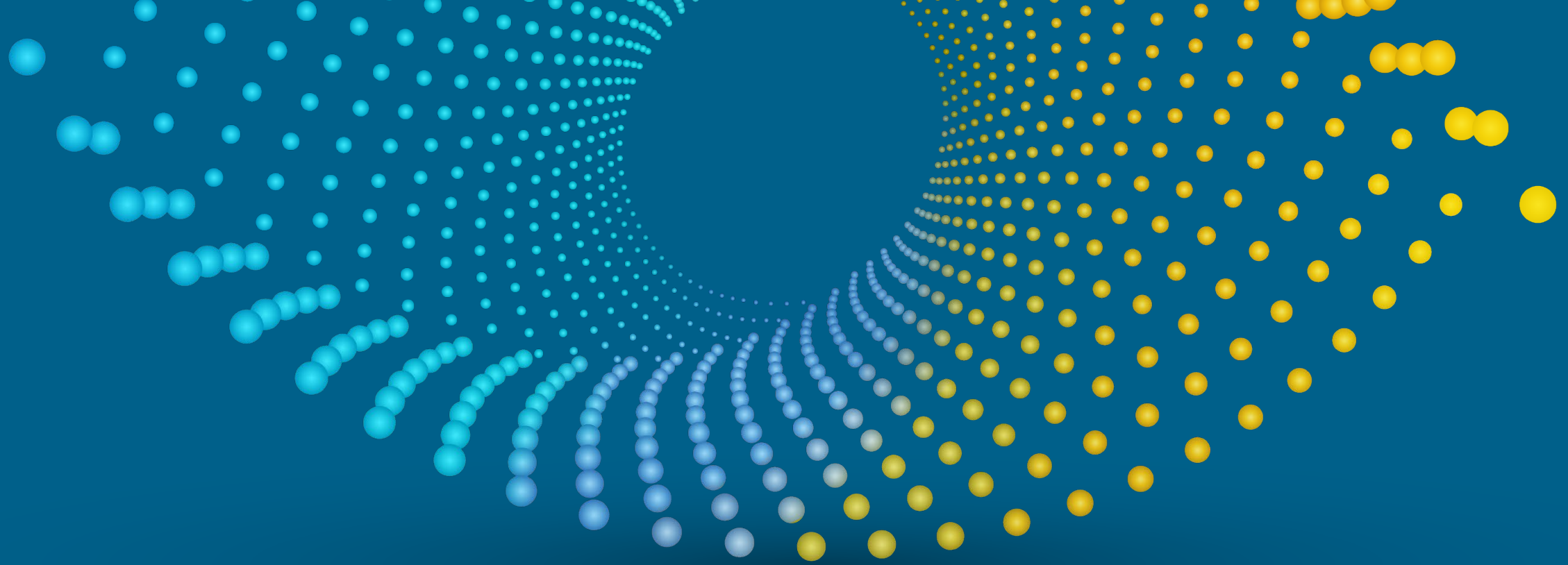

Two-year results from the eight highest recruiting countries included in the global observational XTEND study of real-world proactive regimens with intravitreal aflibercept in patients with nAMD

Jean-François Korobelnik,[1,2] Varun Chaudhary,[3] Paul Mitchell,[4] Se Woong Kang,[5] Ramin Tadayoni,[6] Helmut Allmeier,[7] JinKyung Lee,[8] Tobias Machewitz,[8] Xin Zhang,[7] Clare Bailey,[9] on behalf of the XTEND study investigators

[1]CHU Bordeaux, Service d'Ophtalmologie, Bordeaux, France; [2]Univ. Bordeaux, INSERM, BPH, UMR 1219, F-33000, Bordeaux, France; [3]Hamilton Regional Eye Institute, St. Joseph's Healthcare Hamilton, McMaster University, Hamilton, Ontario, Canada; [4]University of Sydney (Westmead Institute for Medical Research), Sydney, NSW, Australia; [5]Samsung Medical Center, Sungkyunkwan University, Seoul, Korea; [6]Université Paris Cité, AP-HP, Lariboisière, Saint Louis and Fondation Adolphe de Rothschild Hospitals, Paris, France; [7]Bayer Consumer Care AG, Basel, Switzerland; [8]Bayer AG, Berlin, Germany; [9]Bristol Eye Hospital, Bristol, United Kingdom

