/62 (70.97%)	41/62 (66.13%)
Eye disorders		
Anterior chamber cell †	11/62 (17.74%)	11/62 (17.74%)
Anterior chamber flare †	6/62 (9.68%)	2/62 (3.23%)
Conjunctival haemorrhage †	10/62 (16.13%)	5/62 (8.06%)
Conjunctival hyperemia †	9/62 (14.52%)	4/62 (6.45%)
Flat anterior chamber of eye †	6/62 (9.68%)	5/62 (8.06%)
Hyphaema †	7/62 (11.29%)	3/62 (4.84%)
Retinal pigmentation †	5/62 (8.06%)	2/62 (3.23%)
Investigations		
Intraocular pressure increased †	17/62 (27.42%)	13/62 (20.97%)

† Indicates events were collected by systematic assessment.

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

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