OPTHEA

2019
Annual General Meeting

CEO Presentation – 2019 AGM, November 21 2019
Megan Baldwin PhD, CEO & Managing Director

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Business Snapshot

Opthea Limited	• Public company listed on ASX (ASX:OPT) developing OPT-302 for wet AMD and Diabetic Macular Edema ("DME") • Market cap A$750m at 20 November 2019 and cash on hand of A$30m at 31 October 2019
OPT-302 has a novel mechanism of action	• OPT-302 (sVEGFR-3) is the first 'Trap' inhibitor of VEGF-C and VEGF-D designed specifically for the eye • In combination with anti-VEGF-A therapies, shown to completely shut-down VEGFR-2 and VEGFR-3 activity • Targets mechanisms of resistance and sub-optimal clinical response to existing therapies
Strong and growing commercial potential	• Current and growing market opportunity of US$10B+ worldwide • OPT-302 being developed for use in combination with any of the existing anti-VEGF-A agents, biosimilars or novel therapies in development for wet AMD and DME • A novel approach seeking to provide additional visual acuity benefit over standard of care • Broad development opportunity in wet AMD, DME, Retinal Vein Occlusion ("RVO") and other retinal pathologies
Primary endpoint met in Phase 2b study of OPT-302 in wet AMD	• OPT-302 combination therapy demonstrated superiority in visual acuity over ranibizumab (Lucentis®) at 24 weeks in an international, randomised, controlled, double-masked trial of 366 patients • Secondary endpoint results also supportive of primary outcome • Exploratory & pre-specified sub-group analyses suggest greater activity of OPT-302 in lesion-types considered more difficult to treat with anti-VEGF-A therapy and highest unmet need • Completed Phase 1/2a trial in 51 wet AMD patients
Ph 2A trial of OPT-302 in persistent DME; Data anticipated in 2Q CY 2020	• Nearing completion of patient recruitment in Phase 2a trial of OPT-302 in combination with aflibercept (Eylea®) for the treatment of persistent centre-involving DME • Completed Phase 1b dose-escalation trial in 9 persistent DME patients • Dose-responsive improvements in visual acuity, reductions in retinal fluid and swelling
Well tolerated safety profile of OPT-302	• Well tolerated safety profile of OPT-302 administered IVT in combination with ranibizumab and aflibercept • Extensive global clinical dosing experience with repeated IVT administration in over 400 patients across three international clinical studies in two disease indications

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Corporate & Operational Achievements

Phase 2b wet AMD

- Reported top-line data from Phase 2b wet AMD trial several months ahead of schedule (Aug 2019)
- Met primary endpoint in Phase 2b trial:
  - OPT-302 combination therapy demonstrated superiority in visual acuity over Lucentis®
- Only novel mechanism of action currently in development that has demonstrated statistically significant clinical benefit in addition to standard of care therapy
- Exploratory & pre-specified sub-group analyses:
  - Suggest greater activity of OPT-302 in lesion-types considered more difficult to treat with anti-VEGF-A therapy and highest unmet need
  - Provide direction for Phase 3 clinical development program
- Results well-recognized by market and international ophthalmology community
- Up 408% over past 12 months

Corporate & Operational Achievements

Phase 2a DME Trial

- Nearing completion of patient recruitment in Phase 2a trial of OPT-302 in combination with aflibercept (Eylea®) for the treatment of persistent centre-involving DME
- Upcoming Phase 2a clinical data anticipated 2Q CY 2020

Safety

- Continued demonstration of well tolerated safety profile in combination with Lucentis and Eylea following administration in ~400 patients (wet AMD and DME) across three international clinical studies in two disease indications

Patents

- OPT-302 patent 'accepted for grant' or granted in multiple countries incl. EU & Japan
- Pending approval in other countries

Publication

- Phase 1/2a wet AMD trial results with OPT-302 published in peer-reviewed journal*

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* *Ophthalmology Retina, Article in Press, 2019*

Corporate & Operational Achievements

Corporate

- Company fully-funded through:
  - Phase 2a DME clinical readout; and
  - Close-out activities for Phase 2b wAMD
  - Planning for Phase 3 program and regulatory engagement
- Received A$14.6m R&D tax credit (Aust & O/S eligible expenditure)
- Added to S&P/ASX All Ordinaries Index (Mar 2019)
- Data presented at international conferences by management, clinical advisory board & investigators
  - OIS@American Academy Ophthalmology Conference (Oct ‘19)
  - EURetina, Retina Society
- Continued to raise company profile with local and international investors & global pharmaceutical companies

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Financial Position (Unaudited)

Key Financial Details	ASX: OPT
Ticker Symbol	ASX:OPT
Share Price (Nov 20 2019)	~A$3.00
Total Ordinary Shares on Issue	250,289,839
Market Capitalisation (Nov 20 2019)	~A750.0m (~USD510m)
Trading Range (last 12 months)	A$0.55 – 4.15
52-week Change	408%
Cash Balance (Oct 31 2019)	~A$30m
Top 20 Shareholders Own	69%
Institutional Holders	84%

Share Price Performance (2017 - 2019)

Analyst Coverage (Aust)

Goldman Sachs — Chris Cooper

WILSONS — Shane Storey

BELL POTTER — Tanushree Jain

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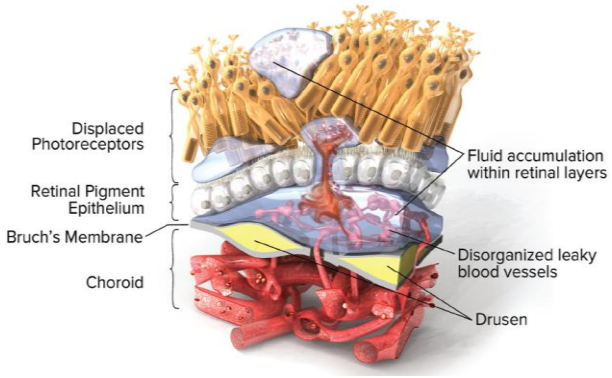
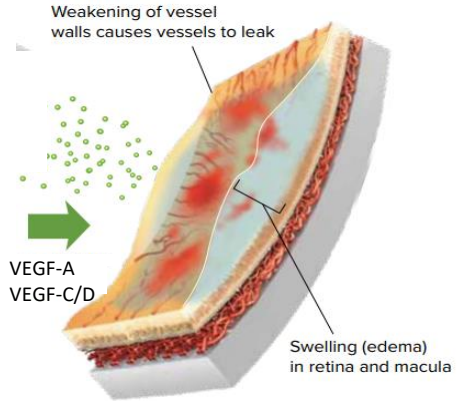
Wet AMD and DME are Leading Causes of Vision Loss in the Elderly & Diabetic Populations Respectively





	Wet Age-Related Macular Degeneration	Central-involved Diabetic Macular Edema
Driver:	Ageing	Sustained hyperglycaemia
Prevalence:	• Increasing prevalence due to ageing population • ~3M people worldwide, including ~1.8M in the US	• Increasing due to diabetes epidemic • DME with visual impairment affects ~1-3% diabetes patients • ~1.3M – 2M people worldwide, many undiagnosed
Primary macular site of pathology:	• Choroid	• Intra-retinal layers
Pathogenesis:	• Changes in ageing eye • Upregulation VEGF-A, -C, -D and other cytokines • Choroidal Neovascularization (CNV) • Sub-retinal, intra-retinal fluid accumulation	• Sustained hyperglycemia • Upregulation VEGF-A, -C, -D and inflammatory mediators • Inflammation • Hyperpermeability and retinal swelling

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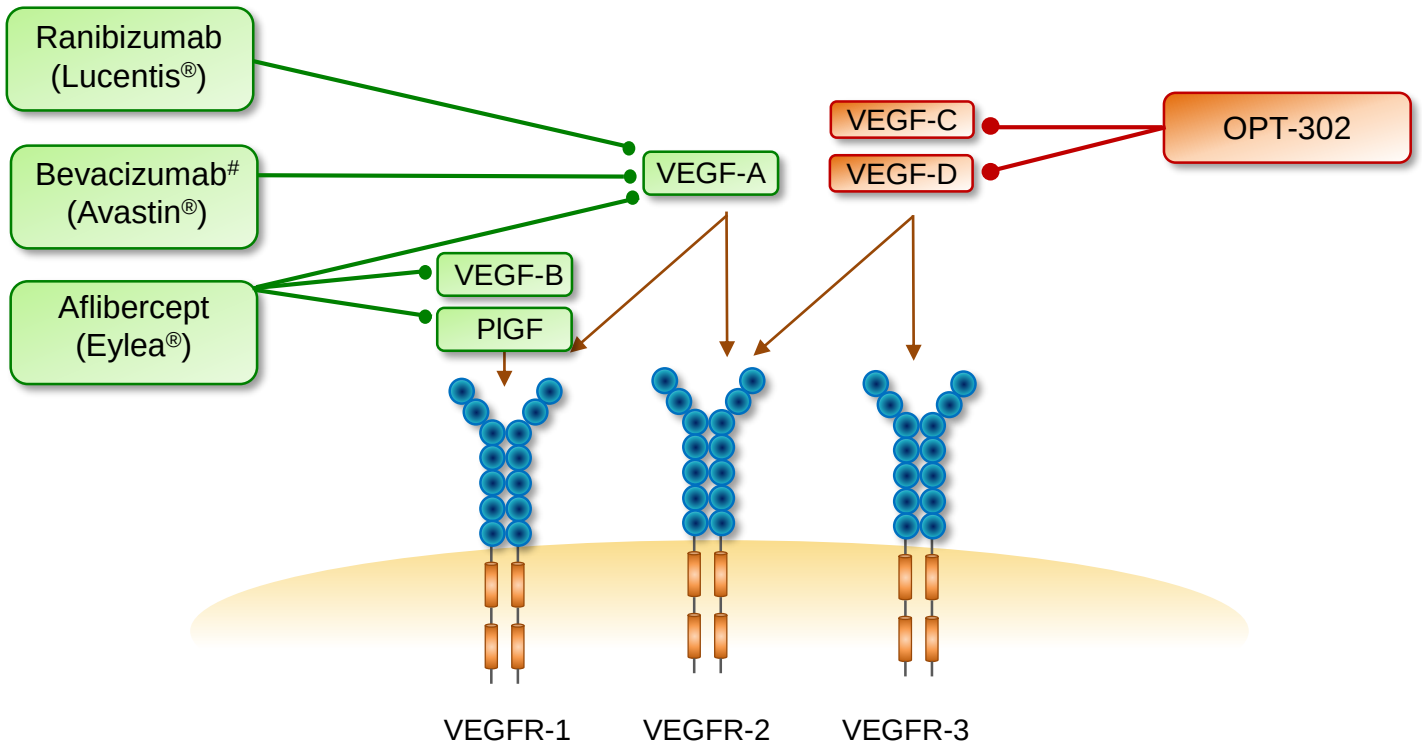
Existing Therapies Primarily Target VEGF-A

OPT-302 inhibits VEGF-C/D



OPT-302: Rationale

- Long-term therapy with selective VEGF-A inhibitors is associated with sub-optimal responses
  - Sub-optimal improvements in visual acuity
  - Persistent retinal fluid
- Resistance to VEGF-A monotherapy may be related to other VEGF family members
- VEGF-C/D signal for angiogenesis and vascular permeability independently of VEGF-A; and
- VEGF-C/D are elevated when VEGF-A is inhibited
- OPT-302 combination therapy achieves a more complete suppression of the VEGF/VEGFR pathway
- OPT-302 targets incomplete response to VEGF-A inhibition

Used in combination with a VEGF-A inhibitor, completely blocks VEGFR-2 and VEGFR-3 signalling

