Up to 7-Year Retinal Fluid Outcomes in Patients With nAMD Treated With the Port Delivery Platform With Ranibizumab: Results from the Portal Extension Trial

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Disclosures

Financial Disclosures

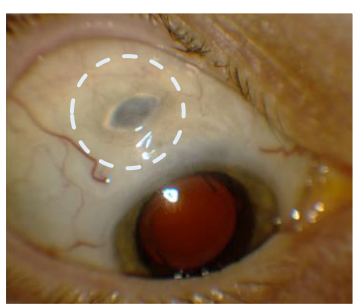
- MS: Consultant, Lecture Fee, Grant Support: AbbVie/Allergan, Bayer, Celltrion, Novartis, Roche, Samsung Bioepis, Sam Chun Dang; Consultant, Grant Support: 4DMT, Alteogen/Altos, Curacle, PharmAbcine, SKAI Therapeutics; Grant Support, Lecture Fee: Alcon, Johnson & Johnson
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- GA-T, DBL: Employment: F. Hoffmann-La Roche AG
- SB, SG, MR, NS: Employment: Genentech, Inc.

Study and Product Disclosures

- SUSVIMO which comprises the devices and the drug in the US has been approved by the US Food and Drug Administration (FDA) for the treatment of nAMD, DME, and DR in adults who have previously responded to ≥ 2 anti-VEGF injections. The FDA issued a boxed warning for the PDS because it has been associated with an up to 3-fold higher rate of endophthalmitis compared with monthly intravitreal injections of ranibizumab[1]
- The Committee for Medicinal Products for Human Use (CHMP) has recommended granting a marketing authorisation in the European Union (EU) for SUSVIMO (ranibizumab 100 mg/mL) to treat adults with nAMD. EU Certification has been obtained for the Port Delivery Platform devices (CONTIVUE) comprising the eye implant through which ranibizumab 100 mg/mL is delivered, and four ancillary devices to initially fill, insert, refill, and remove the implant
- The PDS has been approved by the Thai Food and Drug Administration for the treatment of nAMD in adults who have previously responded to anti-VEGF injections[2]
- This study includes research conducted on human subjects
- Institutional Review Board approval was obtained prior to study initiation
- Funding was provided by F. Hoffmann-La Roche Ltd. for the study and third-party writing assistance, which was provided by Jason Vuong, BPharm, CMPP, of Envision Pharma Group

CHMP, Committee for Medicinal Products for Human Use; DME, diabetic macular edema; DR, diabetic retinopathy; FDA, Food and Drug Administration; nAMD, neovascular age-related macular degeneration; PDS, Port Delivery Platform with ranibizumab; VEGF, vascular endothelial growth factor. 1. Susvimo [US prescribing information]. South San Francisco, CA: Genentech, Inc.; 2025. 2. Susvimo [Thai prescribing information]. Bangkok: Roche Thailand Co., Ltd.; 2026.

PDS is the First Approved Continuous Delivery of Anti-VEGF With Sustained Durability to Reduce Treatment Burden for Patients With Retinal Diseases



PDS **surgically implanted** at the pars plana; **sustained release** of customized ranibizumab via **passive diffusion**



Implant Refill needle

Refill-exchange procedures every **6 or 9 months[a]** in the clinical setting[1,2]

To date, **> 2100 PDS implants** and **> 11,300 refill-exchanges** with **11 years** of surgical experience

Archway-to-Portal and **Ladder-to-Portal** are respectively the **largest** and **longest** prospective nAMD cohorts with **5 years[b]** and **up to 7 years[b]** of follow-up

Archway
Phase 3 trial
96 weeks
PDS Q24W
(n = 248)
vs
IVT ranibizumab 0.5 mg Q4W
(n = 167)

Ladder
Phase 2 trial
88 weeks[c]
PDS 10, 40 or 100 mg/mL PRN
(n = 179)
vs
IVT ranibizumab 0.5 mg Q4W
(n = 41)

Portal
Long-term extension study
5 years[b] of follow-up
All patients implanted with PDS 100 mg/mL Q24W

Archway-to-Portal (n = 352)
Follow-up: mean 203.5 weeks, max 5.9 study years[b]

