Assessment of intravitreal aflibercept treatment and disease monitoring in the UK for anti-vascular endothelial growth factor treatment-naïve patients with diabetic macular oedema (DRAKO): Year 1 results

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INTRODUCTION

- DRAKO (NCT02850263) is a prospective, observational, 2-year study evaluating the effectiveness of intravitreal aflibercept (IVT-AFL) injection for the treatment of patients with diabetic macular oedema (DMO) within routine clinical practice
- Year 1 results are described here for the study eye of the anti-vascular endothelial growth factor therapy treatment-naïve patient cohort

METHODS

Patients

- Male and female patients with DMO from 35 National Health Service (NHS) centres were enrolled from July 2016 to April 2018
- Patients had not previously received any of the following: Intravitreal dexamethasone or fluocinolone acetonide, pan-retinal photocoagulation in the previous 8 weeks, or macular laser photocoagulation in the previous 4 months

Objectives

- **Primary:** To evaluate the change from Baseline (BL) in best-corrected visual acuity (BCVA) and central subfield thickness (CST) at Month 12 (M12)
- **Secondary:** To assess the monitoring of disease activity and evaluate adherence to IVT-AFL treatment protocols

IVT-AFL Treatment and Ocular Assessments

- IVT-AFL summary of product characteristics (SmPC)[1] remained unchanged throughout the study period; the posology included five initial monthly injections, followed by bi-monthly injections throughout Year 1 (equating to 8–9 injections in Year 1)
- Patients were treated as per each study site's local standard protocol, with all visits, assessments and treatments recorded
- Early Treatment Diabetic Retinopathy Study letters measured by BCVA with refraction and spectral domain optical coherence tomography measurement of CST were measured at BL and M12

Statistical Analysis

- Patients with BCVA or CST data at BL and the nominated M12 visit (12 months +/- 1 month) were included in this analysis
- Summary statistics were calculated for all quantitative variables and the patient care pathway, and 95% confidence intervals (CI) were calculated for the primary endpoints

RESULTS

Patient Population

- A total of 507 treatment-naïve patients were enrolled in the study (safety population); 388 met the defined requirements and were included in this analysis

Functional and Anatomic Outcomes

- High BCVA was reported at BL (≥70 letters), indicating that patients presented early with DMO (**Table 1**)
- An improvement in both BCVA and CST were observed at M12 (**Table 1**)

TABLE 1:
BCVA and CST outcomes observed at M12

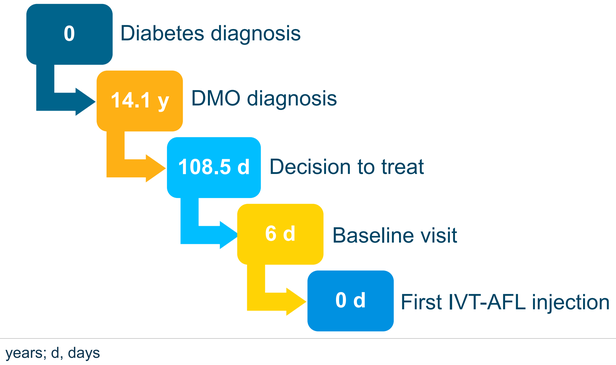
		Mean (SD)	95% CI	n
BCVA (Letters)	BL	71.4 (12.0)	-	375
	M12	73.6 (13.9)	-	362
	Change from BL	**2.5 (12.2)**	1.3, 3.8	353
CST (µm)	BL	448.7 (88.7)	-	388
	M12	329.8 (92.3)	-	386
	Change from BL	**–119.1 (116.4)**	–130.7, –107.4	386

SD, standard deviation

Patient Population Care Pathway

- Data were collected to determine key stages of the patient's disease progression and care pathway. The median time to each event from diabetes diagnosis is described in **Figure 1**

FIGURE 1:
Median time between events from diabetes diagnosis to first IVT-AFL injection

