Final, 3-year results from the 8 highest recruiting countries included in the global, observational XTEND study of real-world proactive regimens with intravitreal aflibercept 2 mg in patients with neovascular age-related macular degeneration

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Presented at the 24th European Society of Retina Specialists (EURETINA) Congress, Barcelona, Spain, September 19–22, 2024

Disclosures

Disclosures: Presenting author

Jean-François Korobelnik: Consultant for AbbVie, Apellis, Bayer, Eyepoint Pharma, Ocuphire, Roche, Théa Pharmaceuticals, and Carl Zeiss Meditec AG; member of a data safety monitoring board or advisory board for Alexion, Novo Nordisk, and Opthea.

Disclosures: Co-author group

VC: Grants from Bayer, Novartis, and Roche; advisory board member for Alcon Laboratories, Appelis, Bayer, Boehringer Ingelheim, Novartis, and Roche. **PM:** Consultant for Allergan Inc, Apellis, Bayer, Novartis, and Roche; lecture honoraria from Bayer; support for attending meetings and/or travel from Bayer and Roche; member of a data safety monitoring board or advisory board for Apellis and Bayer. **SWK:** Personal fees and non-financial support from Bayer Korea. **HA & XZ:** Employees of Bayer Consumer Care AG, Basel, Switzerland. **TM:** Employee of Bayer AG, Berlin, Germany. **CB:** Honoraria/advisory board meetings for Alimera Sciences, Apellis, Bayer, Boehringer Ingelheim, Janssen, Novartis, and Roche.

Introduction

T&E is a proactive, individualized treatment regimen that is used to minimize the risk of disease recurrence, whilst maintaining visual gains and reducing treatment burden associated with anti-VEGF therapy

XTEND[a] was a 36-month, multicenter, observational, prospective study recruiting patients from 127 sites in 17 countries[1]

The **XTEND study** examined treatment outcomes of **real-world proactive IVT-AFL 2 mg treatment regimens** (fixed dosing or T&E) in treatment-naïve patients with nAMD in routine clinical practice

This final analysis presents the **3-year results** from countries that enrolled **at least 50 patients** in the **XTEND study**

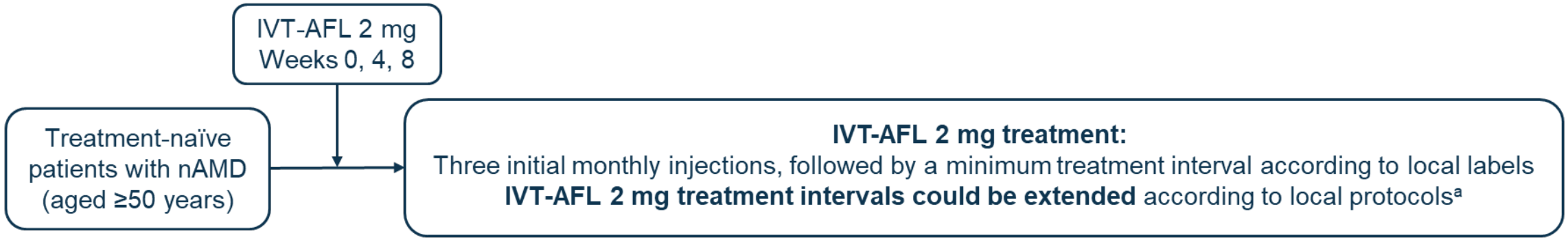
[a]Evaluation of an e**X**tended and proac**T**ive dosing regim**E**n in treatment-**N**aïve patients with neovascular age-related macular **D**egeneration (nAMD). This study was initiated in May 2019 and data collection concluded in October 2023. **IVT-AFL**, intravitreal aflibercept; **nAMD,** neovascular age-related macular degeneration; **T&E,** treat-and-extend; **VEGF,** vascular endothelial growth factor.