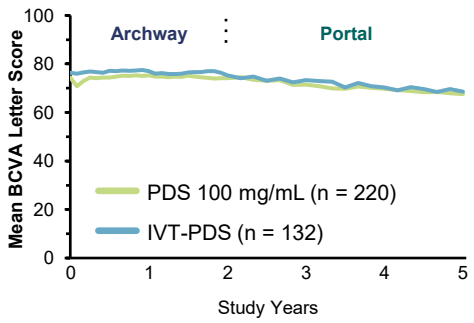
Ladder-to-Portal (n = 100)
Follow-up: mean 274.8 weeks, max 8.4 study years[b]

Ladder [NCT02510794]; Archway [NCT03677934]; Portal [NCT03683251]. [a] The PDS is approved for nAMD and DME with refill-exchanges Q24W and for DR with refill-exchanges Q36W. [b] Study year = 48 weeks (12 months with 4 weeks). [c] Mean time on study for all PDS patients. DME, diabetic macular edema; DR, diabetic retinopathy; IVT, intravitreal; max, maximum; nAMD, neovascular age-related macular degeneration; PDS, Port Delivery Platform with ranibizumab; PRN, pro re nata; Q4W, every 4 weeks; Q24W, every 24 weeks; Q36W, every 36 weeks. 1. Susvimo [US prescribing information]. South San Francisco, CA: Genentech, Inc.; 2025. 2. Susvimo [Thai prescribing information]. Bangkok: Roche Thailand Co., Ltd.; 2026.

PDS Maintained Vision and Retinal Anatomy With Sustained Durability and Was Generally Well-Tolerated Over 5 Years and Up to 7 Years

Archway-to-Portal Over 5 Years[a]

Vision: **50%** of patients **maintained > 20/40 vision**



At 5 years[a]

Mean **67.6** letters (20/45)
Median **73.0** letters (20/35)
PDS arm

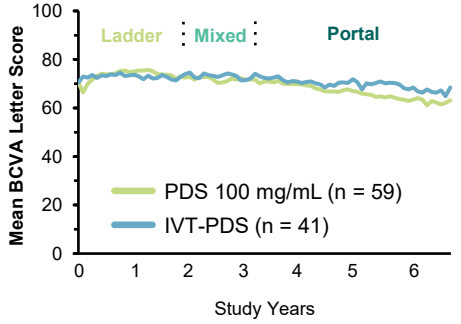
Mean **68.6** letters (20/45)
Median **73.5** letters (20/35)
IVT-PDS arm

Anatomy: PDS resulted in **consistent anatomical** control

Durability: **~95%** of patients did **not receive supplemental treatment** between each 6-month refill-exchange interval

Ladder-to-Portal Up to 7 Years[a]

Vision: **50%** of patients **maintained ~20/40 vision**



At ~7 years[a]

Mean **63.2** letters (20/55)
Median **70.0** letters (20/40)
PDS arm

Mean **68.4** letters (20/45)
Median **67.5** letters (20/45)
IVT-PDS arm

Anatomy: PDS resulted in **consistent anatomical** control

Durability: **~95%** of patients did **not receive supplemental treatment** between each 6-month refill-exchange interval

PDS was **generally well tolerated** over the study period; the overall incidence of endophthalmitis was 2.8% over a **maximum follow-up of 8.4 years[a]** of patients across Archway, Ladder, and Portal

Ladder [NCT02510794]; Archway [NCT03677934]; Portal [NCT03683251]. For efficacy endpoints observed data are reported through January 31, 2024. Ladder efficacy includes only patients randomized to PDS 100 mg/mL or ranibizumab 0.5 mg monthly IVT injections arm and followed in Portal. Snellen values are approximate. Durability was measured from Archway baseline for Archway-to-Portal patients and Portal baseline for Ladder-to-Portal patients. [a] Study year = 48 weeks (12 months with 4 weeks). Safety follow-up includes PDS patients who were implanted in Archway or Ladder or after rollover to Portal. BCVA, best-corrected visual acuity; IVT, intravitreal; PDS, Port Delivery Platform with ranibizumab; Q24W, every 24 weeks.

PDS May Preserve Vision Better Than SOC Injection Regimens Over the Long Term

Optimizing Visual Outcomes in Patients With Neovascular Age-Related Macular Degeneration: The Potential Value of Sustained Anti-VEGF Therapy
Weng CY et al. *Ophthalmic Surg Lasers Imaging Retina*. 2023;54(11):654-659.

