

BRIEF COMMUNICATION OPEN



SPECTRUM: Early clinical experience from the first global real-world study of aflibercept 8 mg in patients with diabetic macular oedema

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INTRODUCTION

The PHOTON Phase 2/3 trial demonstrated the efficacy and safety of intravitreal aflibercept 8 mg in the treatment of diabetic macular oedema (DME) [1]. SPECTRUM is a global study evaluating aflibercept

8 mg treatment of DME and neovascular age-related macular degeneration (nAMD) in routine clinical practice. This SPECTRUM analysis presents early clinical experience with aflibercept 8 mg among patients with treatment-naïve (TN) or previously treated (PT) DME.

Table 1. Baseline demographics and disease characteristics of patients in the SPECTRUM Week 8 analysis of the treatment-naïve and previously treated DME cohorts.

	Treatment-naïve DME (N = 104)	Previously treated DME (N = 103)
Age, years	67.1 ± 10.1	65.5 ± 11.3
Female, n (%)	38 (36.5)	33 (32.0)
Race, n (%) ^a		
American Indian or Alaska Native	1 (1.0)	–
Asian	37 (35.6)	20 (19.4)
Black or African American	4 (3.9)	2 (1.9)
White	55 (52.9)	73 (70.9)
Not reported	7 (6.7)	8 (7.8)
Visual acuity, ETDRS letters ^b	64.7 ± 16.3	70.2 ± 13.5
Central retinal thickness, µm ^c	412 ± 110	361 ± 141
Median time (range) since DME diagnosis, months	0.5 (0.0, 93.6)	47.8 (3.3, 411.1)
Median duration (range) of prior DME treatment, days	–	865 (29, 5516)
Prior treatment for DME, n (%)		
Aflibercept 2 mg	–	62 (60.2)
Faricimab 6 mg	–	18 (17.5)
Ranibizumab 0.5 mg	–	11 (10.7)
Brolucizumab 6 mg	–	5 (4.9)
Other	–	5 (4.9)
Bevacizumab (variable dosage)	–	1 (1.0)
Steroids	–	1 (1.0)

FAS. Data are mean ± SD unless otherwise stated; percentages may not add up to 100 due to rounding.

DME diabetic macular oedema, ETDRS Early Treatment of Diabetic Retinopathy Study, FAS full analysis set (all patients receiving ≥1 dose of study drug plus ≥1 post-baseline assessment), SD standard deviation.

^aData on race were collected in Australia, Canada, Germany, Italy, Japan, Portugal, South Korea, Saudi Arabia, Spain, Switzerland, United Arab Emirates and the United Kingdom only; for France, Denmark, Finland, The Netherlands, Norway and Sweden, data on race were not collected according to local laws/regulations.

^bVisual outcomes were assessed during routine clinical practice and reported in ETDRS letter scores; where ETDRS charts were unavailable, approximate Snellen scores were converted to ETDRS letter scores.

^cCentral retinal thickness was determined by optical coherence tomography per physician discretion with the instrument available at each study site.

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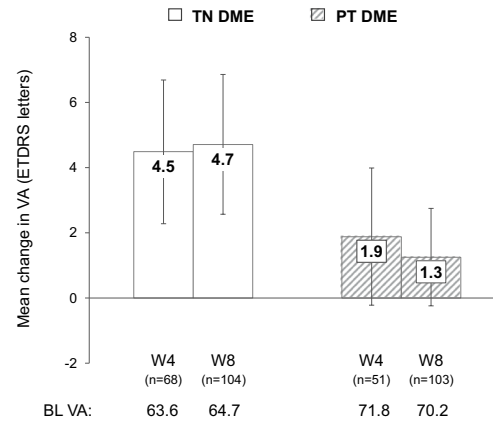
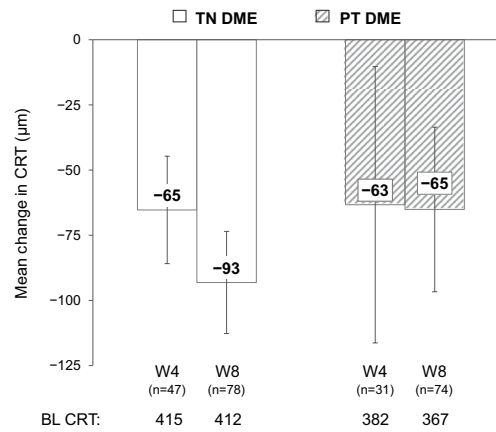
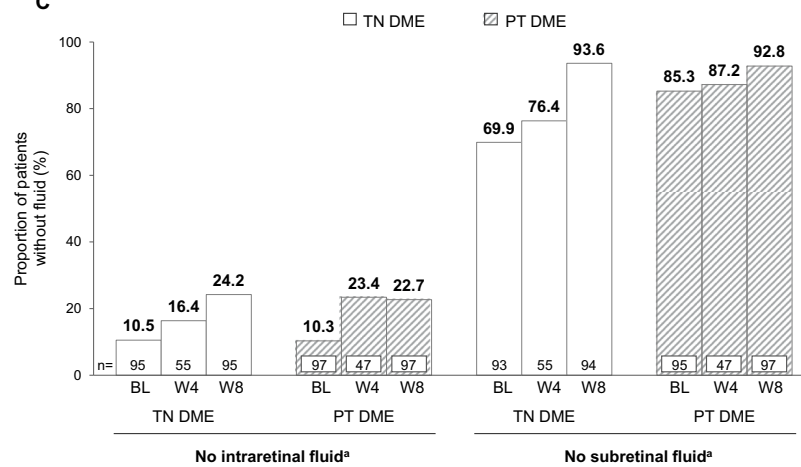
A**B****C**

