PHASE 3 ARCHWAY TRIAL OF THE PORT DELIVERY SYSTEM WITH RANIBIZUMAB IN NEOVASCULAR AGE-RELATED MACULAR DEGENERATION

**Matthias Becker**¹, Giulio Barteselli², Natasha Singh³, Steven Blotner⁴, Jaya Chidambaram⁵, Katie Maass⁶, Jeff Willis², Merce Morral⁷

¹Department of Ophthalmology, Triemli City Hospital, Switzerland
²Ophthalmology Clinical Science, Genentech, Inc., USA
³Clinical Safety, Genentech, Inc., USA
⁴US Medical Affairs Biostatistics and Data Science, Genentech, Inc., USA
⁵Ophthalmology Clinical Science, Roche Products Limited, UK
⁶Clinical Pharmacology, Genentech, Inc., USA
⁷Global Product Development Medical Affairs Ophthalmology, Hoffmann-La Roche, Switzerland

**Purpose:** To report primary analysis results of the phase 3 Archway trial (NCT03677934) of the Port Delivery System with ranibizumab (PDS) for the treatment of neovascular age-related macular degeneration (nAMD) and describe the evolution of the implant insertion procedure.

**Methods:** Patients with nAMD were randomized 3:2 to PDS with ranibizumab 100 mg/mL with fixed 24-week refill-exchanges (PDS Q24W) or intravitreal ranibizumab 0.5 mg injections every 4 weeks (monthly ranibizumab). The trial evaluated noninferiority and equivalence (margins of −4.5 and ±4.5 Early Treatment Diabetic Retinopathy Scale letters, respectively) on a primary endpoint of change in best-corrected visual acuity (BCVA) from baseline averaged over weeks (W) 36 and 40.

**Results:** Overall, 248 and 167 patients were treated in the PDS Q24W and monthly ranibizumab arms, respectively. PDS Q24W was noninferior and equivalent to monthly ranibizumab for the primary BCVA endpoint (difference in adjusted means between treatment arms, −0.3 letters; 95% CI, −1.7, +1.1). During the first PDS treatment interval, 242 of the 246 PDS patients assessed at W16 and/or W20 (98.4%) did not receive supplemental ranibizumab treatment. Based on the PDS Patient Preference Questionnaire, overall, 93.2% of PDS-treated patients preferred ranibizumab as delivered via the PDS versus intravitreal injection. PDS procedures were generally well tolerated; systemic safety was comparable across arms. Meticulous implant insertion technique, with attention to hemostasis, incision size, and conjunctival management, is important to help optimize patient outcomes.

**Conclusions:** Archway met its primary endpoint and demonstrated that the PDS with ranibizumab 100 mg/mL Q24W had a favorable benefit-risk profile.