

SUPPLEMENTARY MATERIALS

XTEND: Two-Year Results from a Global Observational Study Investigating Proactive Dosing of Intravitreal Aflibercept in Neovascular Age-Related Macular Degeneration

Authors

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Online Supplementary Table S1 Ethics approval boards

| Country | Site # | Site name | Name of the ethics committees | Number/ID of the approvals |
|-----------|--------|--------------------------------------|--|--|
| Argentina | 43001 | Centro Oftalmológico | Comité de Etica en Investigación Clínica | 6/13/2019 13Mar20 |
| Argentina | 43002 | Salud Ocular | Comité de Etica en Investigación Clínica | 6/13/2019 13Mar20 |
| Argentina | 43003 | Centro Oftalmológico | Comité de Etica en Investigación Clínica | 6/13/2019 13Mar20 |
| Argentina | 43004 | Centro de Estudios Oftalmológico | Comité de Etica en Investigación Clínica | 6/13/2019 13Mar20 |
| Argentina | 43005 | Clinica Privada de Oftalmológico | Comité de Etica en Investigación-Instituto de Investigaciones Clínicas | 10/4/2019 09Oct20 |
| Australia | 40001 | Sydney Retina Clinic | Bellberry Human Research Ethics Committee | EC00444 |
| Australia | 40002 | Southwest Retina | | |
| Australia | 40003 | Sydney West Retina | | |
| Australia | 40004 | Specialist Eye Group | | |
| Australia | 40005 | Adelaide Eye and Retina | | |
| Belgium | 28001 | UZ (Universitair Ziekenhuis Leuven) | Ethische Commissie Onderzoek UZ/KU Leuven | EC: S62610, Belg. Regnr: B322201940359 |
| Belgium | 28002 | UZ Brussel - Ophthalmology | | |
| Belgium | 28003 | ZNA-Ziekenhuizen | | |
| Belgium | 28004 | AZ Sint-Jan Brugge-Oostende | | |
| Belgium | 28005 | Cliniques Universitaires Saint-Luc | | |
| Belgium | 28006 | UZ (Universitair Ziekenhuis Brussel) | | |
| Belgium | 28007 | Private practice Alk | | |
| Belgium | 28008 | CHR Peltzer-La Tourelle | | |
| Belgium | 28009 | Oculus Leper | | |
| Belgium | 28010 | CHR de la Citadelle | | |
| Canada | 26001 | OculoVision | Advarra, Inc. | Pro00033372 27MAY2019 |
| Canada | 26007 | Arif Samad | Advarra, Inc. | Pro00033372 11SEPT2019 |
| Canada | 26008 | Clinique de Rétine de l'Est | Advarra, Inc. | Pro00033372 3SEPT2019 |
| Canada | 26009 | Institut de l'oeil | Advarra, Inc. | Pro00033372 19AUG2019 |
| Canada | 26010 | RETINA MD | Advarra, Inc. | Pro00033372 29OCT2019 |
| Canada | 26011 | North Toronto Eye Care | Advarra, Inc. | Pro00033372 23SEPT2019 |
| Canada | 26012 | Ivey Eye Institute | Western University Health Science Research Ethics Board (HSREB) | 114566 7OCT2019 |
| Canada | 26013 | Hamilton Regional Eye | Hamilton Integrated Research Ethics Board | 7484 9/10/2019 |
| Canada | 26014 | Kensington Eye Clinic | Advarra, Inc. | Pro00033372 11/25/2019 |