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Disclosures

Presenting author

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

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Introduction

Treat-and-extend 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] is an ongoing, 36-month, multicenter, observational, prospective study recruiting patients from 127 sites in 17 countries

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

This analysis presents the **2-year results** from countries that enrolled **at least 50 patients** into 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 is due to conclude in August 2023.

nAMD, neovascular age-related macular degeneration; **T&E,** treat-and-extend; **VEGF,** vascular endothelial growth factor.

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 24; mean change in CST from baseline to Month 12 and 24; mean number of IVT-AFL injections by Months 12 and 24

	Australia (n=60)	Belgium (n=81)	Canada (n=190)	France (n=147)	South Korea (n=100)	Spain (n=69)	Switzerland (n=51)	UK (n=496)
Age, years	78.0±9.2	79.3±8.3	81.1±8.2	80.4±7.1	72.3±9.1	79.8±6.9	79.2±7.4	79.7±8.1
Female, n (%)	34 (56.7)	53 (65.4)	121 (63.7)	100 (68.0)	46 (46.0)	43 (62.3)	31 (60.8)	319 (64.3)

FAS. Data are mean±SD unless stated otherwise. Decision to treat with an IVT-AFL proactive regimen (fixed dosing or T&E) made by the investigator prior to enrollment.
[a]Treatment intervals could be extended in 2- 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

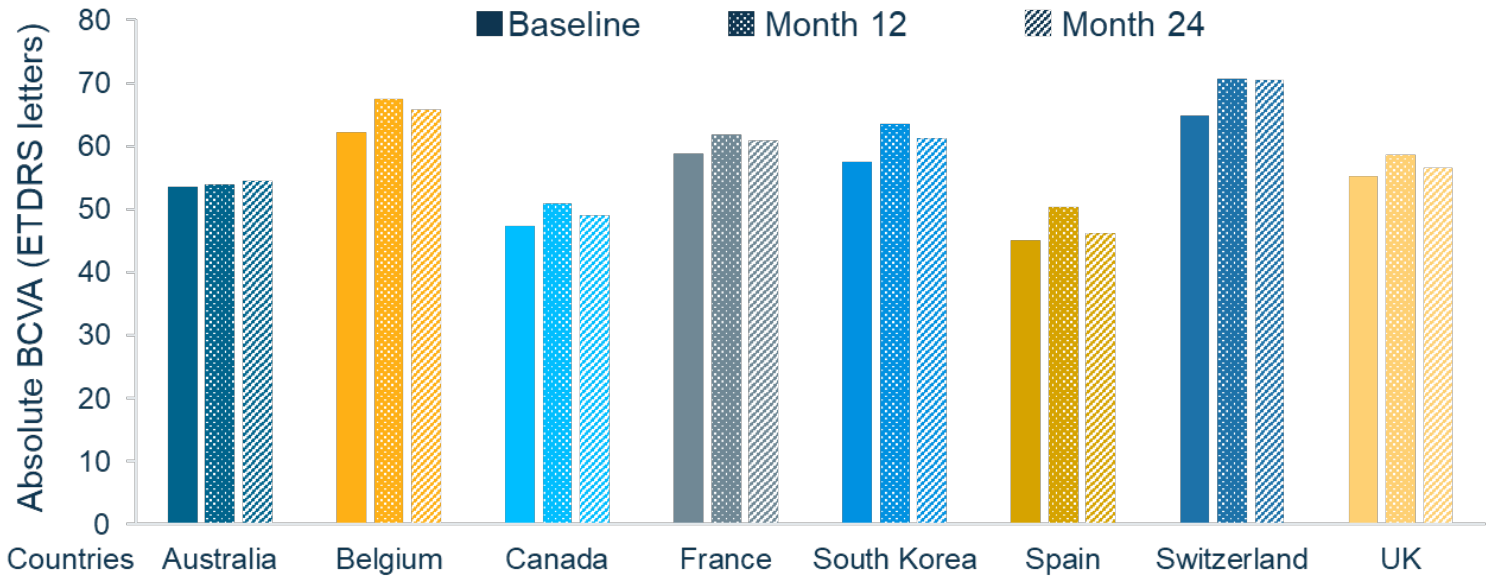
	Australia (n=60)	Belgium (n=81)	Canada (n=190)	France (n=147)	South Korea (n=100)	Spain (n=69)	Switzerland (n=51)	UK (n=496)
Mean BVCA, ETDRS letters[a]	**53.5**±19.6	**62.2**±16.4	**47.3**±22.0	**58.8**±19.0	**57.5**±20.5	**45.0**±23.2	**64.9**±17.9	**55.2**±15.8
BCVA letter score category, n (%)								
<35	8 (13.3)	2 (2.5)	35 (18.4)	12 (8.2)	9 (9.0)	19 (27.5)	3 (5.9)	44 (8.9)
≥35 to <70	36 (60.0)	45 (55.6)	121 (63.7)	88 (59.9)	51 (51.0)	35 (50.7)	20 (39.2)	339 (68.3)
≥70	16 (26.7)	34 (42.0)	34 (17.9)	47 (32.0)	40 (40.0)	15 (21.7)	28 (54.9)	113 (22.8)
Mean CST, µm[b]	322±85.6	354±96	364±109	384±122	332±126	395±129	402±106	395±143
Primary intended treatment regimen after initial monthly injections, n (%)								
Proactive T&E	57 (95.0)	81 (100.0)	177 (93.2)	135 (91.8)	81 (81.0)	63 (91.3)	50 (98.0)	380 (76.6)
Proactive fixed treatment	3 (5.0)	0 (0.0)	13 (6.8)	12 (8.2)	19 (19.0)	6 (8.7)	1 (2.0)	116 (23.4)