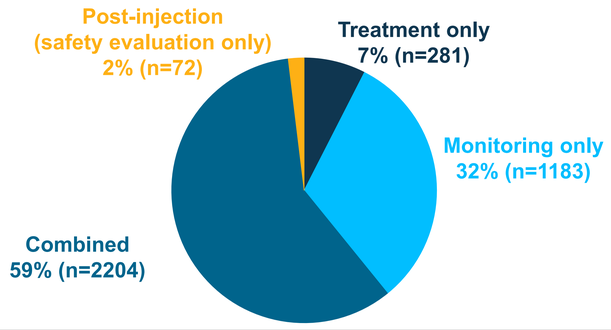


y, years; d, days

Visit Composition and Treatment Adherence

- A total of 3740 visits were conducted in Year 1, equating to a mean of 9.6 visits and 6.4 injections per patient
- 66.4% of visits were related to IVT-AFL treatment, the majority of which were combined visits where monitoring assessments were also conducted (**Figure 2**)

FIGURE 2:
Percentage and number of patient visits by visit type in Year 1



- At study initiation, 22 (77.1%) sites intended to administer five initial monthly injections and 21 (60.0%) sites planned to adhere to the IVT-AFL SmPC in Year 1
- In practice, 117 (30.2%) patients received five initial injections and nine (2.3%) patients adhered to the SmPC in Year 1
- Less than 3% of patients discontinued treatment (**Table 2**)

Monitoring Assessments

- Assessments conducted during the study to monitor disease progression and functional and anatomic outcomes following treatment were recorded (**Figure 3**)

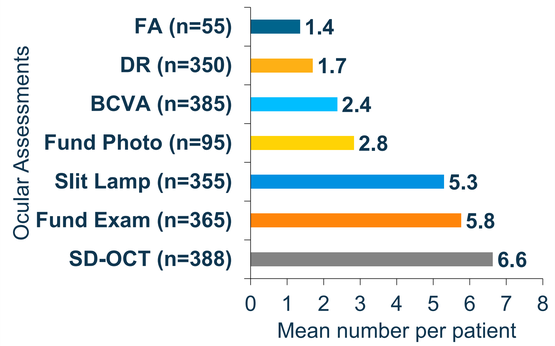
Safety Assessment

- The safety profile of IVT-AFL was consistent with previous studies

TABLE 2:
Reasons for patient discontinuation (n=11)

Reasons for ending the study	n (%)
Death	6 (1.5%)
Patient lost to follow-up	1 (0.3%)
Patient withdrawal	1 (0.3%)
Change of centre	1 (0.3%)
Other	2 (0.5%)

FIGURE 3:
Mean number of monitoring assessments per patient in Year 1



FA, fluorescein angiography; DR, Diabetic Retinopathy; Fund Photo, fundus photography; Slit Lamp, slit lamp biomicroscopy; Fund Exam, fundoscopy examinations; SD-OCT, spectral domain optical coherence tomography.

CONCLUSIONS

- **DRAKO Year 1 results indicate that IVT-AFL was effective for DMO treatment in real-world clinical practice in the UK, even though patients were undertreated versus SmPC (mean 6.4 injections per patient versus an expected 8–9 injections)**
- **The study demonstrated that NHS DMO patients presented early with good BCVA and were treated quickly, and that two-thirds of clinic visits involved treatment**

References

1. Eylea 40mg/mL solution of injection in a vial summary of product characteristics. 2012. https://www.medicines.org.uk/emc/product/2879/smpc#gref. Accessed 12 April 2021.

Disclosures

Faruque Ghanchi has been a consultant and speaker for Novartis, Bayer, Allergan, Alimera and Roche; and has received travel grants from Bayer and Novartis; **Sobha Sivaprasad** received consultancy fees from Bayer, Allergan, Novartis Pharma AG, Roche, Boehringer Ingelheim, Optos and Heidelberg Engineering; **Simon P Kelly** received travel grants from Bayer; research support from Bayer and Novartis Pharma AG; and participated in advisory boards for Novartis Pharma AG and Polyphotopics; **Ajay Kotagiri** received travel support from Novartis, Bayer and Allergan; and speaker fees from Allergan and Bayer; **James Talks** participated in advisory boards for Bayer and Novartis; received travel support from Bayer; and received research grants from Bayer, Novartis and Roche; **Peter Scanlon** attended advisory boards for Pfizer, Allergan, Boehringer, Roche and Bayer; and his department has received educational, research, and audit grants from Allergan, Boehringer Ingelheim, Novartis and Bayer; **Moneeb Saddiq** is an employee of O4 Research; **Jackie Napier** is an employee of Bayer Plc.

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