 # Bevacizumab is used 'off-label' for the treatment of wAMD

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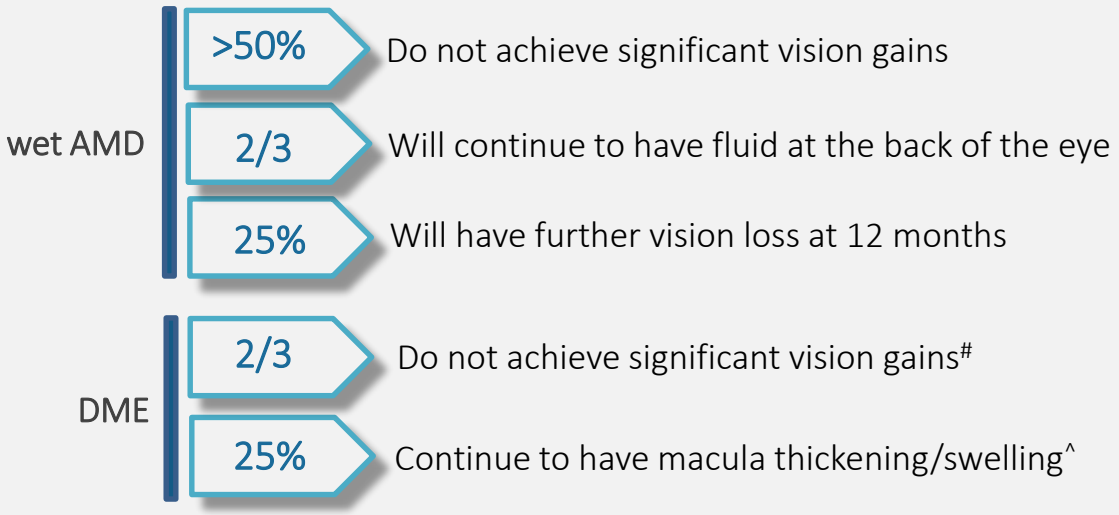
A Currently Unmet Medical Need for wet AMD and DME

Despite receiving a VEGF-A inhibitor (ranibizumab, aflibercept or bevacizumab)*:



Opportunity: New Products that Improve Efficacy and Durability

Large and Growing Market Opportunity

- Wet AMD and DME are the leading causes of blindness in the elderly and diabetic populations respectively
- Prevalence is increasing
- Market opportunity is growing
- Approved VEGF-A inhibitors (ranibizumab and aflibercept) generated revenues >US$10b in 2018
- Approximately 50% of wet AMD and DME patients worldwide receive bevacizumab as an off-label, less-costly treatment option

Opthea's strategy is to develop OPT-302 as a combination therapy to be administered with any of the approved a-VEGF-A therapies or new VEGF-A inhibitors in development

** Based on randomised, controlled clinical trial data; # Fail to achieve ≥ 2 lines improvement in BCVA;*
^ SD-OCT CST ≥ 300 µM or Time-Domain OCT CST ≥ 250 µM

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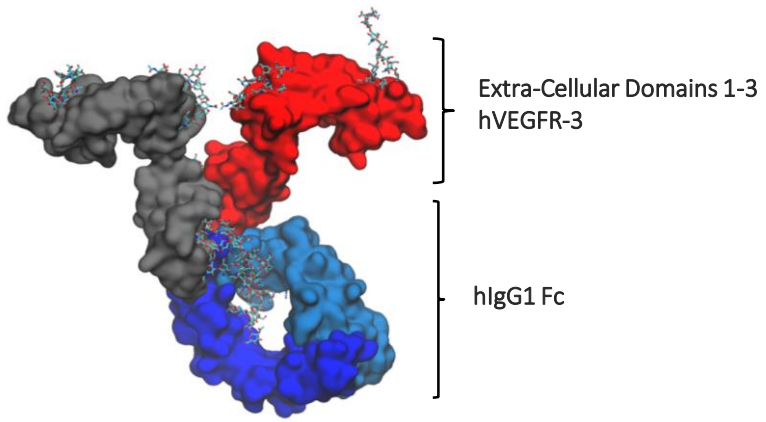
OPT-302: A 'trap' inhibitor of VEGF-C and VEGF-D

OPT-302: A soluble form of VEGFR-3

- Comprises the extracellular domains 1-3 of VEGFR-3 and the Fc fragment of human IgG1
- Potent inhibitor of VEGF-C (~5 pM) and VEGF-D (~0.5 nM)
- A 'trap' that blocks VEGF-C and VEGF-D binding to the receptors VEGFR-2 and VEGFR-3
- Targets a validated pathway involved in wet AMD progression
- Targets a mechanism of escape from existing therapies that is differentiated to VEGF-A therapies



Strategy

- To develop OPT-302 for use in combination with inhibitors of VEGF-A to address the unmet medical need in wet AMD and DME
- To demonstrate superior gains in visual acuity in patients administered OPT-302 in combination with a VEGF-A inhibitor
- Currently administered as a sequential intravitreal injection every 4 weeks (q4w), with the potential to also:
  - investigate OPT-302 efficacy and durability in patients receiving less frequent doses (e.g. q8w, q12w), and
  - co-formulate with other agents
- Wet AMD and DME landscape includes only a limited number of novel combination therapies that may address the sub-optimal clinical responses that many patients experience on anti-VEGF-A therapies

OPT-302 has comparable ocular biodistribution and PK profile to aflibercept, with low systemic exposure

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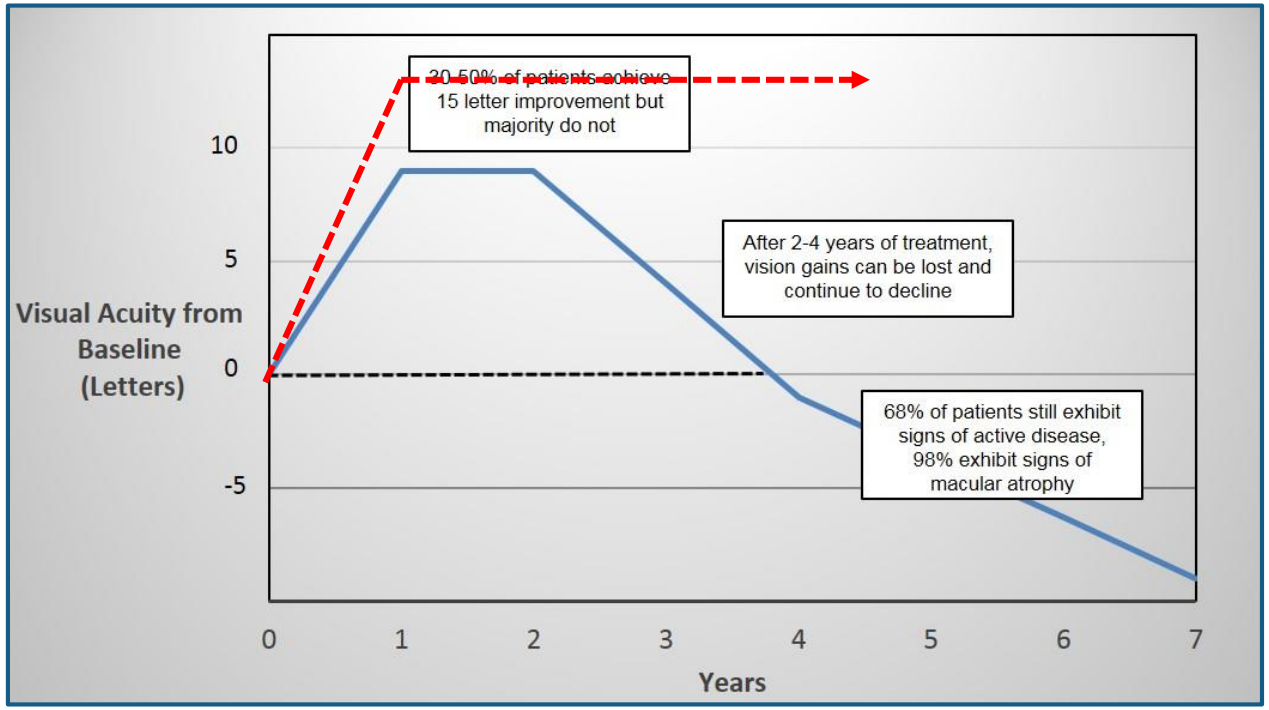
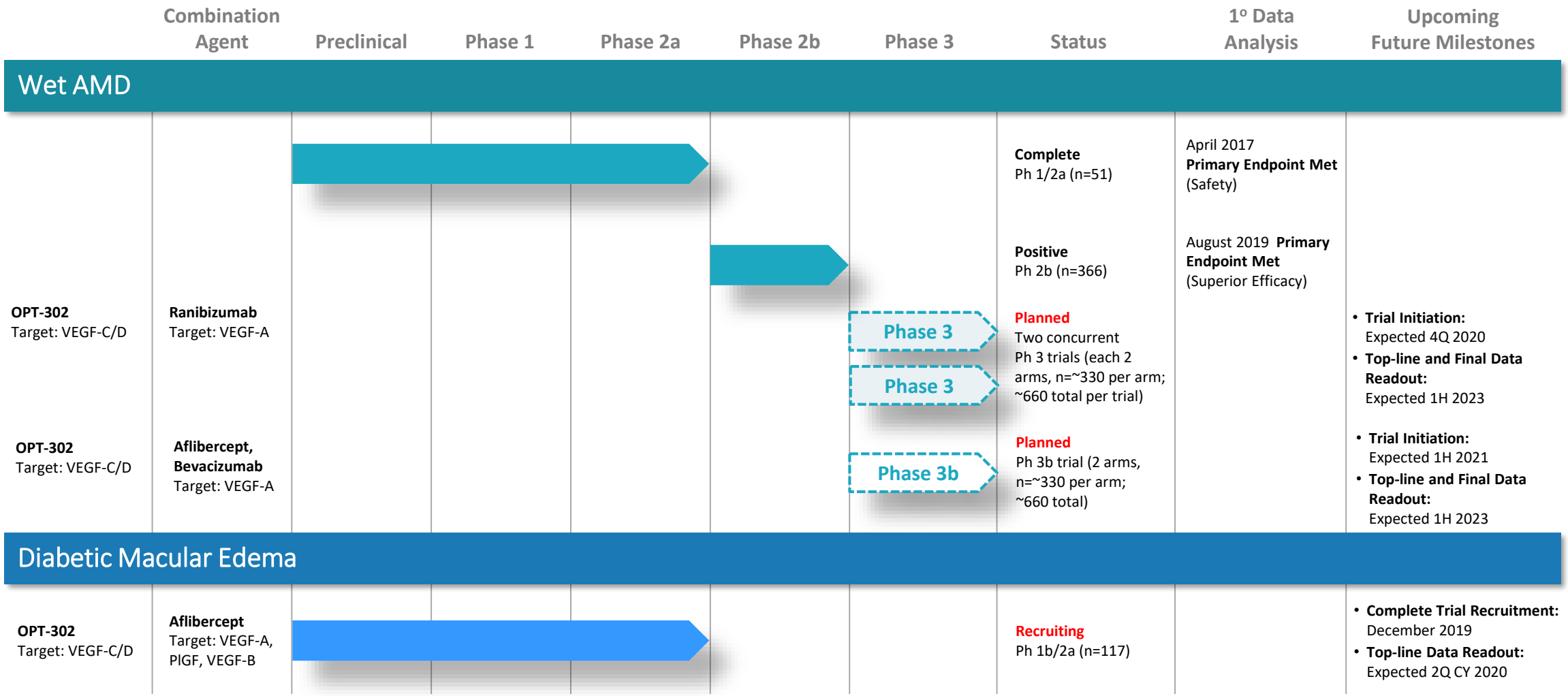
The Opportunity for OPT-302



- To increase the number of patients who experience a significant gain in vision
- To increase the magnitude of the vision gain
- To prolong response to therapy and prevent visual decline
- Potential to reduce dosing frequency

OPT-302 Clinical Program



Note: The final design of the phase 3 trials is to be confirmed following receipt of regulatory advice and confirmation of the design of the phase 3 clinical program.