Across the eight countries included in this analysis, **1194 patients were included in the FAS**

In total, 325 patients discontinued treatment, including 60 patients who were lost to follow-up

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

Functional and anatomic outcomes by Month 24



Across the eight countries included in this analysis, **mean change** (95% CI) in **CST** from baseline to **12 months** was **−79** (−110, −47) **to −125** (−161, −90) **µm**, and from baseline to **24 months** was **−93** (−117, 69) **to −127** (−162, −93) **µm**

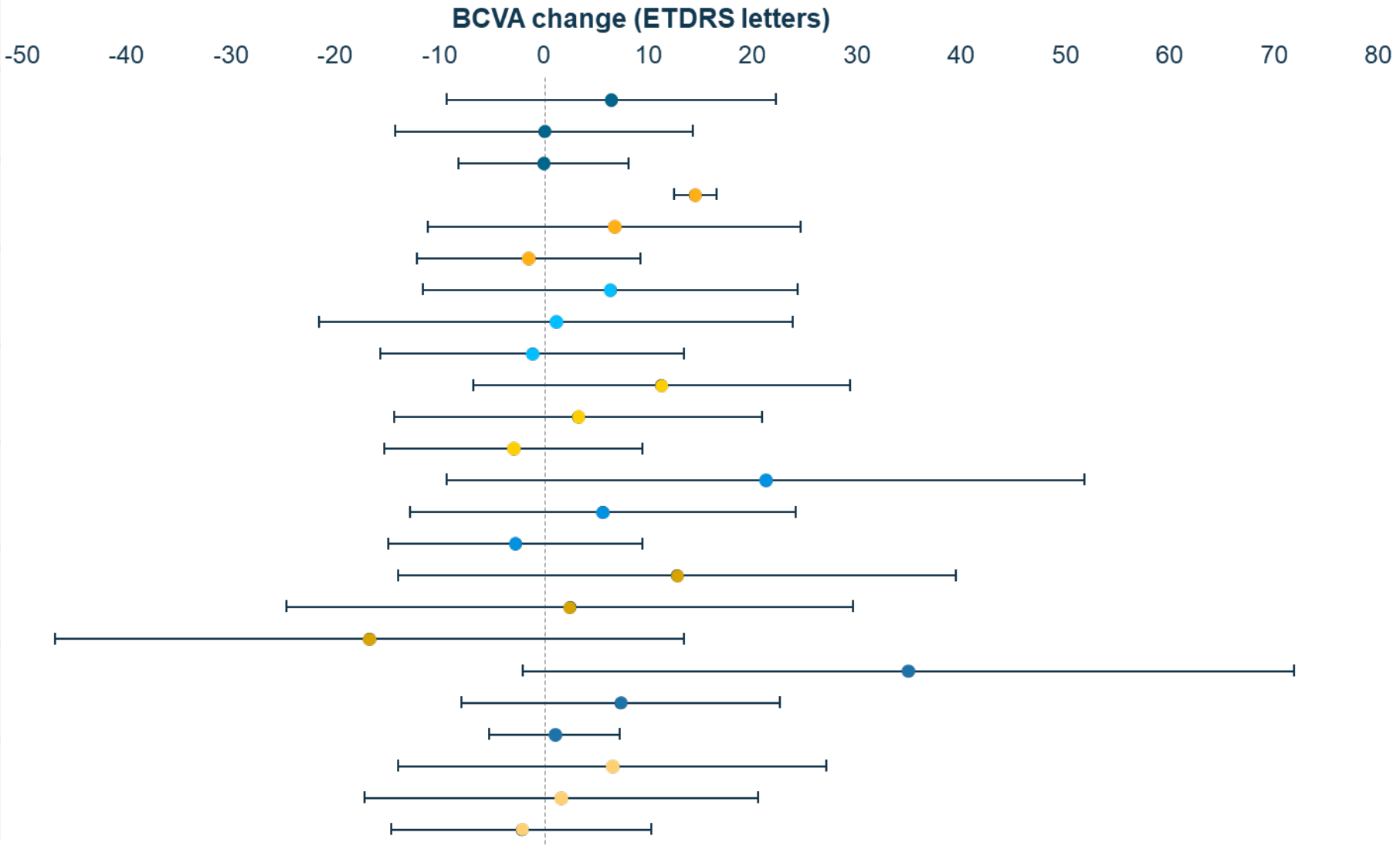
Mean (95% CI) change in BCVA (ETDRS letters[a]) from baseline

	Australia (n=60)	Belgium (n=81)	Canada (n=190)	France (n=147)	South Korea (n=100)	Spain (n=69)	Switzerland (n=51)	UK (n=496)
Baseline	**53.5**±19.6	**62.2**±16.4	**47.3**±22.0	**58.8**±19.0	**57.5**±20.5	**45.0**±23.2	**64.9**±17.9	**55.2**±15.8
M12	**0.3** (−3.0, 3.6)	**5.2** (2.6, 7.8)	**3.7** (1.1, 6.3)	**3.4** (0.8, 6.1)	**5.8** (2.7, 8.8)	**5.5** (−1.8, 12.8)	**5.7** (1.9, 9.4)	**3.4** (2.0, 4.9)
M24	**0.9** (−2.5, 4.3)	**3.6** (0.1, 7.0)	**1.7** (−1.2, 4.7)	**2.0** (−0.7, 4.7)	**3.7** (−0.0, 7.5)	**1.2** (−5.8, 8.2)	**5.6** (1.3, 9.8)	**1.3** (−0.3, 2.9)