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|----------|-------|---|--|------------------------------------|
| Canada | 26015 | Prism Eye Institute | Advarra, Inc. | Pro00033372 11/26/2019 |
| China | 54001 | Beijing Hospital | Institutional Review Board of Beijing Hospital | 2019BJYYEC-092- 02 |
| China | 54002 | The First Affiliated Hospital of Zhengzhou University | Research and Clinical Trial Ethics Committee of the First Affiliated Hospital of Zhengzhou University | SS-2019-062 |
| China | 54003 | Xi' an No.4 Hospital | IRB of Institution for National Drug Clinical Trials, Xi'an People's Hospital (Xi'an Fourth Hospital) | Put Record No.001 |
| China | 54004 | Xuzhou No.1 People's Hospital | Xuzhou No.1 People's Hospital Medical Ethics Committee | No. xyyl[2019]25 |
| China | 54005 | The Affiliated Eye Hospital of Nanjing Medical University | IRB of The Affiliated Eye Hospital of Nanjing Medical University | [2019] Lun Shen Zi No.(2019009) |
| China | 54006 | Shenzhen Ophthalmic Hospital | Medical Ethics Committee of Shenzhen Eyes Hospital | No. 20191021-01 |
| China | 54007 | Peking Union Medical College Hospital | Ethics Review Committee of Peking Union Medical College Hospital | B336 |
| Colombia | 48001 | Fundación de oftalmólogos en Bogotá | Cómite de Ética en Investigación de la Fundación Oftalmológica Nacional | 15-Aug-19 |
| Colombia | 48002 | Fundación Oftalmológica del Caribe | Cómite de Ética en Investigación Clínica Oftalmológica del Caribe | 24-Sep-19 |
| Colombia | 48003 | DRA. Beatriz Elvira Endo Abella | Cómite de Ética en Investigación Fundación BIOS | 05-Sep-19 |
| Colombia | 48005 | INICIO | Cómite de Ética en Investigación Instituto Neurológico de Colombia | 25-Sep-19 |
| Colombia | 48006 | Clínica FOSCAL | Cómite de Ética en Investigación FOSCAL | 13-Sep-19 |
| Colombia | 48008 | DRA. Myriam Hernández | Cómite de Ética en Investigación Fundación BIOS | 05-Sep-19 |
| Denmark | 35001 | Hospital of Southern Denmark | no need to submit | NA |
| Denmark | 35002 | Aalborg University Hospital | no need to submit | NA |
| France | 16001 | CHU Bordeaux | C.P.P. I.D.F VII (Comité de Protection des Personnes Ile- de-France VII) | 19-050 |
| France | 16002 | CIL (Centre Ophtalmologique) | | |
| France | 16003 | Cabinet Ophtalmologique | | |
| France | 16004 | Cabinet Ophtalmologique | | |
| France | 16005 | Centre Odéon Paris | | |
| France | 16006 | CHU de Dijon | | |
| France | 16007 | Hôpital d'instruction des armées | | |
| France | 16008 | Cabinet d'Ophtalmologique | | |

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|---------|-------|---|---|---|
| France | 16009 | Hôpital de la Croix-Rousse | | |
| France | 16010 | Pôle Vision Val d'Ouest | | |
| France | 16011 | CHU Gabriel-Montpied Clermont-Ferrand | | |
| France | 16012 | Clinique Honoré Cave | | |
| France | 16013 | Centre de Rétine Médicale | | |
| France | 16014 | Centre Ophtalmologie Rétine Gallien à Bordeaux | | |
| France | 16015 | Centre Ophtalmologique | | |
| France | 16016 | CHU de Nice | | |
| France | 16017 | CHU de Marseille | | |
| France | 16018 | Hôpital Lariboisière | | |
| France | 16019 | Cabinet Ophtalmologique | | |
| France | 16020 | Cabinet Ophtalmologique | | |
| France | 16021 | Fondation Ophtalmologique | | |
| France | 16022 | Cabinet Ophtalmologique | | |
| France | 16023 | Centre Explore Vision | | |
| France | 16024 | Cabinet Ophtalmologique | | |
| France | 16025 | CHIC Intercommunal de Creteil | | |
| France | 16026 | Hôpital Purpan, CHU de Toulouse | | |
| France | 16027 | Hôpital des Quinze-Vingts | | |
| France | 16028 | La Pitié Salpêtrière | | |
| France | 16029 | Cabinet Ophtalmologique | | |
| France | 16030 | Hôpital Cochin | | |
| France | 16031 | Clinique Mathilde Rouen | | |
| Ireland | 80001 | Progressive Vision | Research Ethics committee administrator, Beacon hospital, Suite 13, Sandyford, Dublin 18, Ireland | BEA0128 |
| Ireland | 80002 | UPMC Whitfield Hospital | Clinical Research Ethics Committee of the Cork Teaching Hospitals, University College Cork, Lancaster Hall, 6 Little Hanover Street, Cork, Ireland | ECM 4 (s) 22/10/2019 & ECM 3 (pp) 05/05/2020 |