OPT-302:

Phase 2b wet AMD

A dose-ranging study of intravitreal OPT-302 in combination with ranibizumab, compared with ranibizumab alone, in participants with wet AMD

(OPT-302-1002; NCT ClinicalTrials.gov Identifier: NCT03345082
113 sites across 10 countries including US, EU, Israel)

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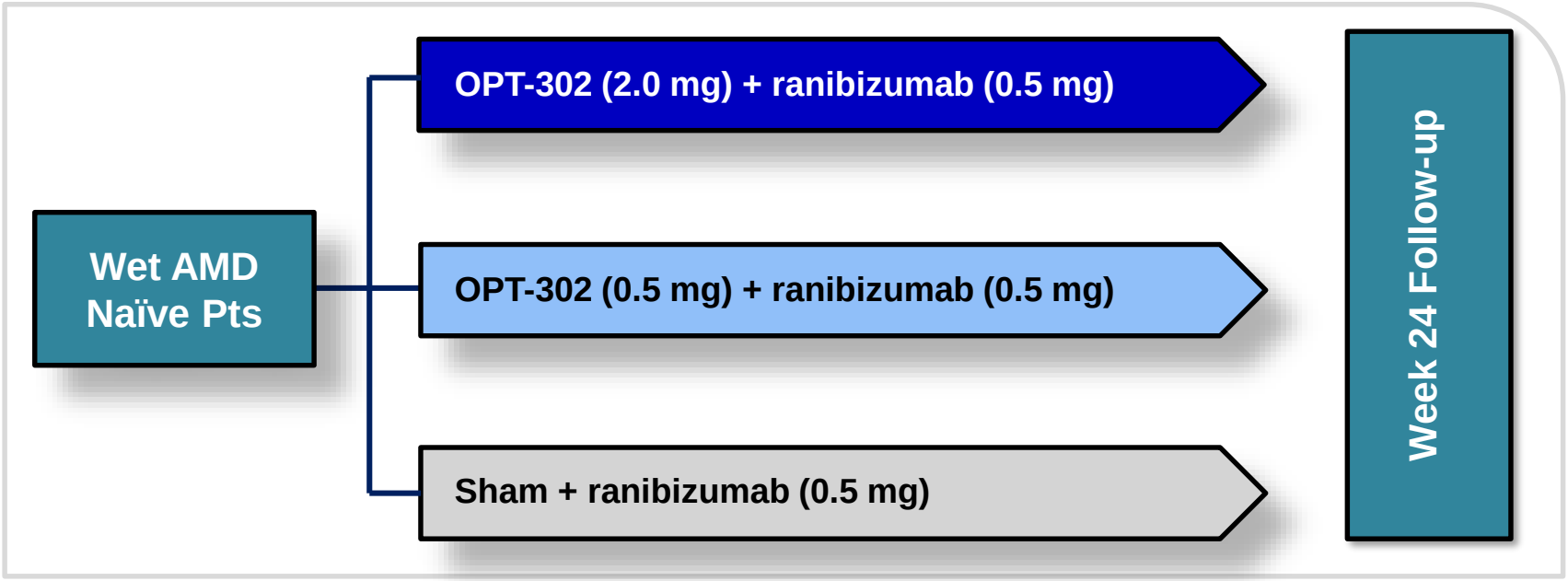
OPT-302 Phase 2b wAMD

ClinicalTrials.gov Identifier: NCT03345082

Randomised 1:1:1 to treatment arms : intravitreal dosing every 4 weeks (x 6)



Primary Outcome:

- Mean change from Baseline in ETDRS best corrected visual acuity at Week 24

Key Secondary Outcomes at Week 24:

- Patients gaining ≥15 or more ETDRS letters
- Patients losing ≥15 or more ETDRS letters
- Change in central subfield thickness (SD-OCT)
- Change in subretinal fluid and intraretinal fluid (SD-OCT)

Key Exploratory Outcomes at Week 24:

- Change in total lesion area and choroidal neovascularisation (CNV) area (FA)

Key Safety Outcome:

- Safety and tolerability

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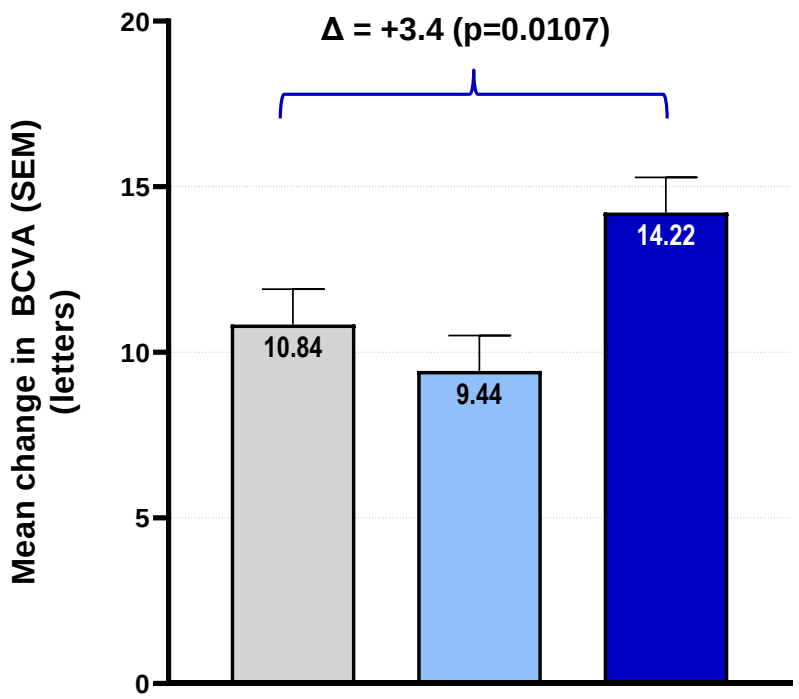
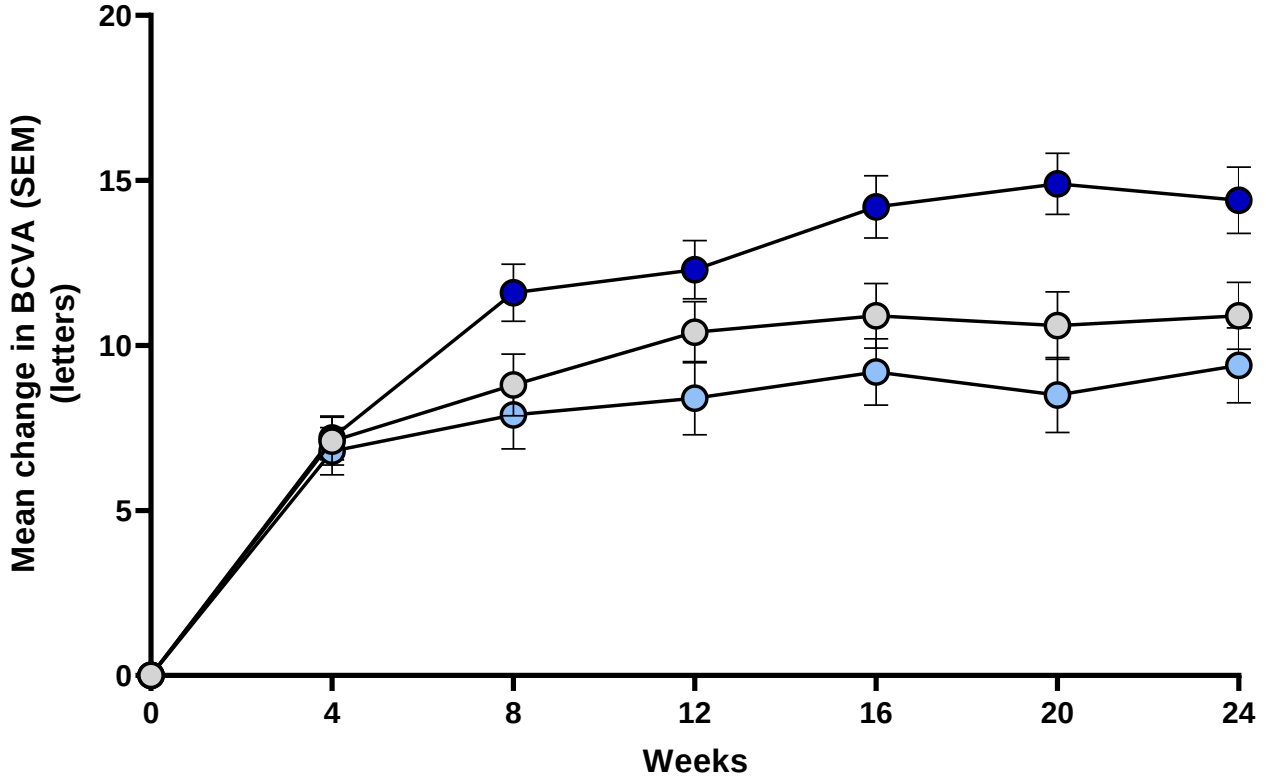
ETDRS – Early Treatment Diabetic Retinopathy Study; SD-OCT – spectral domain optical coherence tomography; FA – fluorescein angiography

Primary Analysis – Mean Change in BCVA Baseline to Week 24

Primary endpoint achieved

OPT-302 (2.0 mg) Combination Therapy Demonstrated Superiority in Visual Acuity over Ranibizumab





Sham + 0.5 mg ranibizumab (n=119)

0.5 mg OPT-302 + 0.5 mg ranibizumab (n=122)

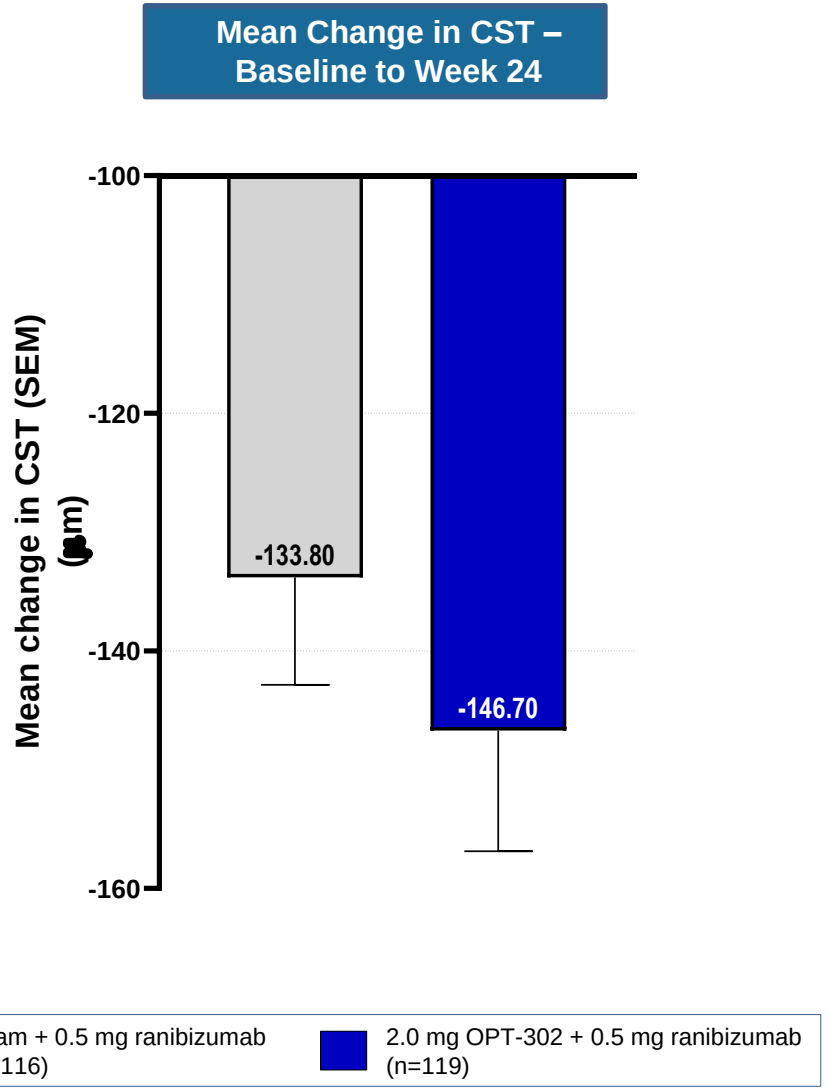
2.0 mg OPT-302 + 0.5 mg ranibizumab (n=121)

mITT; BCVA – best corrected visual acuity

Left: Difference in Least Square Means, using Model for Repeated Measures (MRM) analysis. Right: Graph represents "as observed" data and SEM