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

Visual outcomes at 24 months stratified by baseline visual

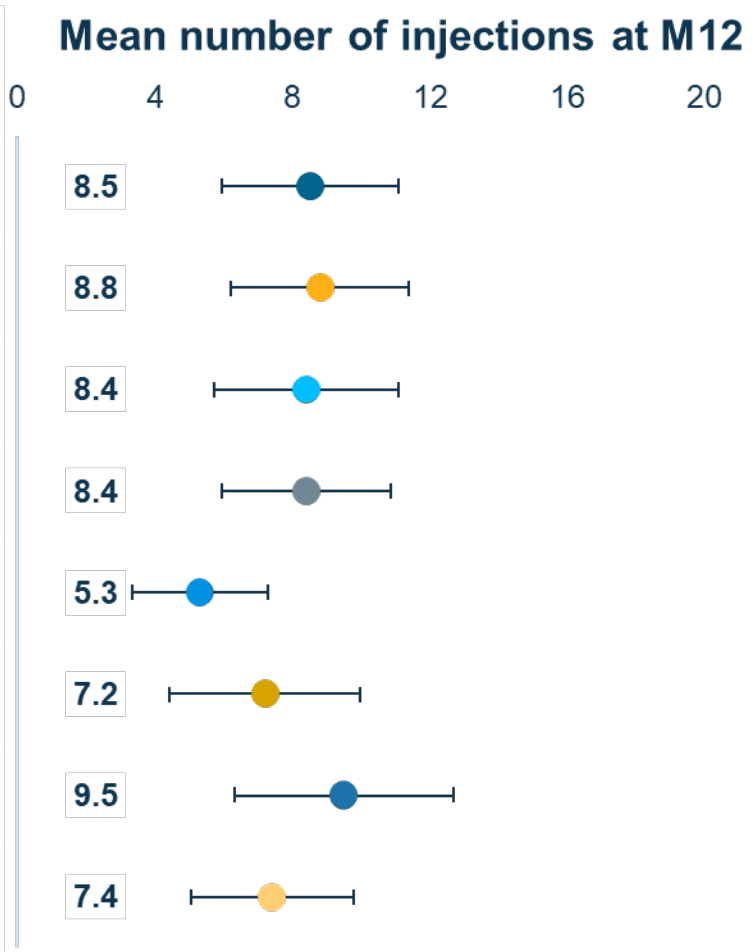
Baseline BCVA		BCVA change at M24[a]
Australia (n=60)	<35 (n=8) ≥35-<70 (n=36) ≥70 (n=16)	6.5 0.1 0
Belgium (n=81)	<35 (n=2) ≥35-<70 (n=45) ≥70 (n=34)	14.5 6.8 −1.4
Canada (n=190)	<35 (n=35) ≥35-<70 (n=121) ≥70 (n=34)	6.4 1.2 −1.1