Fig. 1 Functional and anatomical outcomes in patients with DME through Week 8 in SPECTRUM. A Mean change in VA from baseline through Week 8. **B** Mean change in CRT from baseline through Week 8. **C** Proportion of patients without intraretinal fluid or subretinal fluid through Week 8. Data are for the FAS (observed cases); error bars represent 95% CI. Mean VA/CRT change at Week 4 and Week 8 from baseline was calculated in patients with a VA/CRT assessment at Week 4 and Week 8, respectively. Week 4 = visits closest to 28 (14–42) days after the first injection (i.e., baseline), and Week 8 = visits closest to 56 (43–70) days after baseline. Note that outcomes described here would not reflect the effect of an injection received at Week 8, and some patients may not have received an injection at this timepoint. BL baseline, CI confidence interval, CRT central retinal thickness, DME diabetic macular oedema, ETDRS Early Treatment Diabetic Retinopathy Study, FAS full analysis set (all patients receiving ≥ 1 dose of study drug plus ≥ 1 post-baseline assessment), PT previously treated, TN treatment-naïve, VA visual acuity, W week. ^aThe presence of intraretinal fluid and subretinal fluid were determined by optical coherence tomography per physician discretion with the instrument available at each study site, and the proportions presented here were calculated based on the number of patients who had an assessment at each of the indicated time points.

METHODS

SPECTRUM (NCT06075147) is a 24-month, prospective observational study being conducted across 18 countries (February 2024–September 2027) in patients (TN or PT) with DME or nAMD. Each study site's independent ethics committee/institutional review board approved the study protocol. Informed consent was collected from all participants.

Patients aged ≥ 18 years with DME and type 1 or type 2 diabetes mellitus, who had already been prescribed aflibercept 8 mg by their physician, were enrolled and treated per physician discretion and local clinical practice. Detailed enrolment criteria are reported at ClinicalTrials.gov [2]. This Week (W)8 analysis (visit closest to 56 [range: 43–70] days after baseline) was prespecified and included the first ~ 100 patients in each DME cohort to have a visit and visual acuity (VA) assessment at W8. All analyses are descriptive only.

RESULTS

Baseline characteristics are shown in Table 1. At W8 in the TN and PT DME cohorts, the mean (95% CI) change in VA was $+4.7$ (2.6, 6.9) and $+1.3$ (−0.2, 2.8) letters (Fig. 1A) from a baseline of 64.7 ± 16.3 and 70.2 ± 13.5 letters, and the mean (95% CI) change in central retinal thickness (CRT) was -93 (−113, −74) and -65 (−97, −34) μm (Fig. 1B) from a baseline of 412 ± 110 and 361 ± 141 μm . The proportions of patients without intraretinal fluid or subretinal fluid increased in both cohorts from baseline to W8 (Fig. 1C). Patients received a mean $\pm$ SD (median) of 2.7 ± 0.5 (3) and 2.5 ± 0.7 (3) injections through W8 in the TN and PT DME cohorts (first injection received at baseline). Note that the W8 injection data include any injections received at W8, whereas W8 outcomes reflect a response to injections administered before the W8 visit.

In the TN and PT DME cohorts, ocular treatment-emergent adverse events (TEAEs) occurred in the study eye in 7/104 (6.7%) and 9/103 (8.7%) patients, and non-ocular TEAEs were observed in 6/104 (5.8%) and 5/103 (4.9%) patients. No new safety concerns were identified.

DISCUSSION

Results from this prespecified Week 8 analysis of SPECTRUM provide valuable insights into early real-world treatment response to aflibercept 8 mg in patients with DME. Patients received their first injection at baseline; by Week 8, both the TN and PT DME cohorts demonstrated improvements in VA and CRT, along with a reduction in retinal fluid. No new safety concerns were identified in this cohort.

As an observational study, the analyses from SPECTRUM are exploratory only. As this Week 8 analysis was based on only a subset of ~ 100 patients in each cohort, the outcomes in these global TN and PT DME cohorts will be more completely characterised once data become available for the full global cohorts.

Supplemental material is available at Eye's website

DATA AVAILABILITY

Availability of the data underlying this publication will be determined according to Bayer's commitment to the European Federation of Pharmaceutical Industries and Associations/Pharmaceutical Research and Manufacturers of America (EFPIA/PhRMA) "Principles for responsible clinical trial data sharing." This pertains to the scope, time point and process of data access. As such, Bayer commits to sharing upon request

from qualified scientific and medical researchers' patient-level clinical trial data, study-level clinical trial data and protocols from clinical trials in patients for medicines and indications approved in the United States of America (USA) and European Union (EU) as necessary for conducting legitimate research. This applies to data on new medicines and indications that have been approved by the EU and US regulatory agencies on or after 1 January 2014. Interested researchers can use www.clinicalstudydatarequest.com to request access to anonymised patient-level data and supporting documents from clinical studies to conduct further research that can help to advance medical science or improve patient care. Information on the Bayer criteria for listing studies and other relevant information is provided in the study sponsors' section of the portal. Data access will be granted for anonymised patient-level data, protocols and clinical study reports after approval by an independent scientific review panel. Bayer is not involved in the decisions made by the independent review panel. Bayer will take all necessary measures to ensure that patient privacy is safeguarded.

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AUTHOR CONTRIBUTIONS

TM, HA, and ZH designed and conceptualised the study. TM was responsible for the statistical analysis. All authors contributed to data acquisition, analysis and interpretation. All authors contributed to drafting the manuscript and reviewing it for intellectual content.

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COMPETING INTERESTS

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ADDITIONAL INFORMATION

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