Central Subfield Thickness

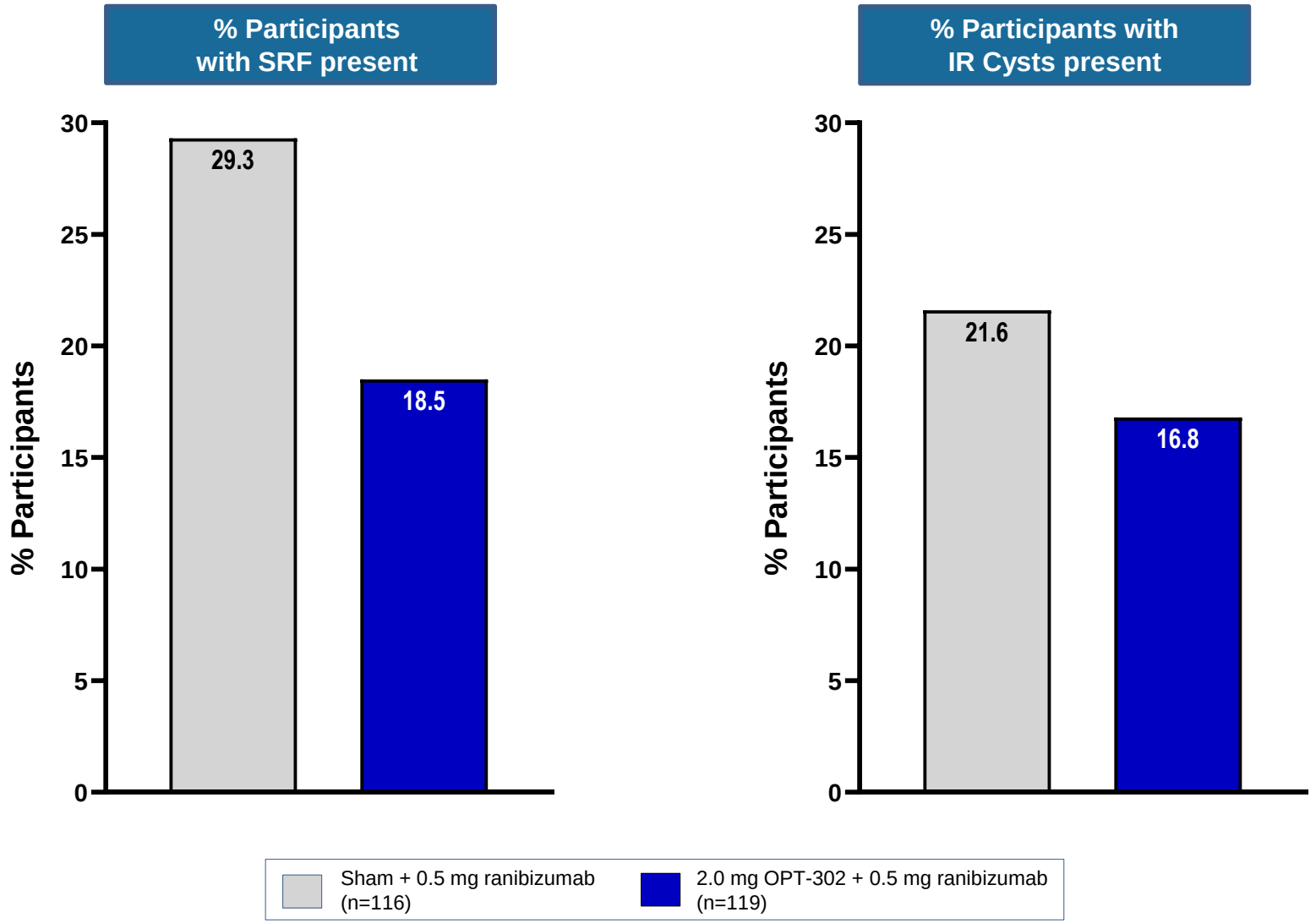
Reduction in CST in OPT-302 combination group compared to sham + ranibizumab



Modified Intent-to-Treat (mITT) population; as observed; CST – central subfield thickness

Sub-retinal Fluid and Intra-retinal Cysts at Week 24

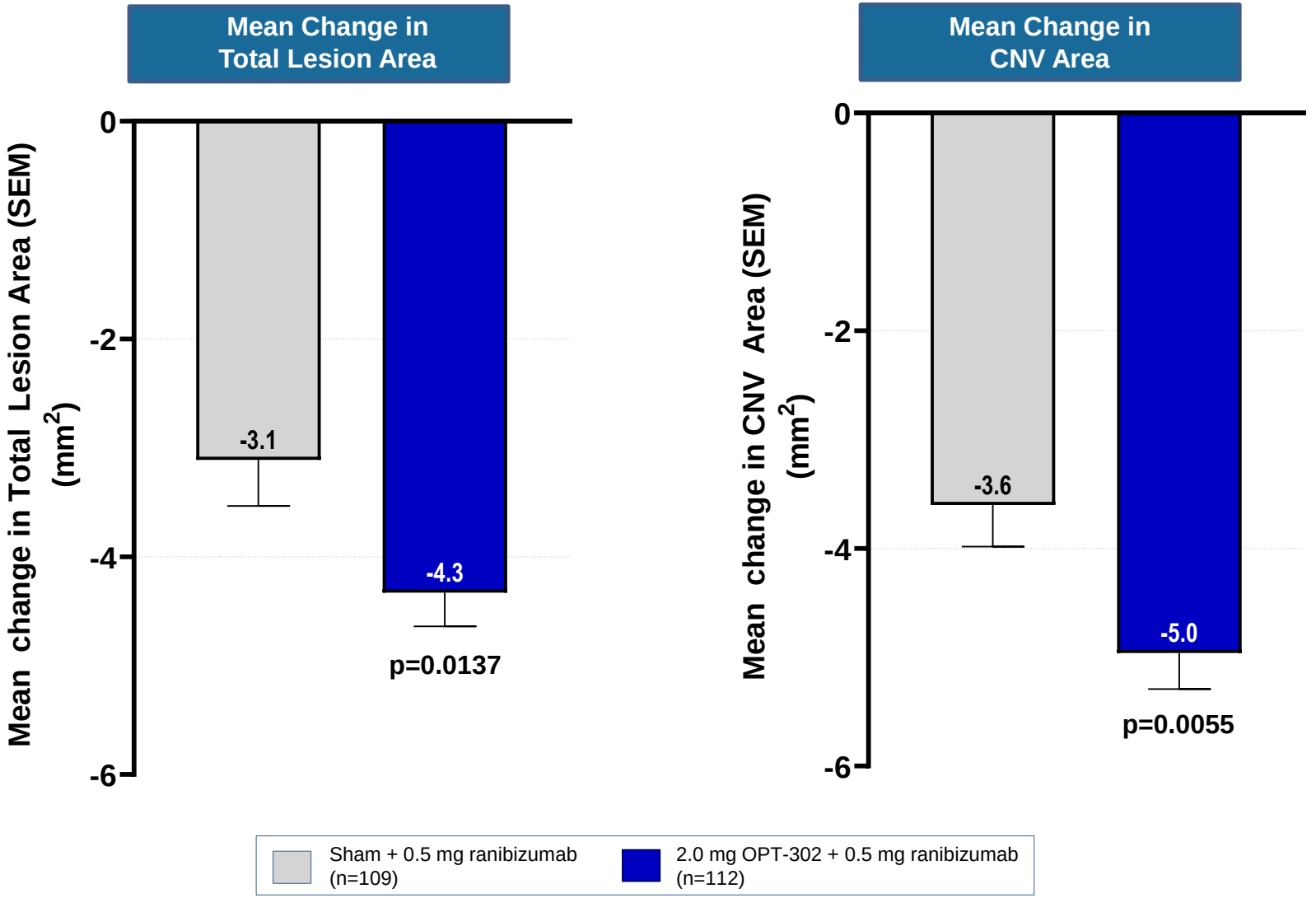
Fewer participants with retinal fluid present in OPT-302 combination group compared to sham + ranibizumab



Modified Intent-to-Treat (mITT) population; as observed; SRF – sub-retinal fluid; IR – intra-retinal

Total Lesion Area and CNV Area – Baseline to Week 24

Greater reduction in Total Lesion and CNV Area in OPT-302 combination group compared to sham + ranibizumab



Modified Intent-to-Treat (mITT) population; as observed; CNV – choroidal neovascularisation; Difference in Least Square Means

Phase 2b

A multicenter, randomized, double-masked, sham controlled study of intravitreal OPT-302 in combination with ranibizumab, in participants with neovascular (wet) AMD

