PERSEUS 24-Month analysis: A Prospective Non-interventional Study to Assess the Effectiveness of Intravitreal Aflibercept in Routine Clinical Practice in Germany in Patients with Neovascular Age-related Macular Degeneration

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Supplementary results:

Reasons for study discontinuation

578 patients of the SAF discontinued the study. The main reasons for discontinuing the study were permanent discontinuation of treatment (14.8%), switch of treatment (14.8%), loss to follow-up (14.5%) and change of treating physician (4.7%). Adverse events were stated in only 1.4% as a reason for discontinuation.

Anatomic outcomes

Data on central retinal thickness (CRT) was available for 232 patients of the treatment-naïve cohort and 203 patients of the previously treated cohort. At baseline, the treatment-naïve cohort had a mean CRT of 359.2 μm which at 12 months was reduced by -90.1 μm. This reduction in CRT was nearly maintained until 24 months (-86.7±108.6 μm compared to baseline). The previously treated cohort had a mean CRT of 341.3 μm at baseline which was reduced by -59.0 μm at month 12 and could be further decreased to -62.3±130.2 μm.
Safety

The safety set (SAF) included data from 857 patients. A total number of 7,390 injections was administered during the 24-month study period. 4.4% of all patients experienced non-ocular treatment-emergent adverse events (TEAE). 10.7% experienced ocular TEAEs including cataract (3.3% of all patients), conjunctival hemorrhage (1.3% of all patients) and corneal erosion (0.8% of all patients). No cases of endophthalmitis occurred. The table details the documented TEAEs.
Table 1: Safety analysis (n = 857)

| Event*                              | N   | %   |
|-------------------------------------|-----|-----|
| TEAE                                | 118 | 13.8|
| Non-ocular TEAE                     | 38  | 4.4 |
| Ocular TEAE                         | 92  | 10.7|
| Cataract                            | 28  | 3.3 |
| Conjunctival hemorrhage             | 11  | 1.3 |
| Corneal erosion                     | 7   | 0.8 |
| Drug-related ocular TEAE            | 31  | 3.6 |
| Conjunctional hemorrhage            | 10  | 1.2 |
| Lacrimation increased               | 3   | 0.4 |
| Anterior chamber cell               | 3   | 0.4 |
| Serious ocular TEAE                 | 9   | 1.1 |
| Cataract                            | 2   | 0.2 |
| Retinal pigment epithelial tear     | 2   | 0.2 |
| Macular fibrosis                    | 2   | 0.2 |
| Retinal epithelial tear             | 4   | 0.5 |
| Arterial thromboembolic event**     | 4   | 0.5 |
| Endophthalmitis                     | 0   | 0.0 |

TEAE = treatment-emergent adverse event (adverse events that occurred after first IVT-AFL and until 30 days after last IVT-AFL injection).

* The three most common documented events; **transient ischaemic attack in one patient with a medical history of a prior arterial thromboembolic event