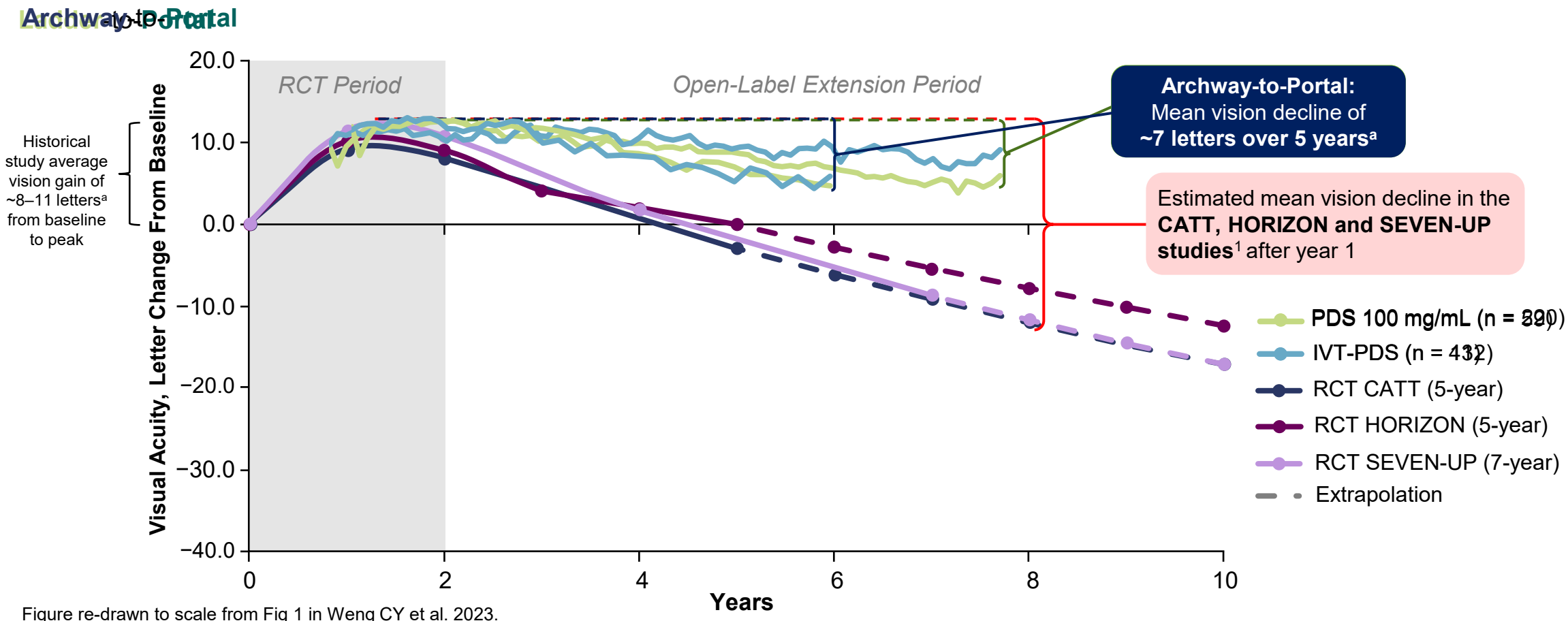


Figure re-drawn to scale from Fig 1 in Weng CY et al. 2023.