Pre-Specified Subgroup Analyses

OPT-302-1002; NCT ClinicalTrials.gov Identifier: NCT03345082

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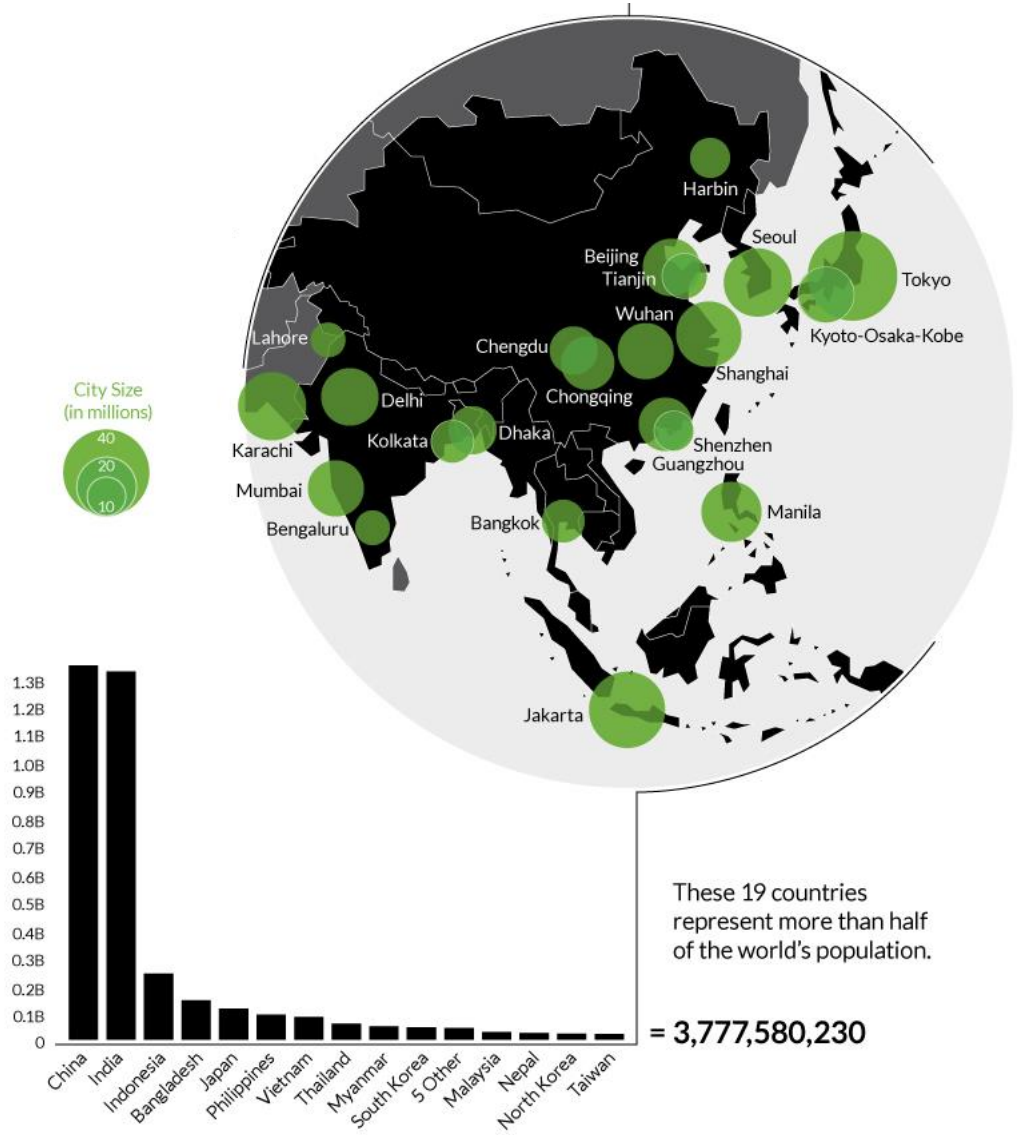
60% of the World's Population is Asian



Polypoidal Choroidal Vasculopathy (PCV)

- Most common sub-type of neovascular (wet) AMD in Asian populations
- Estimated to be the most prevalent form of wet AMD world-wide
- PCV lesions typically less responsive to anti-VEGF-A therapy

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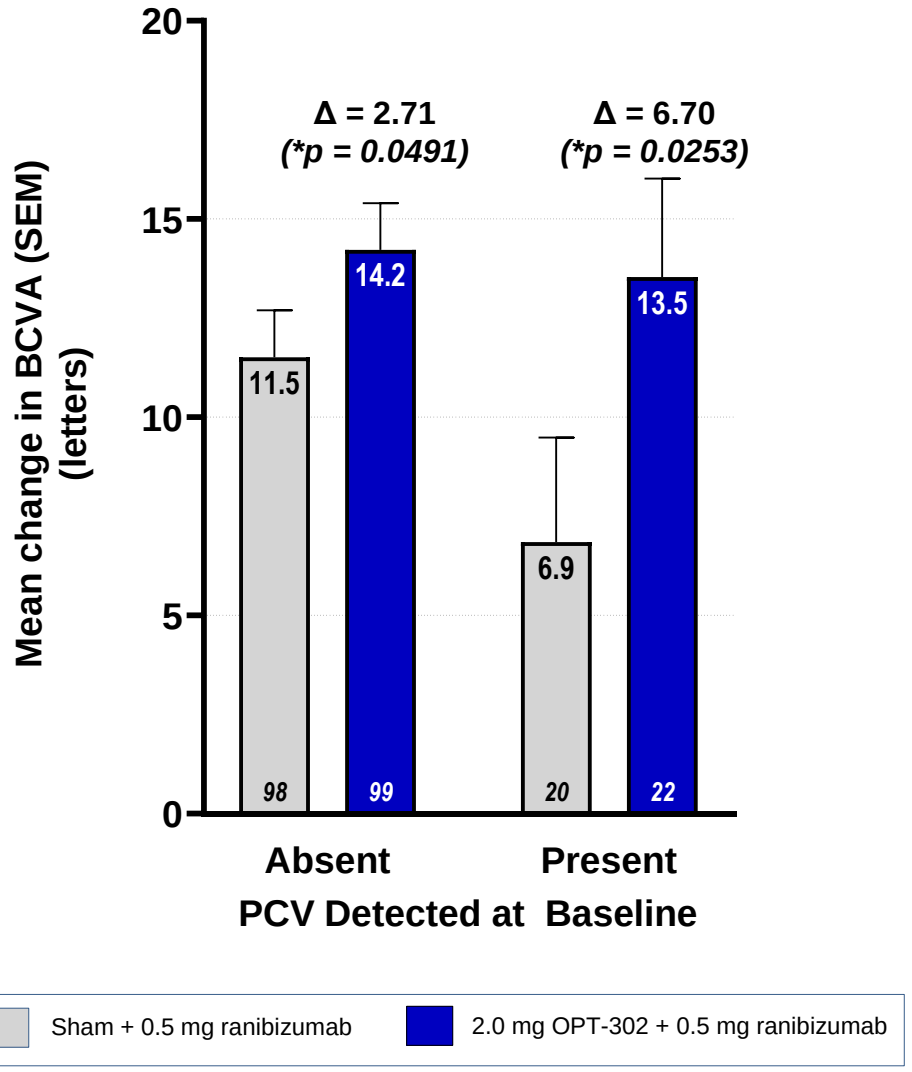
Polypoidal Choroidal Vasculopathy

Mean change in BCVA to Week 24 in participants with and without PCV at baseline

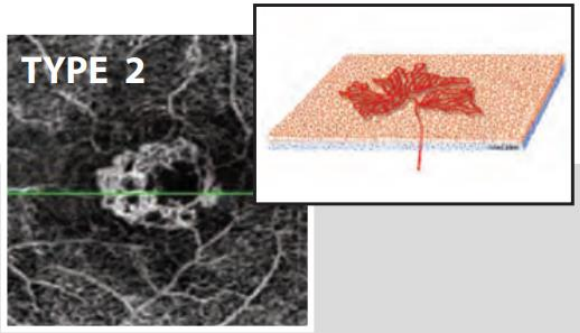


mITT; PCV – polypoidal choroidal vasculopathy;
Least square means determined using Model for Repeated Measures (MRM) analysis (adjusted for baseline vision and lesion type (randomisation) as covariates).
PCV determination by SD-OCT, FA and fundus photography

Neovascular (wet) AMD Lesion Types

Differ in vessel location, leakiness and responsiveness to VEGF-A inhibitors

Predominantly Classic

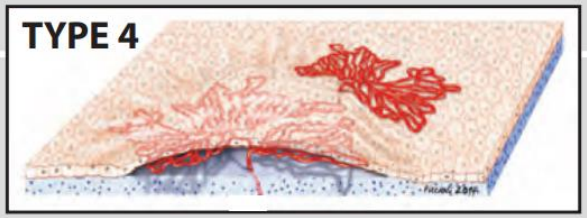


Type 2 (Classic) CNV: Choroidal neovascular membranes located above the pigment epithelium, penetrating the retina. Note the dark halo around the new vessels.

- >50% of vessels are above the RPE
- Highly responsive to a-VEGF-A

~12%

Minimally Classic

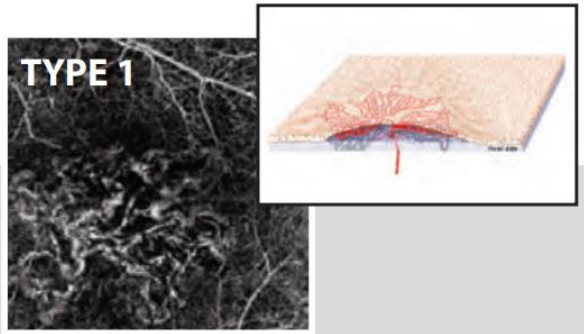


Type 4 CNV: mixed CNV (Type 1+Type 2) located below the pigment epithelium (occult) and above the pigment epithelium (classic). Note the dark halo around the new vessels.

- <50% of vessels are above the RPE
- Occult vessels may be present
- Moderately responsive to a-VEGF-A

~44%

Occult



Type 1 (Occult) CNV - Neovascular membranes located below the pigment epithelium. Note the dark halo around the new vessels.

- Vessels 100% beneath RPE
- Least responsive to a-VEGF-A
- Lesions shift to occult following a-VEGF-A (largest population)

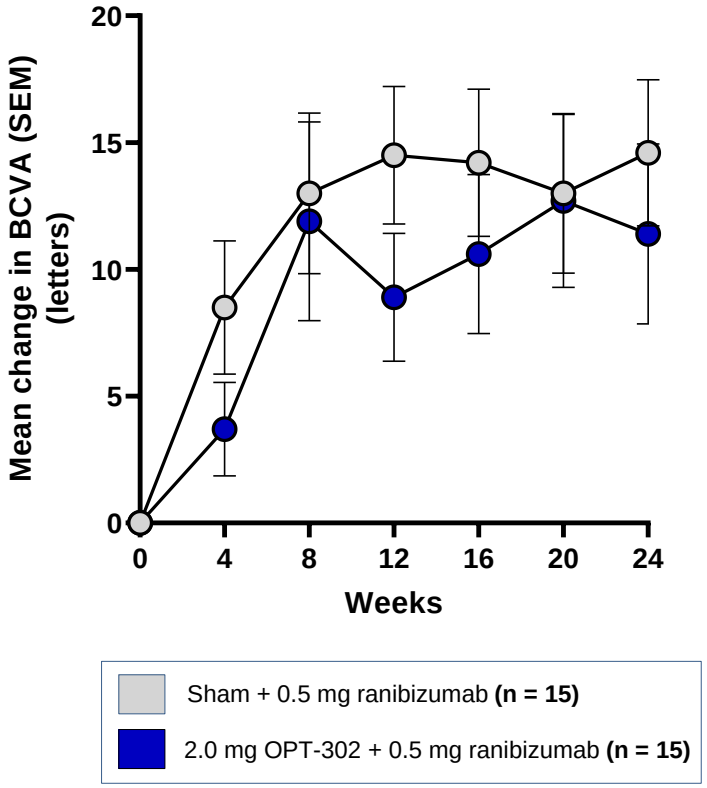
~44%

Percentages shown are represent the proportion of patients with each lesion type randomised into Opthea's Phase 2b clinical trial

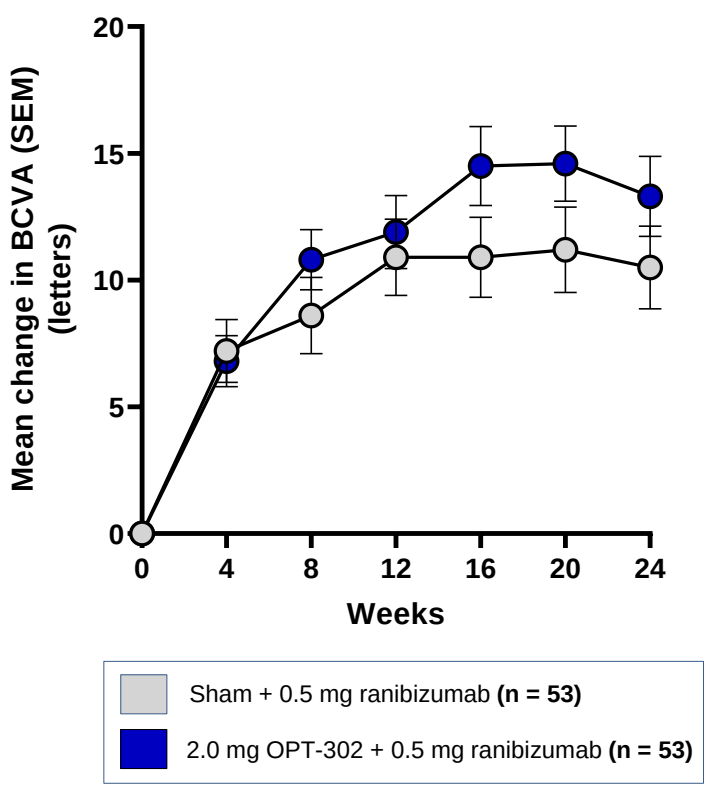
Mean Change in BCVA Over Time by Lesion Type