1. Korobelnik JF, et al. *Ophthalmol Ther* 2024;13:725–738.

XTEND (NCT03939767) study design and patient demographics

Primary endpoint: Mean change in BCVA (ETDRS letters) from baseline to Month 12

Secondary endpoints included: Mean change in BCVA from baseline to Month 36; mean change in CST from baseline to Month 12 and 36; mean number of IVT-AFL 2 mg injections by Months 12 and 36



	Australia (n=72)	Belgium (n=81)	Canada (n=190)	France (n=149)	South Korea (n=100)	Spain (n=69)	Switzerland (n=51)	UK (n=497)
Age, years	78.7±9.0	79.3±8.3	81.1±8.2	80.6±7.1	72.3±9.1	79.8±6.9	79.2±7.4	79.7±8.1
Female, n (%)	37 (51.4)	53 (65.4)	121 (63.7)	101 (67.8)	46 (46.0)	43 (62.3)	31 (60.8)	319 (64.2)

FAS. Data are mean±SD unless stated otherwise. Decision to treat with an IVT-AFL 2 mg proactive regimen (fixed dosing or T&E) made by the investigator prior to enrollment.
[a]Treatment intervals could be extended in 2-week to 4-week increments up to a maximum of 12 or 16 weeks according to the local label.
BCVA, best-corrected visual acuity; **CST**, central subfield thickness; **ETDRS,** Early Treatment Diabetic Retinopathy Study; **FAS**, full analysis set; **SD**, standard deviation.

Patient baseline demographics

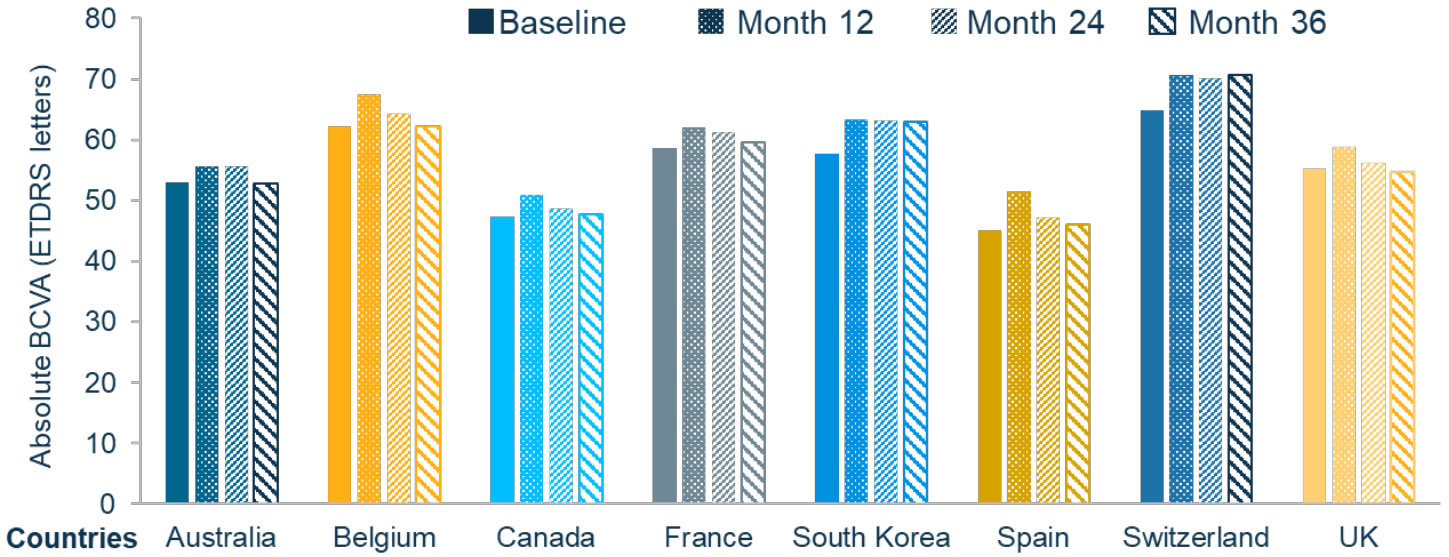
	Australia (n=72)	Belgium (n=81)	Canada (n=190)	France (n=149)	South Korea (n=100)	Spain (n=69)	Switzerland (n=51)	UK (n=497)
Mean BVCA, ETDRS letters[a]	**52.9**±19.5	**62.2**±16.4	**47.3**±22.0	**58.7**±18.9	**57.7**±20.3	**45.0**±23.2	**64.9**±17.9	**55.3**±15.8
BCVA letter score category, n (%)								
<35	10 (13.9)	2 (2.5)	35 (18.4)	12 (8.1)	8 (8.0)	19 (27.5)	3 (5.9)	44 (8.9)
≥35 to <70	45 (62.5)	45 (55.6)	121 (63.7)	90 (60.4)	52 (52.0)	35 (50.7)	20 (39.2)	340 (68.4)
≥70	17 (23.6)	34 (42.0)	34 (17.9)	47 (31.5)	40 (40.0)	15 (21.7)	28 (54.9)	113 (22.7)
Mean CST, µm[b]	346±109 n=69	354±96 n=77	364±109 n=167	384±121 n=138	332±126 n=84	395±129 n=68	399±107 n=49	395±143 n=345
Primary intended treatment regimen after initial monthly injections, n (%)								
Proactive T&E	69 (95.8)	81 (100.0)	177 (93.2)	137 (91.9)	81 (81.0)	63 (91.3)	50 (98.0)	378 (76.1)
Proactive fixed treatment	3 (4.2)	0 (0.0)	13 (6.8)	12 (8.1)	19 (19.0)	6 (8.7)	1 (2.0)	119 (23.9)