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|--------------------|-------|---|--|--|
| Ireland | 80003 | The Mater Hospital | Institutional review board, Mater Misericordiae University Hospital, Eccles Street, Dublin, Ireland | 1/378/2087 |
| Italy | 22001 | IRCCS Fondazione G. Bietti per lo Studio e la Ricerca in Oftalmologia ONLUS | COMITATO ETICO CENTRALE I.R.C.C.S. LAZIO Sezione IRCCS I.F.O. – Fondazione G.B. Bietti | Registro Sperimentazioni 87/19/FB/verbale 7 del 16/07/2019 |
| Italy | 22002 | Presidio Ospedaliero San Giovanni di Dio, Cagliari | COMITATO ETICO INDIPENDENTE Azienda Ospedaliero Universitaria di Cagliari | |
| Italy | 22003 | Ospedale Santa Maria della Misericordia | Comitato Etico Unico Regionale FVG | ID Studio 2920/Parere CEUR-2019-Os-160 |
| Korea, Republic Of | 56001 | Yeungnam University Hospital | Yeungnam University IRB | YUMC 2019-03-047 |
| Korea, Republic Of | 56002 | Seoul National University Hospital | Clinical Research Information Service Seoul National University Hospital | H-1906-095-1040 |
| Korea, Republic Of | 56003 | Ajou University Hospital | Ajou University Hospital IRB | AJIRB-MED-OBS-19-197 |
| Korea, Republic Of | 56004 | Samsung Medical Center | Samsung Medical Center IRB | SMC-2019-07-079 |
| Korea, Republic Of | 56005 | Pusan National University Hospital | Pusan National University IRB | H-1903-004-090 |
| Korea, Republic Of | 56006 | GangNam Severance Hospital | Yonsei University GangNam Severance Hospital IRB | 3-2019-0054 |
| Korea, Republic Of | 56007 | The Catholic University Hospital | The Catholic University Hospital IRB | KC19MOGE0416 |
| Korea, Republic Of | 56008 | Hanyang University Guri University Hospital | Hanyang University Guri Hospital IRB | GURI 2019-06-021 |
| Korea, Republic Of | 56009 | Kim's Eye Hospital | Kim's Eye Hospital IRB | KEH 2019-06-005-007 |
| Korea, Republic Of | 56010 | ChungNam National University Hospital | ChungNam National University IRB | CNUH-2019-06-060 |
| Norway | 36001 | Hospital of Southern Norway | REC South-East, Gullhaugveien 1-3, 0484 Oslo, Norway | 2019/894 |
| Norway | 36001 | Sørlandet Sykehus, Arendal | REC South-East, Gullhaugveien 1-3, 0484 Oslo, Norway | 2019/894 |
| Spain | 24002 | Hospital Universitare | Comité de Ética de la Investigación de Cádiz | |
| Spain | 24004 | Hospital Universitario Virgen de la Arrixaca | | |
| Spain | 24007 | Hospital Virgen del Rocio | | |