Small number of predominantly classic patients

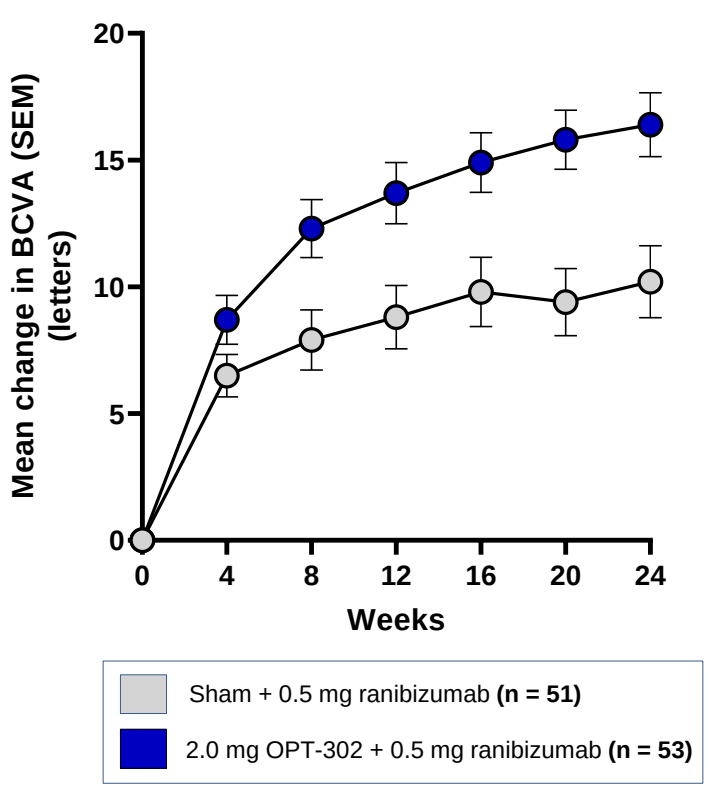
Predominantly Classic



Minimally Classic



Occult



mITT; as observed

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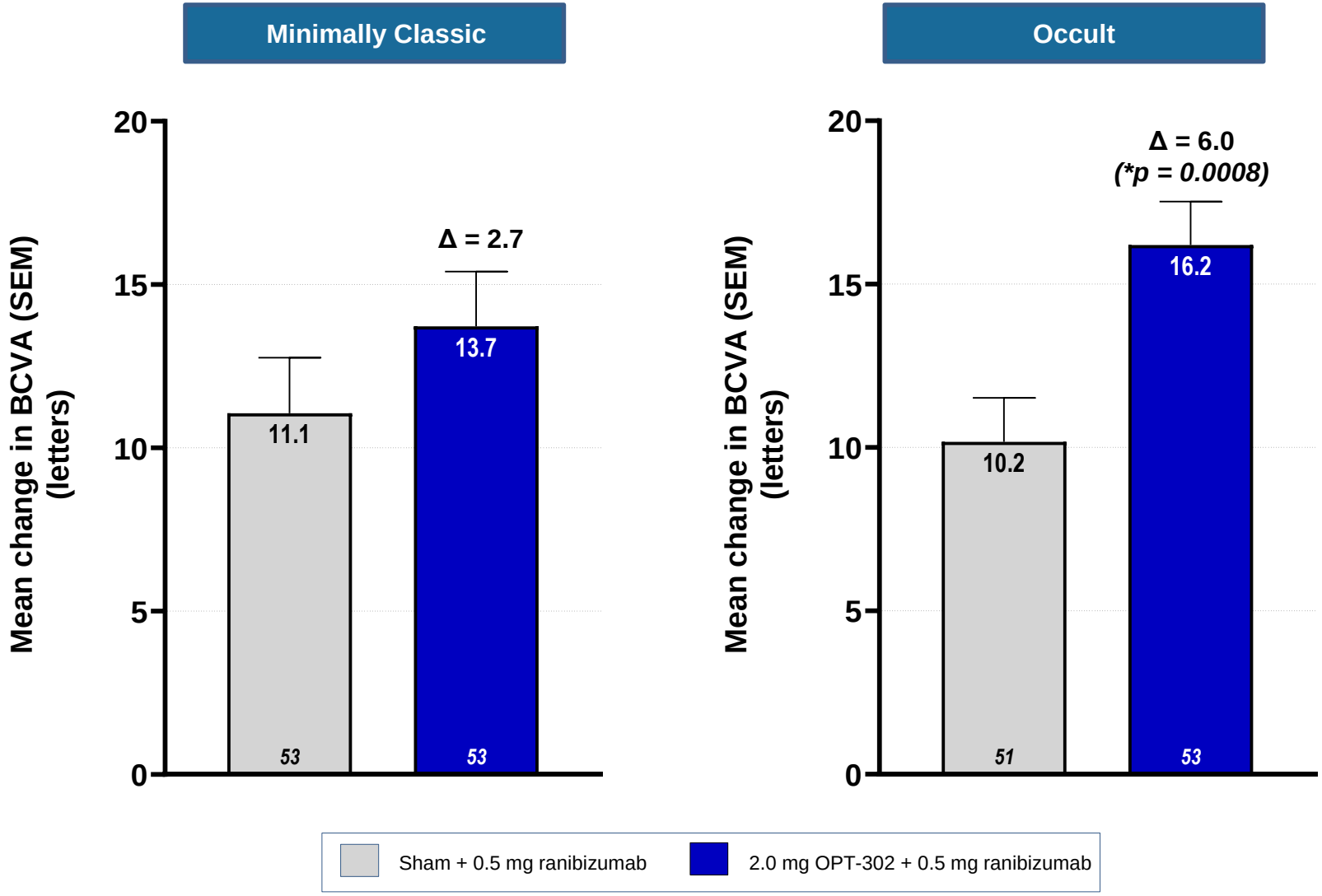
Mean Change in BCVA at Week 24 by Lesion Type

Greater vision gains at Week 24 in OPT-302 2.0 mg group in minimally classic and occult lesions



mITT; Least square means determined using Model for Repeated Measures (MRM) analysis (adjusted for baseline vision and lesion type (randomisation) as covariates).

Retinal Angiomatous Proliferation (RAP) Lesions

Have a distinct biology and vessel proliferation occurs within the retina (not the choroid)

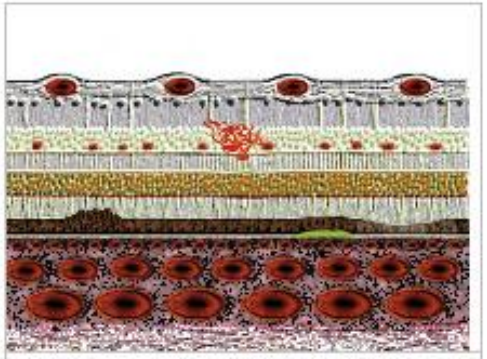


Figure 1: Retinal angiomatous proliferation (RAP) Stage I: intraretinal neovascularization.

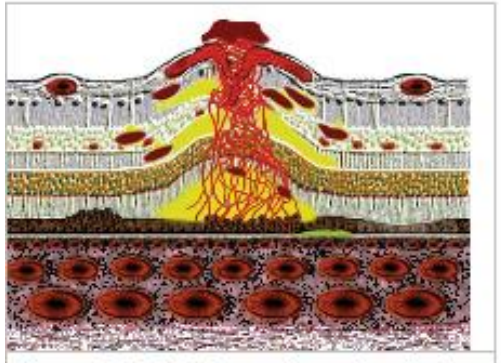


Figure 2: RAP Stage II: subretinal neovascularization with a retinal-retinal anastomosis.

Figure 3: RAP Stage II: subretinal neovascularization with a serous pigment epithelial detachment.

Figure 4: RAP Stage III: Choroidal neovascularization with a vascularized pigment epithelial detachment and a retinal-retinal anastomosis.

- No consensus of which treatment is optimal for RAP lesions*
- Favorable short-term results with anti-VEGF-A treatments but long-term results are conflicting

Nb. RAP lesions were excluded from: e.g. Phase 3 Ophthotech trials, Abicipar (Allergan) Phase 2 study, early conbercept studies

** Tsai AS et al., Surv Ophthalmology, 2017 Jul-Aug; 62(4):462-92. de Jong et al., Ophthalmologica 2019; 241:143-153.*

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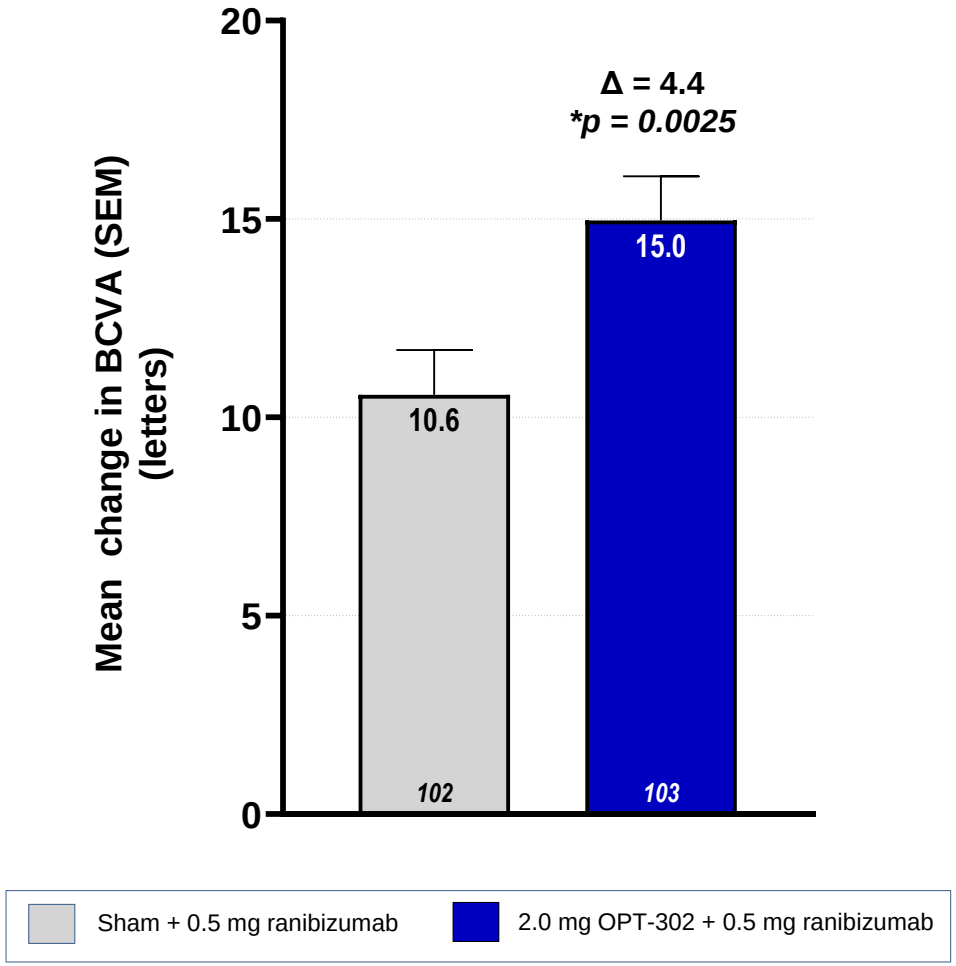
Retinal Angiomatous Proliferation (RAP) Lesions