Across the 8 countries included in this analysis, **1209 patients were included in the FAS**

In total, 514 patients discontinued treatment, including 151 patients who were lost to follow-up

FAS. Data are mean±SD unless otherwise stated. Percentages may not add up to 100% due to rounding. [a]ETDRS or Snellen chart with conversion to ETDRS were recommended to measure BCVA; [b]Spectral-domain and time-domain optical coherence tomography were used to measure CST, and results were interpreted at local sites.

Functional and anatomic outcomes by Month 36



Across the 8 countries included in this analysis, **mean change** (95% CI) in **CST** from baseline to **12 months** was: **−85** (−111, −60) to **−123** (−158, −87) **µm**,

from baseline to **24 months** was: **−91** (−118, –63) to **−123** (−157, −89) **µm**,

and from baseline to **36 months** was: **−77** (−106, –48) to **−122** (−156, −88) **µm**

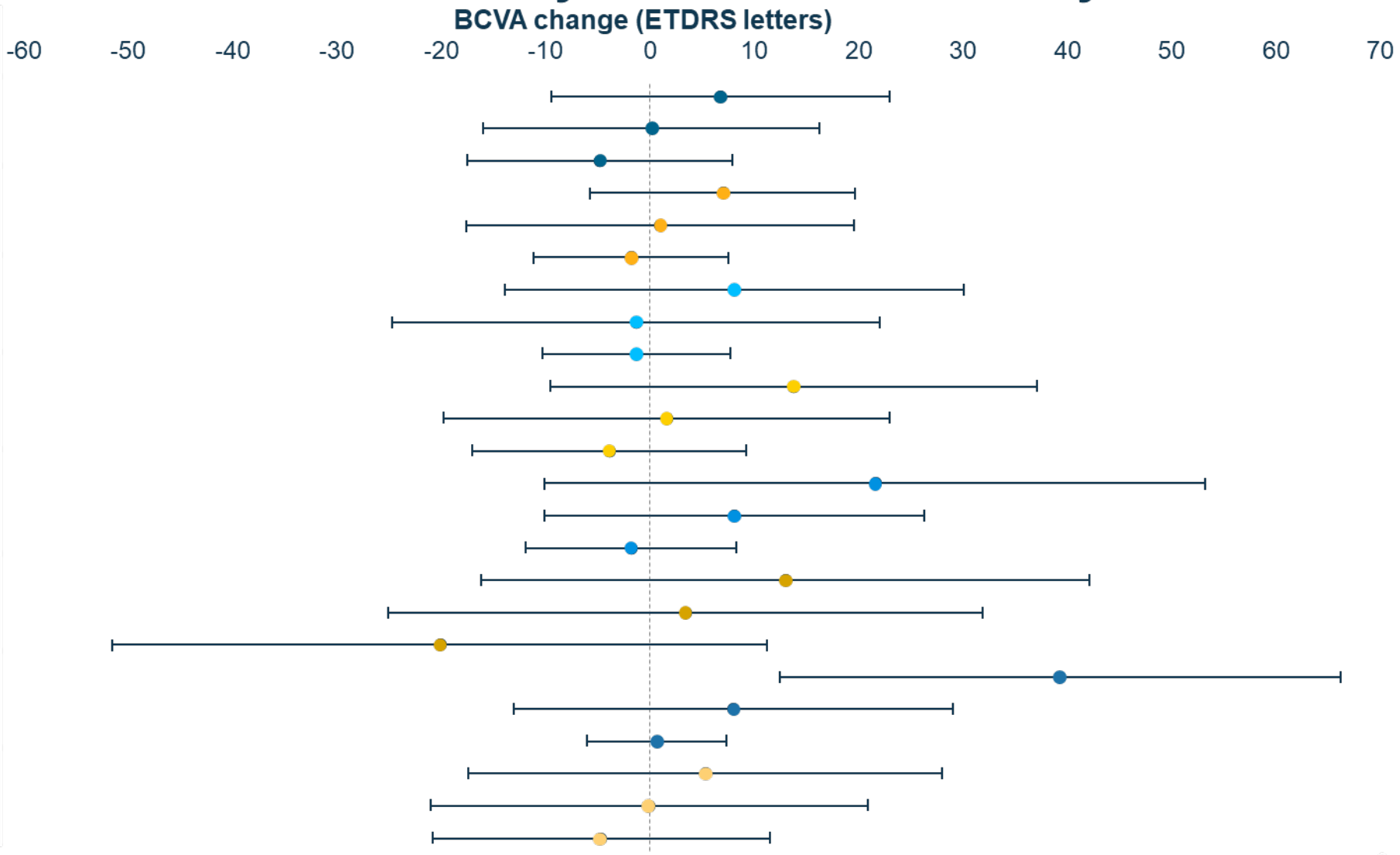
Mean (95% CI) change in BCVA (ETDRS letters[a]) from baseline

