Three-year follow-up of outcomes from the ILUVIEN (190 micrograms fluocinolone acetonide) RegIstry Safety Study (IRISS)

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Purpose

1. IRISS is a non-randomized, open-label, observational phase IV study collecting real-world data on the safety and effectiveness of the 0.2 µg/day fluocinolone acetonide (FAc) implant in patients treated with ILUVIEN®, for any clinical indication and was conducted at the request of the Reference Member State, the UK Medicines and Healthcare products Regulatory Agency, as a Specific Obligation for marketing authorisation application for ILUVIEN.
2. The IRISS study has now completed and here we report the safety and effectiveness findings from the IRISS registry study.

Methods

1. The IRISS study (clinicaltrials.gov identifier NCT01998412) is a post-authorisation observational open label, registry study of the 0.19 mg FAc implant in Europe.
2. Subjects were enrolled either prospectively or retrospectively with up to 6 years of follow-up.
3. The last patient completed the study 9th January 2020.
4. A total of 556 patients (695 eyes) were enrolled from 31 sites in UK, 11 in Germany and 5 in Portugal.
5. Safety was assessed in terms of the occurrence of IOP events and their management.
6. Effectiveness was determined from changes in stable / improved best-recorded visual acuity (VA) and the percentage of patients achieving 6/12 vision.

Patient demographics

Mean age of the patients was 67.4 years. The majority of eyes (96.7%) had been treated for DMO and had a pseudophakic lens (82.3%). Mean IOP was 15.2 mmHg at baseline and mean visual acuity was 52.2 letters.

Patients (eyes)	556 (695)
Gender, male : female, %	55.8 : 44.2
Age, yrs, mean ± SD	67.4 ± 10.8
Lens status, %	82.3 pseudophakic : 16.3 phakic : 0.7 aphakic : 0.7 missing
Duration of follow-up, days, mean ± SD	1150.5 ± 357.36
IOP, mmHg, mean ± SD	15.2 ± 3.1
Visual acuity, letters, mean ± SD	52.2 ± 19.1
Mean number of FAc implants injected (1, 2, 3, >3 implant, %)	1.07 (93.2, 6.6, 0.1, 0.0)
Mean time to 2nd FAc implant, days, mean ± SD (range)	986.1 ± 318.0 (224 – 1742)

Conclusions

1. Overall, this study confirms previous findings of a favourable benefit-risk profile of ILUVIEN.
2. Steroid class-related IOP & cataract side effects remain the primary safety concerns.
3. Patients did not show any additional safety risks to those identified in previous trials and included in the SmPC.
4. Analysis of visual acuity data showed that ILUVIEN treatment consistently provided clinical benefits to patients as evidenced by improvement in ETDRS visual acuity scores.

Results

Prior therapies

Treatment	Eyes / number treatments
Any prior treatment (IVT or laser)	94.8% / 7.9
Intravitreal anti-VEGF	*78.8% / 5.9*
Laser treatments[1]	*59.4% / 2.8*
Corticosteroids	*38.4% / 2.3*
Other[2]	*16.8% / 1.6*

[1]Any prior laser treatment, includes focal, grid and PRP [2]Includes verteporfin, pegaptanib sodium and 'other' . IVT, intravitreal.

Supplemental therapies – at Month 36

Treatment	Eyes / number treatments
Any prior treatment (IVT or laser)	41.2% / 4.4
Intravitreal anti-VEGF	*24.3% / 5.4*
Corticosteroids	*10.6% / 1.9*
Laser	*23.7% / 1.6*

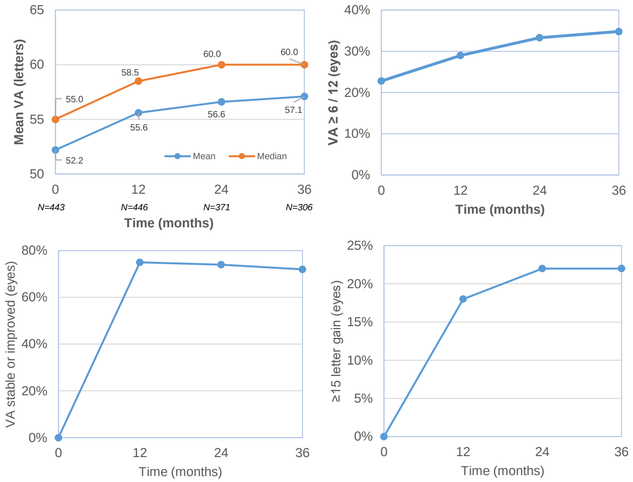
IVT, intravitreal.

IOP outcomes – at Month 36

IOP-related event	Eyes (n)
Treatment-emergent IOP-lowering medication	32.2% (224/695)
IOP increase of ≥ 10 mmHg	14.0% (97/695)
IOP > 30 mmHg	12.2% (85/695)
IOP-lowering procedures*	
Trabeculoplasty	*1.2% (8/695)*
IOP-lowering surgeries	*3.3% (23/695)*

All non-medical interventions to lower IOP including Ahmed Valve, Baerveldt tube, cyclophotocoagulation, canaloplasty, cyclodiode laser, Express Implant, Glaukos iStent, Xen implant, laser trabeculoplasty, trabeculectomy, surgical iridectomy, Molteno implant and viscocanalostomy.

VA outcomes – at Month 36



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