France (n=147)	<35 (n=12) ≥35-<70 (n=88) ≥70 (n=47)	11.3 3.3 0.5
South Korea (n=100)	<35 (n=9) ≥35-<70 (n=51) ≥70 (n=40)	21.3 5.7 −2.7
Spain (n=69)	<35 (n=19) ≥35-<70 (n=35) ≥70 (n=15)	12.8 2.5 −16.7
Switzerland (n=51)	<35 (n=3) ≥35-<70 (n=20) ≥70 (n=28)	35 7.4 1.1
UK (n=496)	<35 (n=44) ≥35-<70 (n=339) ≥70 (n=113)	6.6 1.7 −2.1



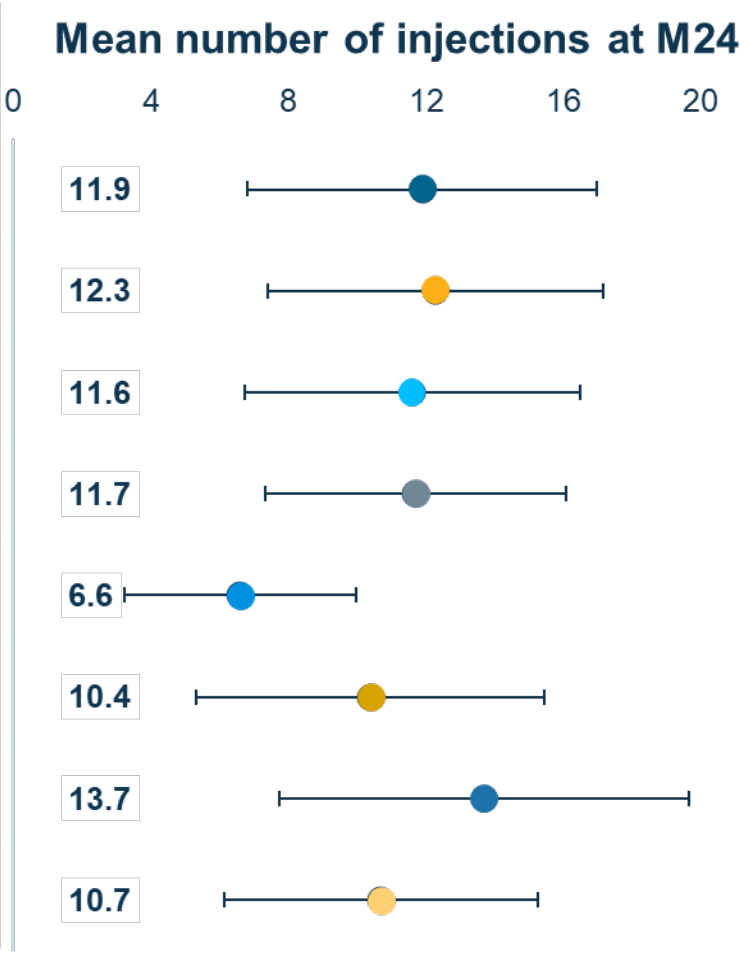
FAS, LOCF. Error bars denote SD. [a]ETDRS letters