	Australia (n=72)	Belgium (n=81)	Canada (n=190)	France (n=149)	South Korea (n=100)	Spain (n=69)	Switzerland (n=51)	UK (n=497)
Baseline	**52.9**±19.5	**62.2**±16.4	**47.3**±22.0	**58.7**±18.9	**57.7**±20.3	**45.0**±23.2	**64.9**±17.9	**55.3**±15.8
M12	**2.7** (−0.0, 5.5)	**5.2** (2.6, 7.8)	**3.6** (1.0, 6.2)	**3.6** (0.9, 6.3)	**5.6** (2.6, 8.7)	**6.5** (−0.8, 13.8)	**5.7** (1.9, 9.4)	**3.4** (2.0, 4.9)
M24	**2.8** (−0.4, 5.9)	**2.0** (–1.8, 5.9)	**1.4** (−1.7, 4.4)	**2.4** (−0.3, 5.2)	**5.5** (2.1, 8.8)	**2.1** (−4.9, 9.1)	**5.3** (1.1, 9.5)	**0.9** (−0.6, 2.5)
M36	**−0.1** (−3.7, 3.6)	**−0.0** (−3.4, 3.3)	**0.4** (−2.6, 3.5)	**0.9** (−2.3, 4.1)	**5.3** (1.7, 8.9)	**1.0** (−6.5, 8.5)	**5.8** (0.9, 10.7)	**−0.6** (−2.4, 1.2)

FAS, LOCF. Data are mean±SD unless otherwise stated. [a]ETDRS or Snellen chart with conversion to ETDRS were recommend to measure BCVA.
CI, confidence interval; **LOCF**, last observation carried forward, **M**, month.