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|----------------|-------|--------------------------------------|---|-------------------------------------|
| Spain | 24009 | Hospital ESPERANÇA | Comité de Ética de la Investigación con medicamentos del Parc de Salut MAR | |
| Spain | 24010 | Hospital Universitario Araba | Comité de Ética en Investigación Clínica (CEIC) de Euskadi | |
| Spain | 24011 | Hospital de Cruces | Comité de Ética en Investigación Clínica (CEIC) de Euskadi | |
| Spain | 24012 | Hospital Arnau de Vilanova | Comité ético de investigación del Hospital Universitario Arnau de Vilanova | |
| Spain | 24013 | Hospital Regional Universitario | | |
| Spain | 24014 | Hospital de Leon | Comité de Ética de la Investigación con medicamentos de las Áreas de Salud de León y del Bierzo | |
| Spain | 24015 | Hospital de Burgos | | |
| Sweden | 34001 | Skaane University Hospital | Swedish Ethical Review Authority, Box 2110, 75002 Uppsala, Sweden | 2019-02642 |
| Sweden | 34002 | Uppsala University | | |
| Sweden | 34003 | OegonCentrum Annedal | | |
| Sweden | 34004 | Helsingborg Hospital | | |
| Sweden | 34001 | Skånes University Hospital Lund | Swedish Ethical Review Authority, Box 2110, 75002 Uppsala, Sweden | 2019-02642 |
| Switzerland | 58001 | Vista Klinik Binningen | Ethikkommission Nordwest- und Zentralschweiz (EKNZ) | 2019-01573 |
| Switzerland | 58002 | Universitätsspital Basel | | |
| Switzerland | 58003 | Stadsspital Triemli | | |
| Switzerland | 58004 | RétinElysée | | |
| Switzerland | 58005 | Universitätsspital Zurich | | |
| Switzerland | 58006 | Luzerner Kantonsspital | | |
| Thailand | 71001 | King Chulalongkorn Memorial Hospital | Institutional Review Board Faculty of Medicine, Chulalongkorn University | COA no.1016/2019 and IRB no. 479/62 |
| Thailand | 71002 | Chiang Mai University | Research Ethics Committee Faculty of Medicine Chiang Mai University | 004/2563 |
| Thailand | 71003 | Khon Kaen University | Khon Kaen University Ethics Committee in Human Research Faculty of Medicine, Khon Kaen University | HE621430 |
| United Kingdom | 12001 | Bristol Eye Hospital | South Central - Oxford C Research Ethics Committee and HRA and Health and Care Research Wales (HCRW) Approval | 19/SC/0148 |
| United Kingdom | 12002 | Queen Alexandra Hospital | | |
| United Kingdom | 12003 | Leicester Royal Infirmary | | |
| United Kingdom | 12004 | King's College Hospital | | |
| United Kingdom | 12005 | Colchester Eye Centre | | |

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|----------------|-------|---|--|--|
| United Kingdom | 12006 | Singleton Hospital | | |
| United Kingdom | 12007 | Stoke Mandeville Hospital | | |
| United Kingdom | 12008 | Westmorland General Hospital | | |
| United Kingdom | 12009 | Royal Victoria Infirmary | | |
| United Kingdom | 12010 | Gloucestershire Royal Hospital | | |
| United Kingdom | 12011 | Aberdeen Royal Infirmary | | |
| United Kingdom | 12012 | Royal Liverpool University | | |
| United Kingdom | 12013 | Norfolk and Norwich University Hospital | | |
| United Kingdom | 12014 | Royal Victoria Hospital | | |
| United Kingdom | 12015 | The York Hospital | | |
| United Kingdom | 12016 | Sunderland Eye Hospital | | |
| United Kingdom | 12017 | Birmingham & Midland Eye Centre | | |
| United Kingdom | 12018 | Frimley Park Hospital | | |
| United Kingdom | 12019 | New Cross Hospital | | |
| United Kingdom | 12020 | Moorfields Eye Hospital | | |
| United Kingdom | 12021 | East Kent Hospitals | | |
| United Kingdom | 12022 | Peterborough City Hospital | | |
| United Kingdom | 12023 | Epsom and St Helier Hospital | | |
| United Kingdom | 12024 | Southampton Hospitals | | |

Online Supplementary Table S2 Inclusion and exclusion criteria

| Inclusion criteria | Exclusion criteria |
|--|---|
| <ul style="list-style-type: none"> ○ A diagnosis of nAMD ○ Patients for whom the decision to initiate treatment with IVT-AFL in a proactive regimen was made as routine clinical practice ○ Treatment naïve in the study eye (no prior therapy for nAMD) ○ Patient aged ≥ 50 years ○ Written informed patient consent before the start of data collection (according to the requirements of the local authorities and laws) | <ul style="list-style-type: none"> ○ Participation in an investigational program with interventions outside of routine clinical practice ○ Patients with contraindications to IVT-AFL listed in the local marketing authorization ○ Planned treatment regimen outside of the local marketing authorization ○ Patients with eye diseases, e.g. advanced glaucoma or visually significant cataracts, likely to require surgery during the observation period in the study eye ○ Concomitant ocular or systemic administration of drugs up to 3 months before IVT-AFL treatment that could interfere with or potentiate the mechanism of action of IVT-AFL, including other anti-VEGF agents in the fellow eye ○ Any other retinal disease that may interfere with the treatment of nAMD |

