A prospective, real-world, French post-reimbursement study (LOUVRE 2) confirms efficacy of the dexamethasone 0.7 mg intravitreal implant (DEX) in treating the most vision-threatening form of uveitis.

**BACKGROUND**

Posterior uveitis is the most vision-threatening and challenging form of uveitis to treat, in part due to the target tissue location (back of the eye) and lack of effective topical treatment delivery.

**OBJECTIVE**

To evaluate real-life

- **efficacy,**
- **safety,** and
- **treatment patterns**

with DEX in a population of adults with posterior segment inflammation due to non-infectious uveitis that was treatment-naive or not.

**STUDY DESIGN**

Prospective, multicenter, non-comparative, post-reimbursement, real-world study.

Patients who received DEX treatment on day 0 were followed.

**TREATMENT**

Treatment selection decisions (including type and frequency) were made at the investigators’ discretion.

In cases of bilateral treatment, the eye with the worse best-corrected visual acuity (BCVA) and/or vitreous haze score at enrollment was the study eye.

**FINDINGS**

Enrolled patients (N=245)

- Treated with DEX on day 0 before DEX recall* (N=97) Included in all analyses
- Not treated with DEX on day 0 (n=144) Analyzed for safety and baseline characteristics
- Enrolled after DEX recall† (n=4) Analyzed for safety only

Completed the following visits pre-recall:

- Month 2 (n=91)
- Month 6 (n=76)
- Month 18 (n=12)

*Specific DEX lots were recalled on October 4, 2018, which led to early termination of the study.

†60 patients treated with DEX on day 0 discontinued the study due to early study termination following DEX recall (n=55); lost to follow-up (n=2); and other (n=3).

Compared with baseline, statistically significant proportions of patients treated with DEX on day 0 gained ≥15 letters in BCVA at months 2 and 6.

- Month 2 (N=88) 20.5% (95% CI, 12.0–28.9)
- Month 6 (N=72) 19.4% (95% CI, 10.3–28.6)

**Mean follow-up:** 14.9 months

**Mean injection interval:** 5.1 months

**Mean injection number:** 1.0
Statistically significant changes in BCVA and CRT from baseline were observed at months 2 and 6

Among patients treated with DEX on day 0, 84 AEs were reported during follow-up; 3 patients discontinued the study due to AEs

| Potentially DEX related | Not serious | Serious |
|-------------------------|-------------|---------|
| 32 (38.1%)              | 80 (95.2%)  | 4 (4.8%) |

AEs reported in the study (probably/possibly due to the injection procedure or implant, or with uncertain causality)

| Adverse events, n     | Total |
|-----------------------|-------|
| Ocular conditions     | 27    |
| Ocular hypertension   | 20    |
| Conjunctive hemorrhage| 3     |
| Vitreous hemorrhage   | 2     |
| Cataract              | 1     |
| Macular fibrosis      | 1     |
| Medical and surgical procedures | 4 |
| Cataract surgery      | 4     |
| General and administrative site complications | 1 |
| Pain at the injection site | 1 |

*All occurred in patients treated with DEX on day 0

There were statistically significant differences in baseline characteristics between patients treated with DEX on day 0 and those not treated with DEX on day 0

| Baseline Characteristics                      | Treated with DEX on day 0 | Not treated with DEX on day 0 |
|-----------------------------------------------|---------------------------|-------------------------------|
| Mean CRT, µm (95% CI)                         | 424.8 (397.2, 452.3)      | 333.6 (313.6, 353.6)         |
| Macular edema present, % (95% CI)             | 70.2 (61.0, 79.5)          | 44.0 (35.8, 52.2)            |
| History of cataract, % (95% CI) (surgically operated or not) | 76.3 (67.8, 84.8) | 56.3 (48.1, 64.4) |
| Presence of ophthalmic comorbidities, % (95% CI) | 88.7 (82.3, 95.0) | 70.8 (63.4, 78.3)          |
| Mean age, y (95% CI)                           | 60.6 (57.7, 63.4)          | 52.7 (49.9, 55.6)            |
| DEX-naïve, % (95% CI)                         | 25.3 (16.5, 34.0)          | 58.5 (50.3, 66.6)            |
| Prior DEX treatment, % (95% CI)               | 54.7 (44.7, 64.7)          | 21.8 (15.0, 28.6)            |

CONCLUSIONS

In French clinical settings, DEX improved functional and anatomic outcomes with acceptable safety through month 6 in patients with inflammation of the posterior segment due to non-infectious uveitis (including those previously treated with DEX) for whom treatment options remain limited

The sample size was smaller than planned due to the product recall/study termination and difficulty in recruiting patients with this disease of low prevalence/incidence

63.9% of patients treated with DEX received concomitant treatment for uveitis; the observed results could thus be due to combined treatments, as opposed to DEX alone