Visual outcomes at 36 months stratified by baseline visual acuity

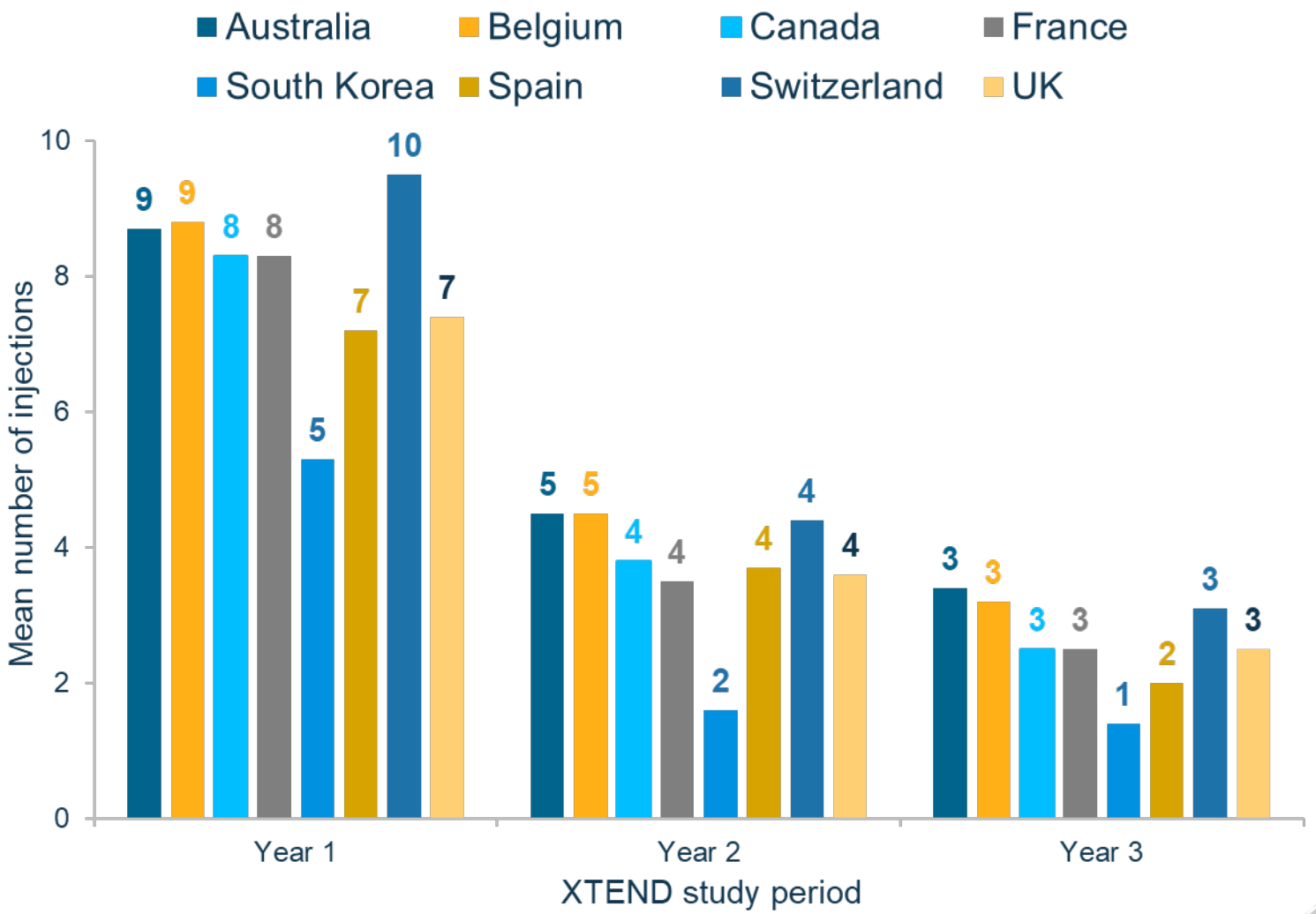
	Baseline BCVA (ETDRS letters)	BCVA change at M36[a]
Australia (n=72)	<35 (n=10)	6.8
	≥30-<70 (n=45)	0.2
	≥70 (n=17)	−4.8
Belgium (n=81)	<35 (n=2)	7.0
	≥35-<70 (n=45)	1.0
	≥70 (n=34)	−1.8[b]
Canada (n=190)	<35 (n=35)	8.1
	≥35-<70 (n=121)	−1.3
	≥70 (n=34)	−1.3[b]
France (n=149)	<35 (n=12)	13.8
	≥35-<70 (n=90)	1.6
	≥70 (n=47)	−3.9[b]
South Korea (n=100)	<35 (n=8)	21.6
	≥35-<70 (n=52)	8.1
	≥70 (n=40)	−1.8[b]
Spain (n=69)	<35 (n=19)	13.0
	≥35-<70 (n=35)	3.4
	≥70 (n=15)	−20.1
Switzerland (n=51)	<35 (n=3)	39.3
	≥35-<70 (n=20)	8.0
	≥70 (n=28)	0.7[b]
UK (n=497)	<35 (n=44)	5.3
	≥35-<70 (n=340)	−0.1
	≥70 (n=113)	−4.7