IVT-AFL intravitreal aflibercept, nAMD neovascular age-related macular degeneration, VEGF vascular endothelial growth factor

Online Supplementary Table S3 Mean change in BCVA from baseline to month 12 and month 24

| | EMA-aligned label <i>n</i> = 1165 | Non-EMA-aligned label <i>n</i> = 301 | Total <i>N</i> = 1466 |
|-----------------|--|---|----------------------------------|
| Baseline | | | |
| Mean VA | 55.1 ± 19.8 | 51.6 ± 21.8 | 54.3 ± 20.3 |
| <i>n</i> (%) | 1165 (100) | 301 (100) | 1466 (100) |
| Month 12 | | | |
| Mean VA | 59.7 ± 21.5 | 54.9 ± 24.9 | 58.7 ± 22.3 |
| Change from BL | 4.6 [3.6, 5.6] | 3.4 [1.5, 5.2] | 4.3 [3.4, 5.3] |
| <i>n</i> (%) | 1150 (98.7) | 301 (100) | 1451 (99.0) |
| Month 24 | | | |
| Mean VA | 57.4 ± 23.2 | 53.8 ± 26.5 | 56.6 ± 24.0 |
| Change from BL | 2.3 [1.2, 3.4] | 2.2 [0.1, 4.3] | 2.3 [1.3, 3.3] |
| <i>n</i> (%) | 1165 (100) | 301 (100) | 1466 (100) |

FAS, LOCF. Data are mean ± SD and mean [95% CI], unless otherwise stated

BCVA best-corrected visual acuity, BL baseline, CI confidence interval, EMA European Medicines Agency, FAS full analysis set, LOCF last observation carried forward, SD standard deviation, VA visual acuity

Online Supplementary Table S4 The proportion of patients (as defined by treatment eyes) achieving a VA letter score ≥ 70 letters (Snellen equivalent of 20/40 or better) in patients with treatment-naïve nAMD following 12 and 24 months of IVT-AFL treatment in routine clinical practice

| | EMA-aligned label <i>n</i> = 1165 | Non-EMA-aligned label <i>n</i> = 301 | Total <i>N</i> = 1466 |
|-------------------|--|---|----------------------------------|
| Baseline | | | |
| ≥ 70 letters | 334 (28.7) | 78 (25.9) | 412 (28.1) |
| < 70 letters | 831 (71.3) | 223 (74.1) | 1054 (71.9) |
| 12 months | | | |
| ≥ 70 letters | 514 (44.1) | 123 (40.9) | 637 (43.5) |
| < 70 letters | 636 (54.6) | 178 (59.1) | 814 (55.5) |
| 24 months | | | |
| ≥ 70 letters | 486 (41.7) | 123 (40.9) | 609 (41.5) |
| < 70 letters | 679 (58.3) | 178 (59.1) | 857 (58.5) |

Data are *n* (%)

FAS, LOCF

EMA European Medicines Agency, FAS full analysis set, IVT-AFL intravitreal aflibercept, LOCF last observation carried forward, nAMD neovascular age-related macular degeneration, VA visual acuity