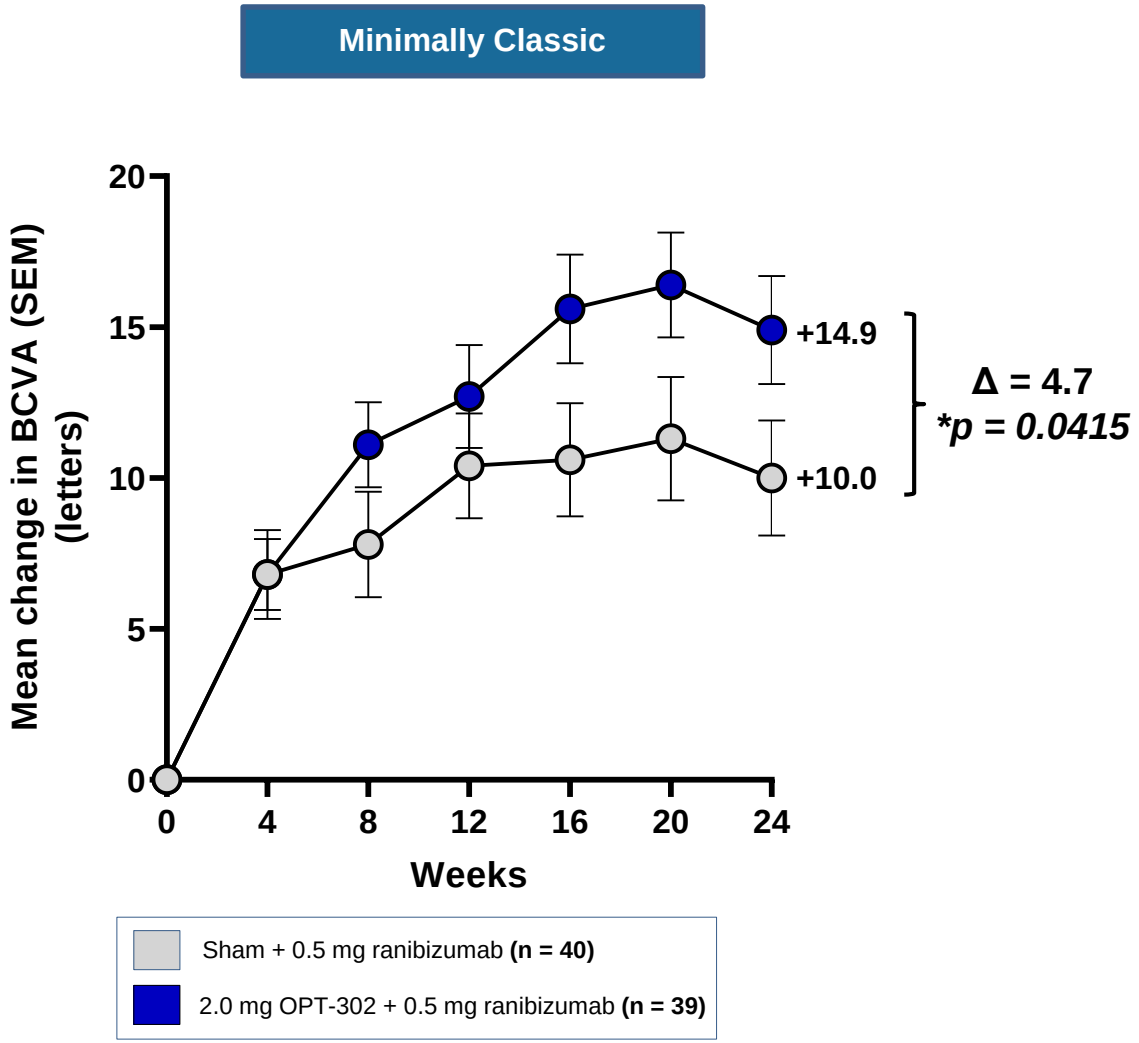
Mean change in BCVA to Week 24 in participants without RAP at baseline

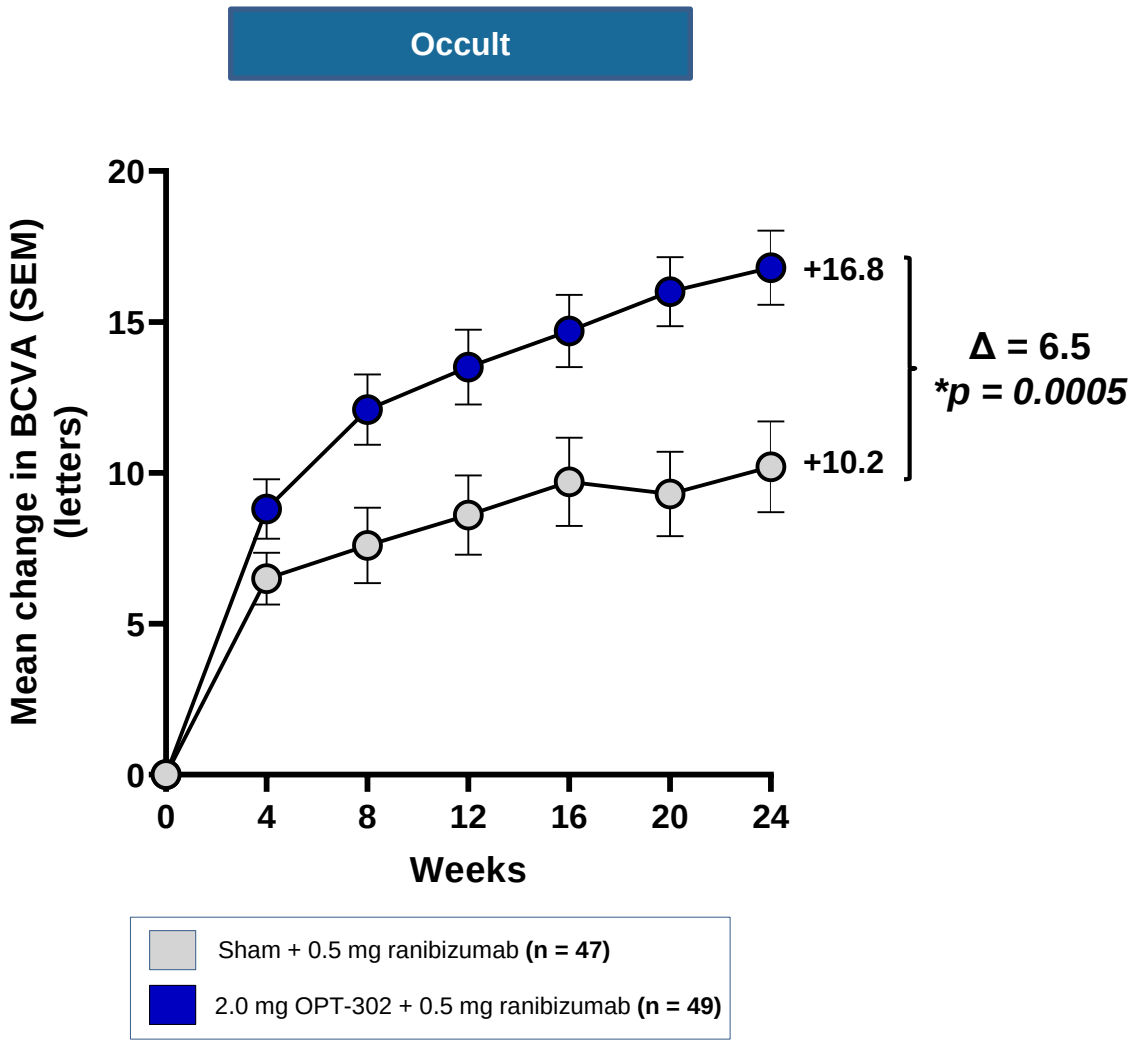


mITT; RAP – retinal angiomatous proliferation;
Least square means (LSM) determined using Model for Repeated Measures (MRM) analysis (adjusted for baseline vision and lesion type as used in the randomisation as covariates).

Mean Change in BCVA Over Time by Lesion Type, RAP Absent

In RAP absent participants, +4.7 letter gain in minimally classic and +6.5 letter gain in occult participants treated with OPT-302 combination therapy compared to sham + ranibizumab





mITT, as observed, Δ based on least square means determined using Model for Repeated Measures (MRM) analysis (adjusted for baseline vision and lesion type (randomisation) as covariates).

Safety – Adverse Events (AEs)

N Participants (%)	Sham + ranibizumab N=121	0.5 mg OPT-302 + ranibizumab N=120	2.0 mg OPT-302 + ranibizumab N=124
Treatment emergent AEs	84 (69.4%)	87 (72.5%)	93 (75.0%)
Ocular AEs - Study Eye – related to study product(s)[1]	17 (14.0%)	17 (14.2%)	19 (15.3%)
Ocular AEs - Study Eye – Severe[2]	1 (0.8%)	2 (1.7%)	1 (0.8%)
Serious AEs	10 (8.3%)	16 (13.3%)	7 (5.6%)
Ocular SAEs in Study Eye	0 (0.0%)	2[3] (1.7%)	0 (0.0%)
Intraocular inflammation[4] – Study Eye	0 (0.0%)	2[3] (1.7%)	1[5] (0.8%)
Participants with AEs leading to study IP discontinuation only	2 (1.7%)	3 (2.5%)	0 (0.0%)
Participants with AEs leading to study discontinuation	1[6] (0.8%)	0 (0.0%)	0 (0.0%)
Any APTC event	0 (0.0%)	1[7] (0.8%)	0 (0.0%)
Deaths	2[8] (1.7%)	0 (0.0%)	0 (0.0%)

Safety population analysed according to medication received

[1] Assessed by investigator to be "possibly related", "probably related" or "definitely related" to administration of study drug(s)

[2] Assessed by Investigator to be National Institutes of Health (NIH) Common Terminology Criteria for Adverse Events (CTCAE) grade 3 or above, or, if CTCAE grade is unavailable, an AE assessed as "causing an inability to perform normal daily activities"

[3] SAE of endophthalmitis, with AEs of hypopyon and anterior chamber cell (n=1), SAE of vitritis (n=1)

[4] AEs considered to be indicative of intraocular inflammation, defined prior to database lock as: Endophthalmitis, iritis, vitritis, iridocyclitis, uveitis, hypopyon, viral iritis, or anterior chamber inflammation

[5] Anterior chamber cell (trace 1-4 cells)

[6] Squamous cell carcinoma of the lung diagnosed shortly after Baseline visit

[7] Non-fatal myocardial infarction

[8] Pneumonia (n=1), infective endocarditis (n=1)

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Study Outcomes - OPT-302 Phase 2b wet AMD Trial

Phase 2b trial met primary endpoint

- OPT-302 (2.0mg) combination therapy demonstrated superiority in visual acuity over ranibizumab + sham
- Vision gain of +3.4 letters
- Statistically significant (p=0.0107)
- High ranibizumab control arm

Secondary outcomes were supportive of the primary endpoint

- Vision
  - More patients gained ≥ 15 letters of vision
  - Fewer patients lost ≥ 15 letters of vision
- Retinal anatomical improvements
  - Reductions in central subfield thickness (CST), sub-retinal and intra-retinal fluid
  - Greater decreases in total lesion area and choroidal neovascularisation (CNV) Area

Exploratory and pre-specified subgroup analyses

- Suggest greater activity of OPT-302 in lesion-types considered more difficult to treat with anti-VGEF-A therapy and highest unmet need
- Promising evidence of activity in polypoidal AMD (PCV) and minimally classic/occult lesions that are less responsive to VEGF-A inhibitors