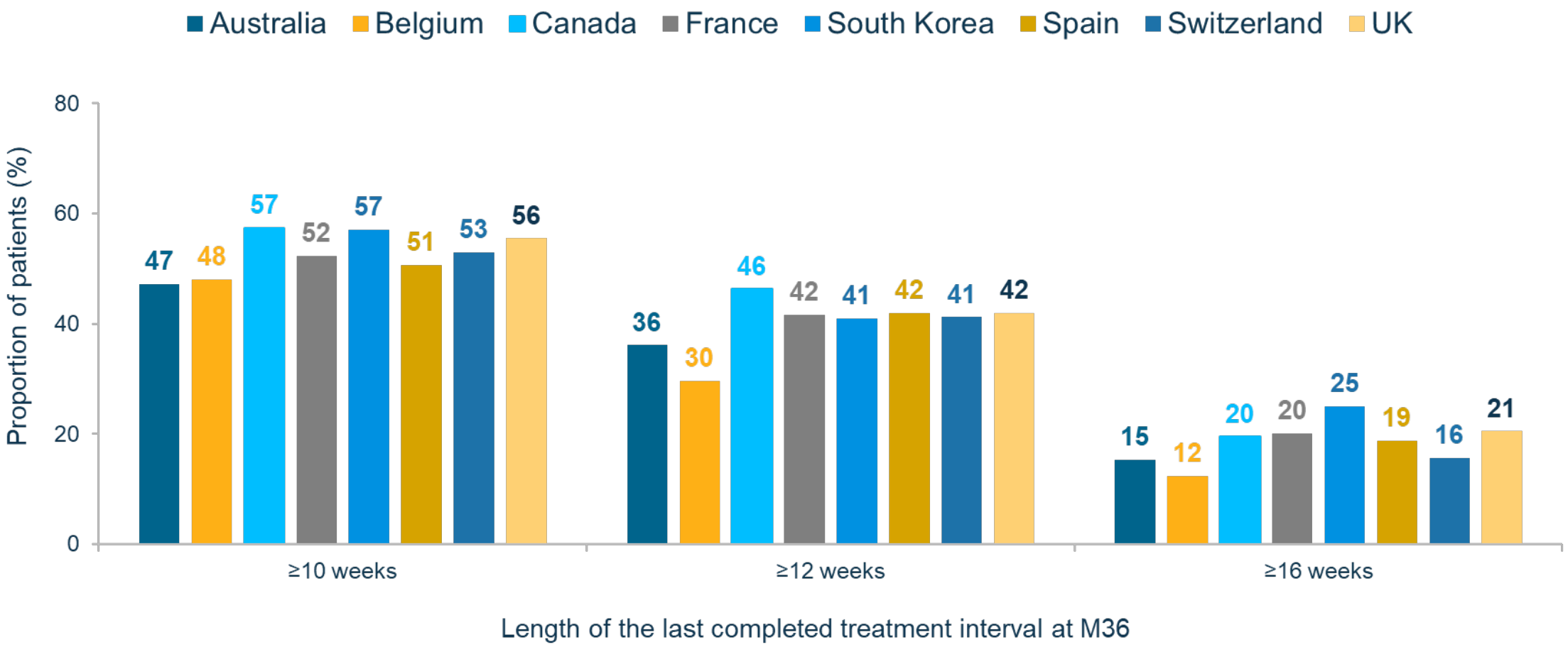
FAS, LOCF. Error bars denote SD. [a]ETDRS letters; [b]Maintained BCVA ≥70 letters at M36.