Online Supplementary Table S5 Mean change in CST measured by OCT (μm) from BL to month 12 and month 24 in patients with treatment-naïve nAMD

| | EMA-aligned label <i>n</i> = 894 | Non-EMA-aligned label <i>n</i> = 273 | Total <i>N</i> = 1167 |
|-----------------|---|---|----------------------------------|
| Baseline | | | |
| Mean CST | 378 \pm 131 | 362 \pm 107 | 374 \pm 126 |
| <i>n</i> (%) | 894 (100) | 273 (100) | 1167 (100) |
| Month 12 | | | |
| Mean CST | 271 \pm 97 | 260 \pm 82 | 269 \pm 93 |
| Change from BL | -107 [-116, -98] | -103 [-118, -86] | -106 [-114, -99] |
| <i>n</i> (%) | 837 (93.6) | 268 (98.2) | 1105 (94.7) |
| Month 24 | | | |
| Mean CST | 267 \pm 96 | 254 \pm 71 | 264 \pm 91 |
| Change from BL | -109 [-118, -100] | -109 [-123, -96] | -109 [-117, -102] |
| <i>n</i> (%) | 860 (96.2) | 268 (98.2) | 1128 (96.7) |

FAS, LOCF. Data are mean \pm SD and mean [95% CI], unless otherwise stated. The mean CST change data are based on the nearest CST assessment within the \pm 60-day visit window of 360 days for month 12 and 720 days for month 24

BL baseline, *CI* confidence interval, *CST* central subfield thickness, *EMA* European Medicines Agency, *FAS* full analysis set, *LOCF* last observation carried forward, *nAMD* neovascular age-related macular degeneration, *OCT* optical coherence tomography, *SD* standard deviation

Online Supplementary Table S6 Safety overview cumulative up to 2 years (SAS)

| Number of patients (%) | EMA-aligned label <i>n</i> = 1221 | Non-EMA-aligned label <i>n</i> = 329 | Total <i>N</i> = 1550 |
|---|--------------------------------------|---|--------------------------|
| Any AE | 88 (7.2) | 13 (4.0) | 101 (6.5) |
| Any TEAE | 384 (31.4) | 80 (24.3) | 464 (29.9) |
| Any ocular TEAE | 271 (22.2) | 54 (16.4) | 325 (21.0) |
| Any non-ocular TEAE | 178 (14.6) | 38 (11.6) | 216 (13.9) |
| Any ocular TEAE in the study eye | 197 (16.1) | 36 (10.9) | 233 (15.0) |
| Any ocular TEAE in the fellow eye | 138 (11.3) | 26 (7.9) | 164 (10.6) |
| Most common ocular TEAEs in the study eye (≥ 1%) | | | |
| Cataract | 38 (3.1) | 5 (1.5) | 43 (2.8) |
| Blepharitis | 18 (1.5) | 1 (0.3) | 19 (1.2) |
| Any SAE | 50 (4.1) | 10 (3.0) | 60 (3.9) |
| Any serious TEAEs | 133 (10.9) | 23 (7.0) | 156 (10.1) |
| Any serious drug-related TEAE | 12 (1.0) | 1 (0.3) | 13 (0.8) |
| Any serious drug-related ocular TEAE | 8 (0.7) | 0 (0) | 8 (0.5) |
| Any serious drug-related non-ocular TEAE | 4 (0.3) | 1 (0.3) | 5 (0.3) |
| Any serious TEAE causally related to IVT injection procedure ^a | 1 (0.1) | 0 (0) | 1 (0.1) |
| Withdrawal of IVT-AFL | | | |
| Ocular TEAE | 12 (4.4) | 1 (1.9) | 13 (4.0) |
| Drug-related ocular TEAE | 7 (11.9) | 1 (5.3) | 8 (10.3) |
| Serious ocular TEAE | 5 (12.8) | 0 (0) | 5 (12.2) |
| Serious drug-related ocular TEAE | 2 (25.0) | 0 (0) | 2 (25.0) |
| Non-ocular TEAE | 3 (1.7) | 0 (0) | 3 (1.4) |
| Drug-related non-ocular TEAE | 1 (12.5) | 0 (0) | 1 (11.1) |
| Serious non-ocular TEAE | 3 (3.1) | 0 (0) | 3 (2.5) |
| Serious drug-related non-ocular TEAE | 1 (25.0) | 0 (0) | 1 (20.0) |

^aInjection site inflammation

AE adverse event, EMA European Medicines Agency, IVT-AFL intravitreal aflibercept, IVT intravitreal, nAMD neovascular age-related macular degeneration, SAE serious adverse event, SAS safety analysis set, TEAE, treatment-emergent adverse event