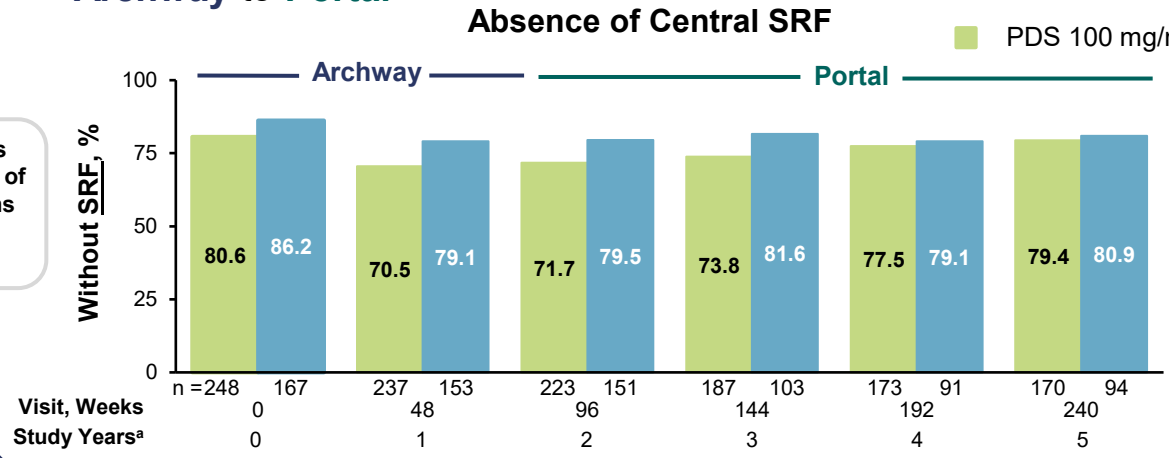
Cross-study comparisons should be interpreted with caution

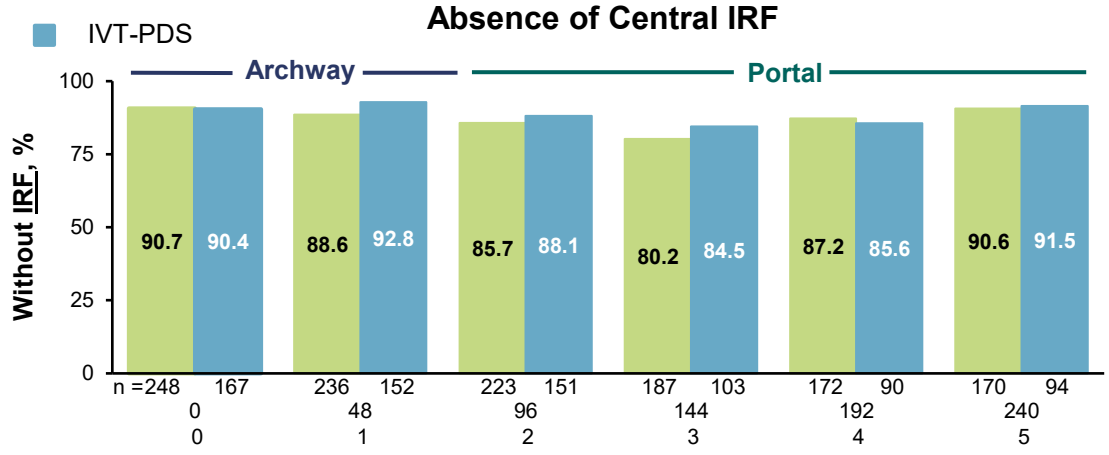
[a] Letter values are approximate and based upon visual inspection of published figures. [b] Study year = 48 weeks (12 months with 4 weeks). IVT, intravitreal; PDS, Port Delivery Platform with ranibizumab; RCT, randomised controlled trial; SOC, standard of care; VEGF, vascular endothelial growth factor. 1. Weng CY et al. *Ophthalmic Surg Lasers Imaging Retina*. 2023;54(11):654-659.

PDS Maintained Absence of Central SRF in ~80% and of Central IRF in ~85% of Patients Over 5 Years and Up to 7 Years