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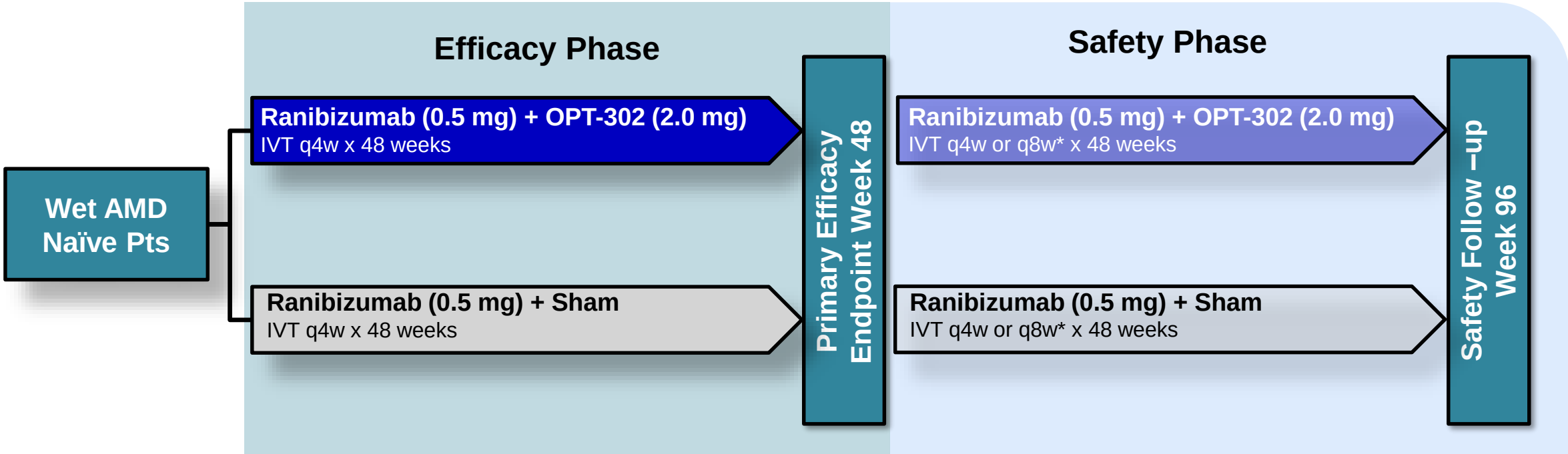
Planned: OPT-302 Pivotal Phase 3 Program



- **Two studies of similar design:** Multi-centre, double-masked, randomised (1:1), sham controlled
- **Regulatory quality:** 90% power, 5% type I error rate
- **Sample size:** 330 patients per arm, 660 per study (1,320 patients across the two studies)
- **Primary Objective:** Mean change from Baseline in BCVA (visual acuity) (ETDRS) at Week 48
- **Trial Initiation:** 4Q 2020
- **Top-line Data Readout:** 1H 2023
- **Full Data Readout:** 1H 2023

** Dosing every 4 or 8 weeks based on clinical signs of disease progression*

Note: The final design of the phase 3 trials is to be confirmed following receipt of regulatory advice and confirmation of the design of the phase 3 clinical program.

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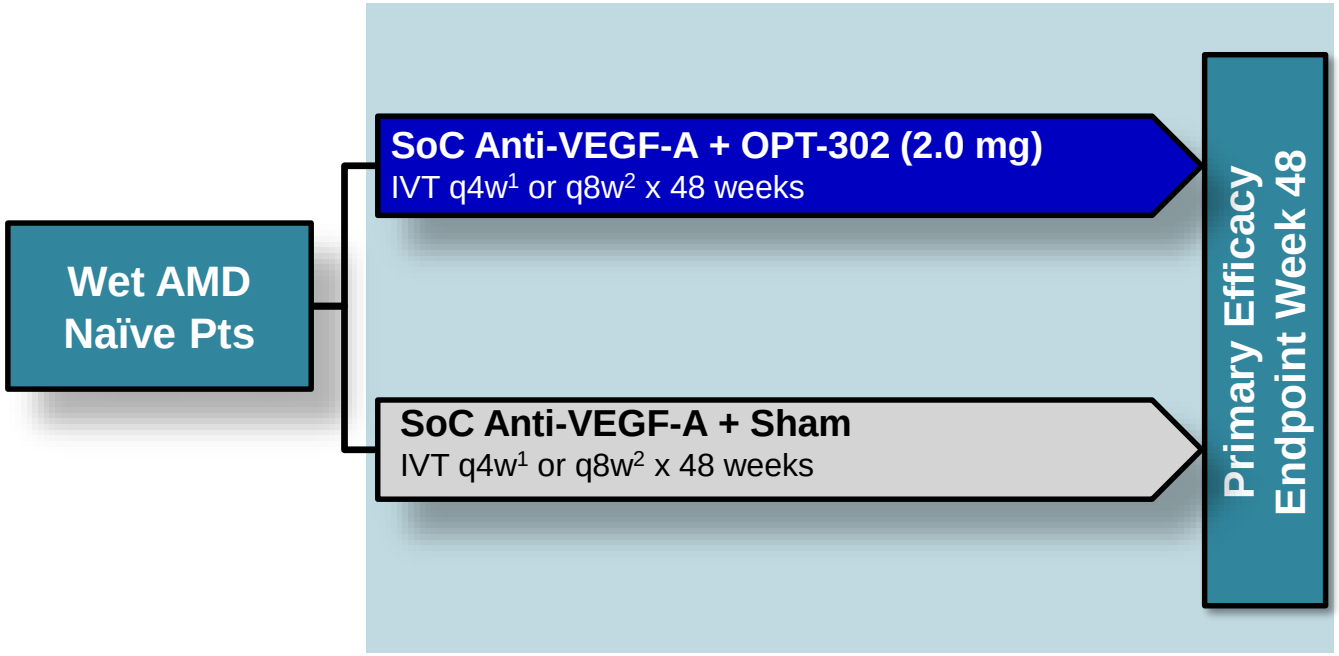
Planned: Phase 3b Trial



- **Similar design to Phase 3:** Multi-centre, double-masked, randomised (1:1), sham controlled
- **Standard of Care (SoC) Anti-VEGF-A:** Standard of Care anti-VEGF-A therapy: 0.5 mg ranibizumab[1], 2.0 mg aflibercept[2], or 1.25 mg bevacizumab[1]
- **Regulatory quality:** 90% power, 5% type I error rate
- **Sample size:** 330 patients per arm, 660 per study, stratified for anti-VEGF-A therapy
- **Primary Objective:** Mean change from Baseline in BCVA (visual acuity) (ETDRS) at Week 48

[1] Dosing schedule: IVT every 4 weeks for 48 weeks
[2] Dosing schedule: IVT every 4 weeks for 12 weeks, then IVT every 8 weeks for 36 weeks

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Note: The final design of the phase 3 trials is to be confirmed following receipt of regulatory advice and confirmation of the design of the phase 3 clinical program.

Ongoing Clinical Trials

Phase 1b/2a DME

Phase 1b/2a study of OPT-302 in combination with aflibercept for persistent central-involved diabetic macular edema

Topline data expected 2Q CY 2019

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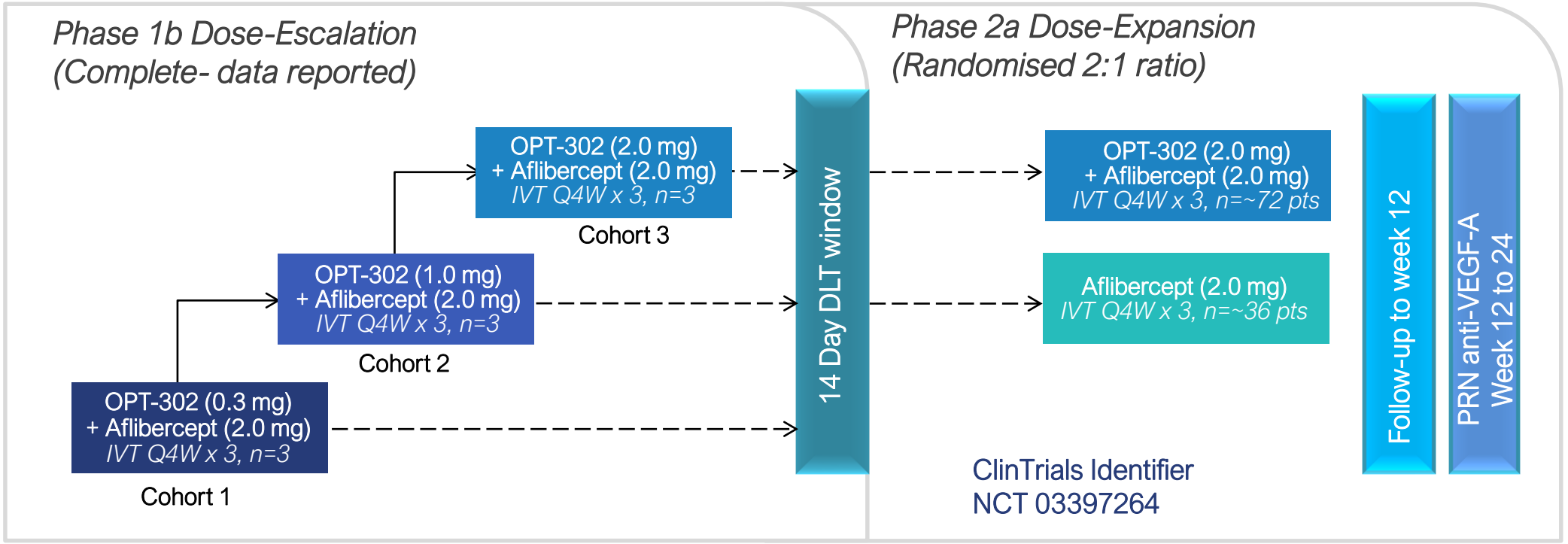
Phase 1b Dose Escalation study of OPT-302 + Aflibercept in DME



Key Inclusion Criteria

- Age ≥ 18 years; centre-involving DME
- CST ≥ 335 µm*
- BCVA 73 – 24 ETDRS letters (20/40 – 20/320 Snellen)
- Prior exposure to anti-VEGF-A therapy with sub-optimal therapeutic response
  - ≥ 3 intravitreal injections
  - Last injection ≤ 6 wks prior to study day 1
  - Prior bevacizumab only allowed if switched to IVT aflibercept or ranibizumab prior to study

Key Exclusion Criteria

- HbA1c ≥ 12%
- Uncontrolled hypertension ≥ 180 mmHg systolic or ≥ 110 mmHg diastolic
- Eyes needing PRP within 3 months of screening
- Concurrent / prior use of intravitreal injections of steroids within 4 months of study start
- Concurrent / prior use of dexamethasone or fluocinolone implant in study eye

CST as measured by Spectralis (Heidelberg) at screening, ≥ 320 µm for Cirrus.

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OPT-302:
An asset with strategic flexibility looking to enter the retinal disease market

Large Unmet Need

Majority of wet AMD & DME patients treated with standard of care anti-VEGF-A treatments respond sub-optimally

>USD 10bn Market Opp.

Lucentis and Eylea generated >$10bn revenue in 2018
OPT-302 is seeking to 'add-on', not 'replace', existing treatments

OPT-302: Superior Vision Gains

OPT-302 combination therapy demonstrated superior gains in visual acuity in a 366 pt Ph2b trial

Upcoming milestone: DME Phase 2a

Phase 2a trial results with OPT-302 + Eylea in 2Q CY 2020
Additional clinical development opportunities

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