Purpose: Evaluate the safety and efficacy of ranibizumab 0.5 mg (RBZ) in DME patients (pts) in the RESTORE extension study.

Methods: 240 of 303 pts who completed RESTORE core study (Day1-Month (M) 12) entered the extension study (M12-M36). All pts (RBZ/RBZ+laser/laser) were eligible for RBZ (based on best-corrected visual acuity (BCVA) stability) and laser. Here we report the 24M interim analysis of incidences of adverse events (AEs), treatment exposure, changes in BCVA, Visual Functioning Questionnaire (VFQ-25) scores.

Results: At M24 the 2-year AE incidences were similar to previously reported results of RBZ in DME. There were no new AEs, no endophthalmitis cases, four deaths (none related to RBZ). With an average of 3.9 (RBZ) and 3.5 (RBZ+laser) RBZ injections (M12-M23), mean BCVA gained during core phase was maintained at M24. Mean BCVA changes (Day1-M24): +7.9 letters (RBZ), +6.7 letters (RBZ+laser). Pts treated with laser in core phase, received an average of 4.1 RBZ injections (M12-M23) with mean BCVA gain of +2.3 (Day1-M12) and +5.4 letters (Day1-M24). Mean VFQ-25 changes (Day1-M24) for RBZ/RBZ+laser/laser (eligible for RBZ as of M12): +10.8/+10.5/+4.6 (near activity), +5.1/+7.0/+2.8 (distance activity), +5.6/+5.8/+4.3 points (composite score).

Conclusion: AEs were consistent with the RBZ safety profile in DME. An average of 3.8 RBZ injections (all pts, M12-M23) was sufficient to maintain BCVA and visual function. The reported results support long-term safety and efficacy of RBZ in DME.