Treatment exposure – number of injections

Mean (95% CI) BCVA change at M12	
Australia (n=60)	**0.3** (−3.0, 3.6)
Belgium (n=81)	**5.2** (2.6, 7.8)
Canada (n=190)	**3.7** (1.1, 6.3)
France (n=144)	**3.4** (0.8, 6.1)
South Korea (n=100)	**5.8** (2.7, 8.8)
Spain (n=68)	**5.5** (−1.8, 12.8)
Switzerland (n=51)	**5.7** (1.9, 9.4)
UK (n=489)	**3.4** (2.0, 4.9)

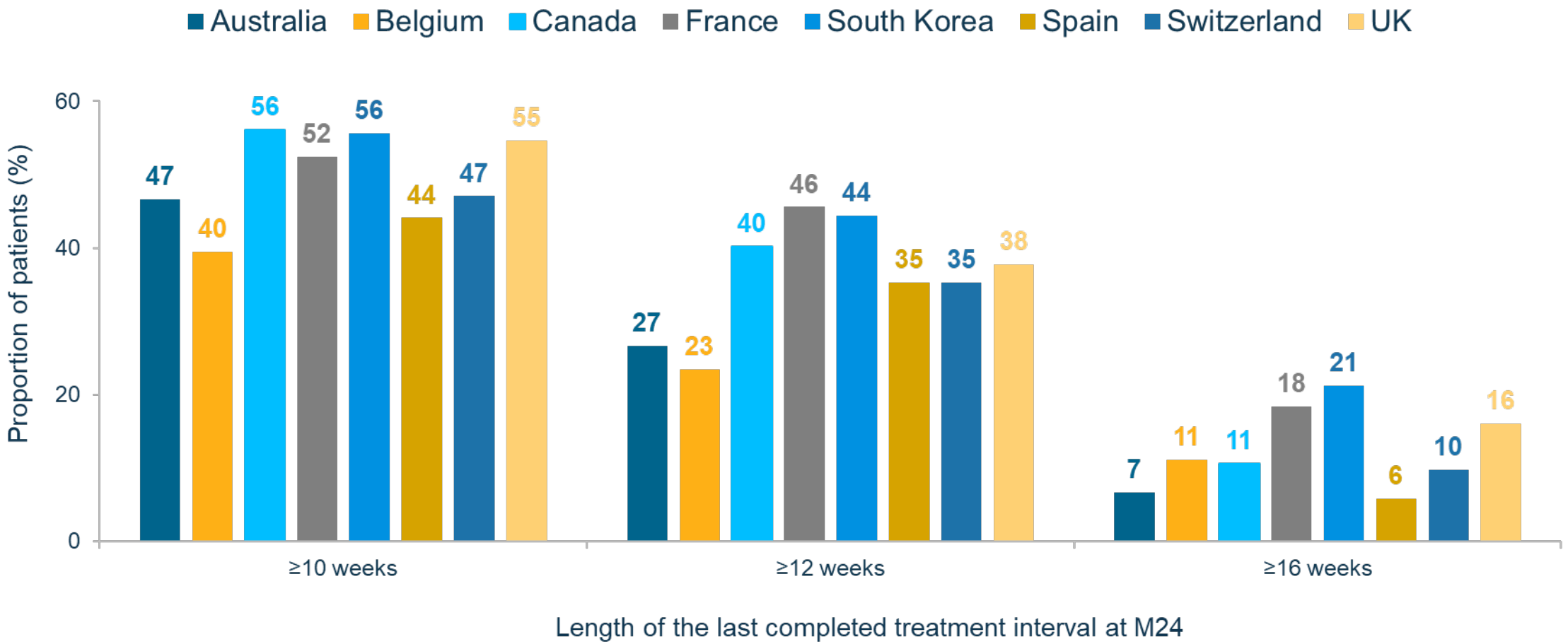


Mean (95% CI) BCVA change at M24	
Australia (n=60)	**0.9** (−2.5, 4.3)
Belgium (n=81)	**3.6** (0.1, 0.7)
Canada (n=190)	**1.7** (−1.2, 4.7)
France (n=147)	**2.0** (−0.7, 4.7)
South Korea (n=100)	**3.7** (0.0, 7.5)
Spain (n=69)	**1.2** (−5.8, 8.2)
Switzerland (n=51)	**5.6** (1.3, 9.8)
UK (n=496)	**1.3** (−0.3, 2.9)



Error bars denote SD.

Treatment exposure – last treatment interval up to 24 months



FAS. Patients included in the analysis: Australia, n=60; Belgium, n=81; Canada, n=189; France, n=147; South Korea, n=99; Spain, n=68; Switzerland, n=50; UK, n=493. Data were missing for 1 patient each in Canada, South Korea, Spain and Switzerland, and 3 patients in the UK.

Conclusions

In the ongoing XTEND study, the majority of patients enrolled with **high baseline BCVA**, suggesting **early initiation of treatment for nAMD**