Treatment exposure – number of injections

Mean (95% CI) BCVA change at:	M12	M24	M36
Australia (n=72)	2.7 (−0.0, 5.5)	2.8 (−0.4, 5.9)	−0.1 (−3.7, 3.6)
Belgium (n=81)	5.2 (2.6, 7.8)	2.0 (−1.8, 5.9)	−0.0 (−3.4, 3.3)
Canada (n=190)	3.6 (1.0, 6.2)	1.4 (−1.7, 4.4)	0.4 (−2.6, 3.5)
France (n=149)	3.6 (0.9, 6.3)	2.4 (−0.3, 5.2)	0.9 (−2.3, 4.1)
South Korea (n=100)	5.6 (2.6, 8.7)	5.5 (2.1, 8.8)	5.3 (1.7, 8.9)
Spain (n=69)	6.5 (−0.8, 13.8)	2.1 (−4.9, 9.1)	1.0 (−6.5, 8.5)
Switzerland (n=51)	5.7 (1.9, 9.4)	5.3 (1.1, 9.5)	5.8 (0.9, 10.7)
UK (n=497)	3.4 (2.0, 4.9)	0.9 (−0.6, 2.5)	−0.6 (−2.4, 1.2)



Treatment exposure – last treatment interval up to 36 months



FAS. Patients included in the analysis: Australia, n=72; Belgium, n=81; Canada, n=190; France, n=149; South Korea, n=100; Spain, n=69; Switzerland, n=51; UK, n=497. Data were missing for 1 patient in Canada, South Korea, and Spain, and 3 patients in the UK.

Conclusions

The breadth and diversity of the XTEND study allowed for this **descriptive analysis** of 8 countries that enrolled ≥50 patients

Baseline BCVA, age, and **CST** varied widely from country to country, indicating differing severity of nAMD across the population

There was a **broad range of injection numbers across the 8 countries**, which could be attributed to differences in disease severity, recruiting practices, and **country-specific regulations** and protocols, especially during the COVID-19 pandemic

The safety profile of IVT-AFL 2 mg was consistent with previous studies[1,2] and is published for XTEND up to Month 24[3]

1. Heier JS, et al. *Ophthalmology* 2012;119:2537–2548. 2. Schmidt-Erfurth U, et al. *Ophthalmology* 2014;121:193–201. 3. Korobelnik JF, et al. *Ophthalmol Ther* 2024;13:725–738.

Thank you to all XTEND patients and investigators

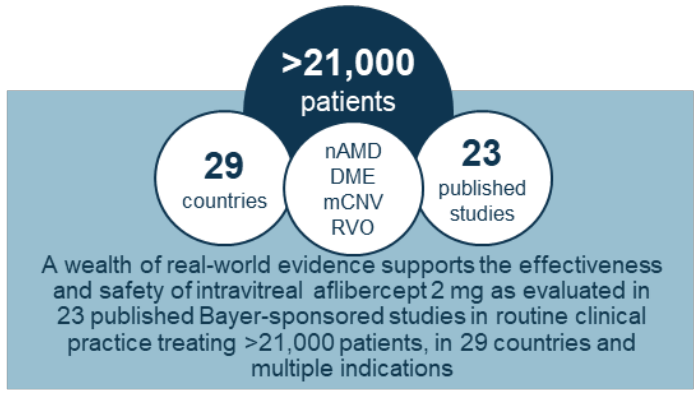
Acknowledgments

The authors would like to posthumously acknowledge Ramin Tadayoni for his involvement in the XTEND study and the EURETINA24 abstract development.

The XTEND study was sponsored by Bayer AG, Leverkusen, Germany. Medical writing support, under the direction of the authors, was provided by ApotheCom and funded by Bayer Consumer Care AG, Basel, Switzerland, in accordance with Good Publication Practice (GPP) guidance (*Ann Intern Med.* 2022;175:1298–1304).

Project management and administrative support for the XTEND study were provided by JinKyung Lee and Marcel Schulze (Bayer AG, Berlin, Germany).

XTEND[1] is part of the aflibercept RWE program:



A wealth of real-world evidence supports the effectiveness and safety of intravitreal aflibercept 2 mg as evaluated in 23 published Bayer-sponsored studies in routine clinical practice treating >21,000 patients, in 29 countries and multiple indications

World map showing XTEND study site countries only.

DME, diabetic macular edema; **mCNV**, myopic choroidal neovascularization; **RVO**, retinal vein occlusion. **RWE**, real-world evidence.

1. Korobelnik JF, et al. *Ophthalmol Ther* 2024;13:725–38.