Archway-to-Portal

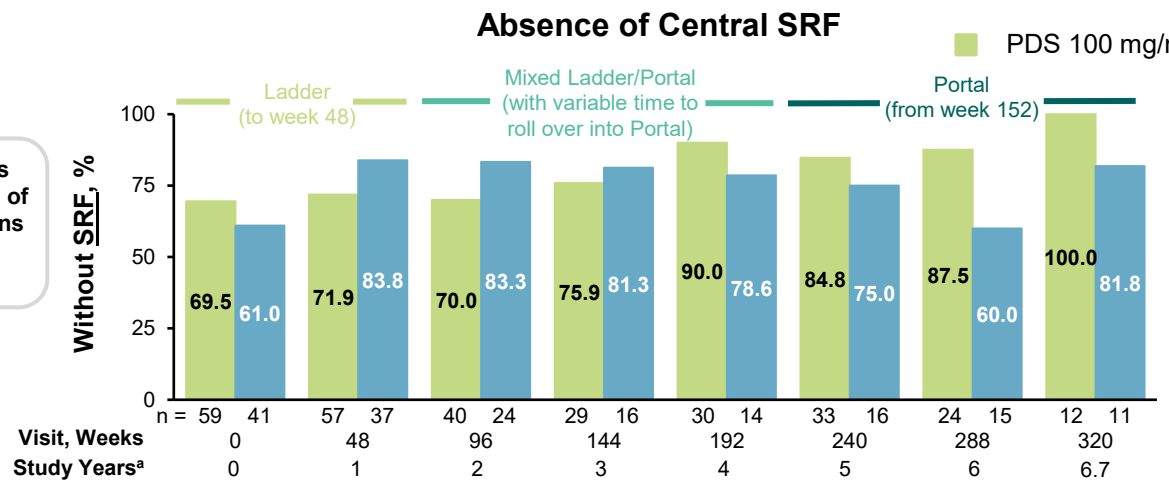
All patients had a mean of 5 injections prior to baseline

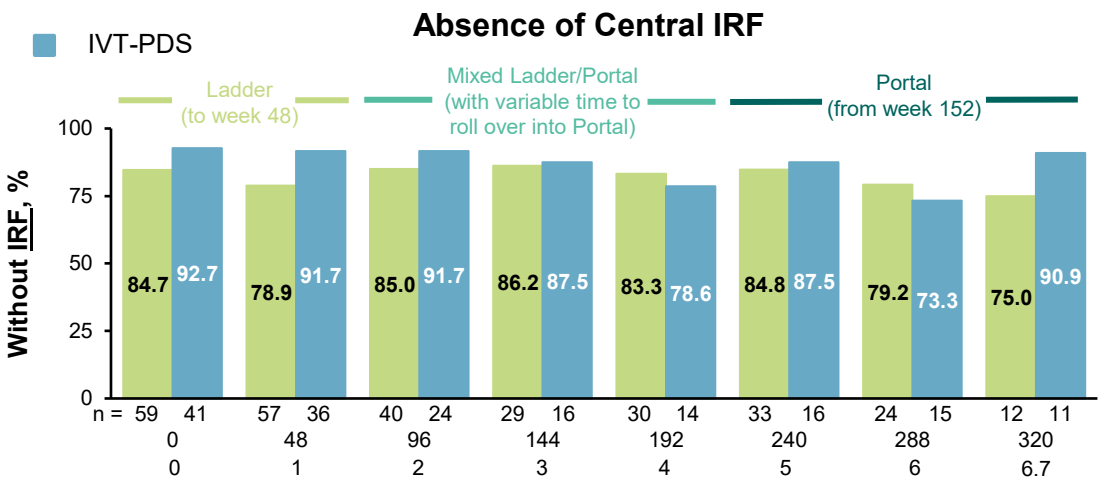




Ladder-to-Portal

All patients had a mean of ~3 injections prior to baseline





Archway [NCT03677934]; Ladder [NCT02510794]; Portal [NCT03683251]. [a] Study year = 48 weeks (12 months with 4 weeks). IRF, Intraretinal fluid; IVT, intravitreal; PDS, Port Delivery Platform with ranibizumab; SRF, subretinal fluid.

Continuous Delivery of Ranibizumab via the PDS Provided Long-Term Disease Control By Minimizing Fluid Presence for Over 5 Years in Archway-to-Portal and Up to 7 Years in Ladder-to-Portal



Vision and Anatomical Outcomes: PDS Q24W **maintained vision** and **retinal anatomy**, with 50% of patients maintaining better than 20/40 vision over 5 years[a] and ~20/40 vision for up to 7 years[a]



Retinal Fluid Outcomes: PDS **minimized fluid presence**, with **central SRF and IRF absent** in most patients through 7 years



Safety: PDS treatment was **generally well tolerated** through 7 years[a] of follow-up

These findings highlight the ability of the PDS to provide consistent and lasting control of disease activity with only two refills a year, supporting the use of PDS for appropriate patients with nAMD in clinical practice

[a] Study year = 48 weeks (12 months with 4 weeks). IRF, intraretinal fluid; nAMD, neovascular age-related macular degeneration; PDS, Port Delivery Platform with ranibizumab; Q24W, every 24 weeks; SRF, subretinal fluid.