There was a **broad range of baseline BCVA and injection numbers across the eight countries** that enrolled ≥50 patients, which could be attributed to differences in recruiting practices and **country-specific regulations** and protocols

In seven of the eight countries, for patients with a **baseline BCVA of ≥70 letters, BCVA was generally maintained** during the first 2 years of the ongoing 3-year study, **even in the setting of the COVID-19 pandemic**

The safety profile of IVT-AFL was consistent with previous studies,[1,2] and was reported at **ARVO 2023**. The study is ongoing, with the **36-month analysis** planned for 2024

1. Heier et al. *Ophthalmology* 2012;119(12):2537–48. 2. Schmidt-Erfurth et al. *Ophthalmology* 2014;121(1):193–201. **ARVO**, The Association for Research in Vision and Ophthalmology.

Thank you to all XTEND patients and investigators

For more information, please contact:

Jean-Francois Korobelnik
jean-francois.korobelnik@chu-bordeaux.fr

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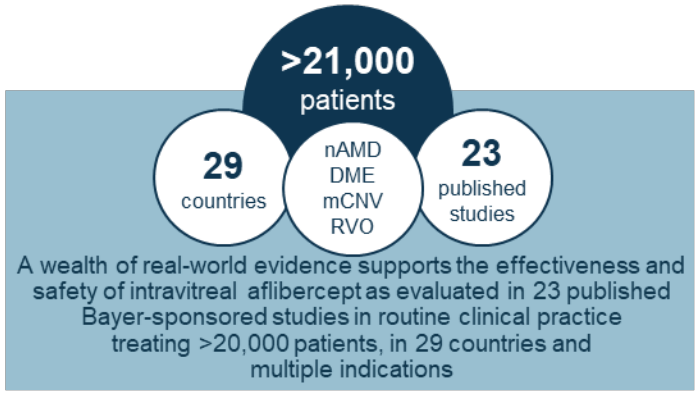

A wealth of real-world evidence supports the effectiveness and safety of intravitreal aflibercept as evaluated in 23 published Bayer-sponsored studies in routine clinical practice treating >20,000 patients, in 29 countries and multiple indications

World map showing XTEND study site countries only.