

# **EFFICACY OF INTRAVITREAL AFLIBERCEPT ADMINISTERED USING TREAT- AND-EXTEND REGIMEN OVER 2 YEARS IN PATIENTS WITH NEOVASCULAR AGE- RELATED MACULAR DEGENERATION: BASELINE CHARACTERISTICS OF ARIES**

**Purpose:** To assess whether intravitreal aflibercept (IVT-AFL) administered in an early-start treat-and-extend (T&E) regimen (initiated after the first 8-week treatment interval) is non-inferior to IVT-AFL administered in a late-start T&E regimen (initiated at the end of Year 1, per label) in patients with nAMD.

**Methods:** ARIES is a multicentre, randomised, open-label, active-controlled, parallel-group, Phase 4 study. All patients received 3 initial monthly doses of IVT-AFL (Weeks 0, 4, 8), followed by a subsequent injection at an 8-week treatment interval (Week 16). At Week 16, patients were randomised 1:1 to early-start T&E (T&E regimen extended by 2 weeks or an initial 4-week interval [maximum 16 weeks]) or late-start T&E (per label: IVT-AFL 2q8 regimen). The primary endpoint is the mean change in BCVA (ETDRS letter score) from randomisation to Week 104. Here we present baseline data.

**Results:** A total of 287 treatment-naïve patients with nAMD were enrolled. At Week 16, 271 patients were randomised to an early- or late-start T&E regimen. Mean age was 76.5 years; 64.9% patients were aged  $\geq$ 75 years. Mean baseline BCVA was 60.4 ETDRS letters; proportions of patients with baseline BCVA 35–300  $\mu$ m in most patients (n = 251, 92.6%).

**Conclusions:** This Phase 4 study will compare the efficacy of IVT-AFL, administered by either an early-start or a late-start T&E regimen, in patients with nAMD.