Treatment Effect of Intravitreal Aflibercept Injection by Baseline Factors in Moderately Severe to Severe NPDR in PANORAMA

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on behalf of the PANORAMA study investigators

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Disclosures

- Dr. Steinle received research funding from and serves as a consultant and speaker for Regeneron Pharmaceuticals, Inc.
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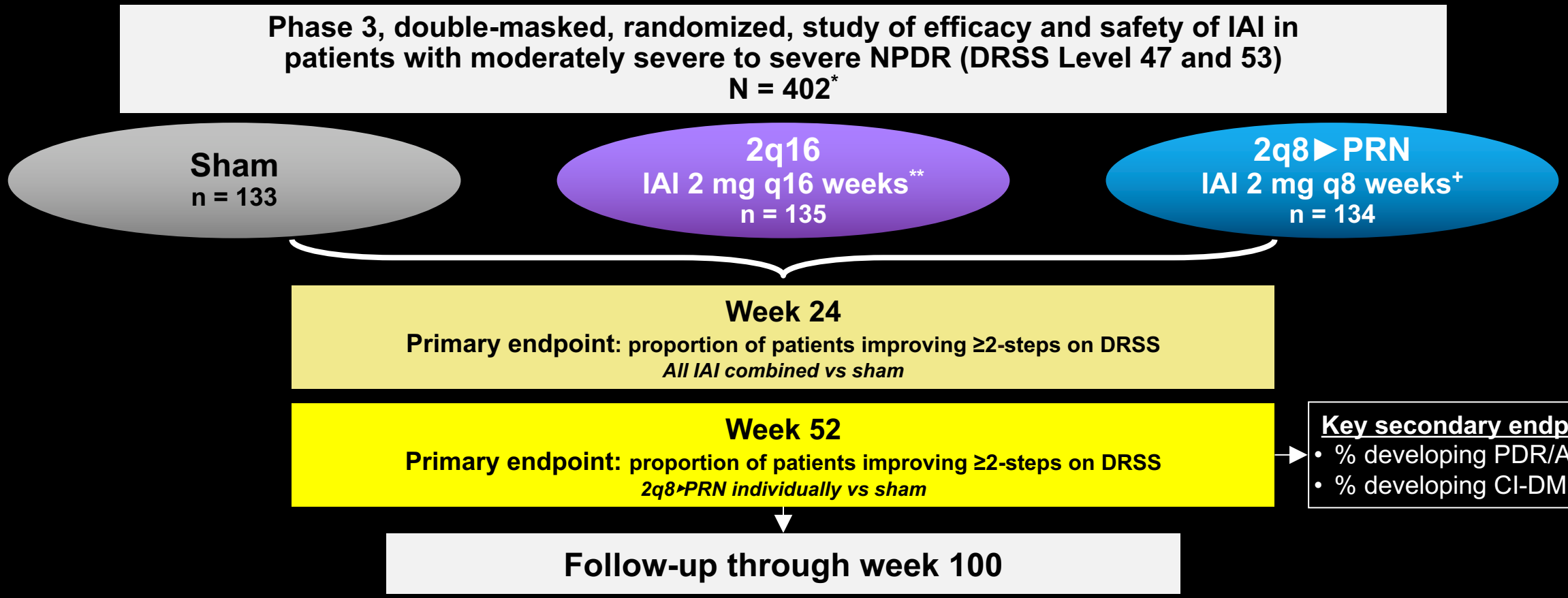
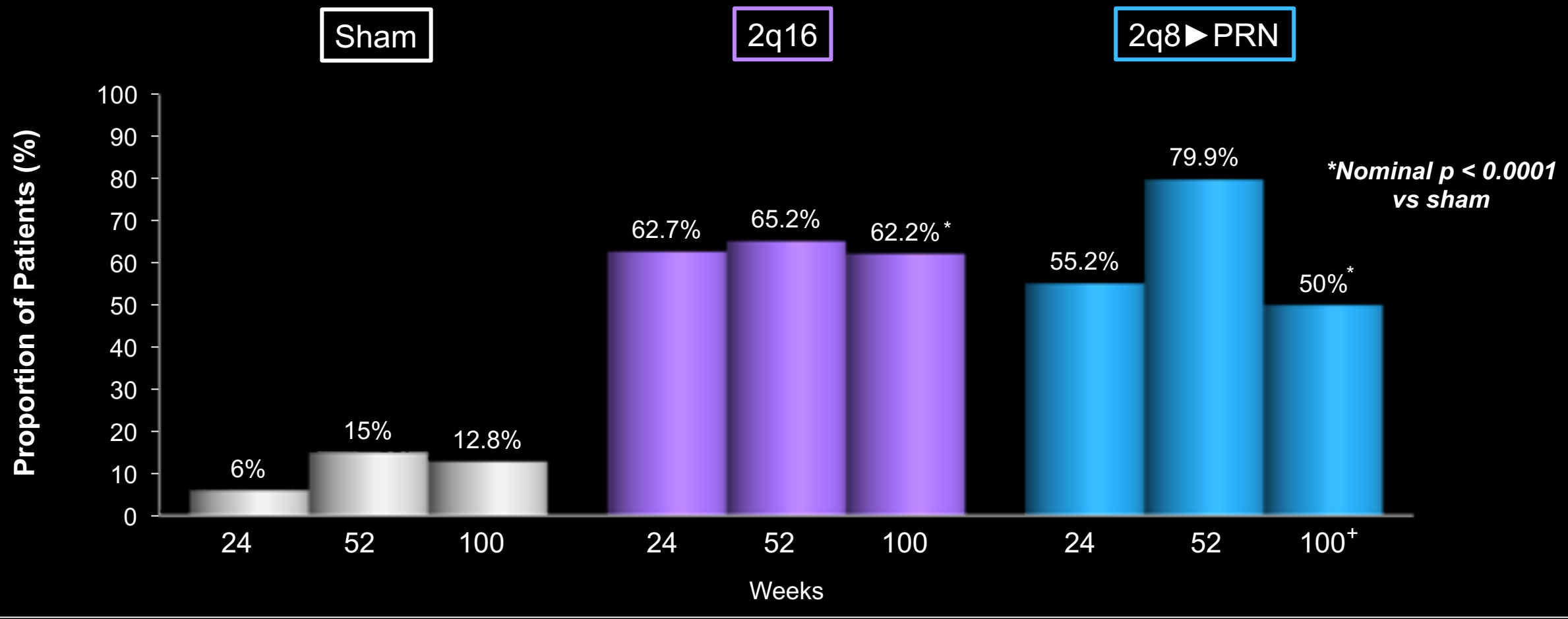
PANORAMA Study Design



*Patients were stratified by baseline DRSS level; **After 3 initial monthly doses and 1 q8 interval; +After 5 initial monthly doses, flexible treatment schedule after week 52.
2q8, 2 mg every 8 weeks; 2q16, 2 mg every 16 weeks; AE, adverse event; ASNV, anterior segment neovascularization; CI-DME, center-involved diabetic macular edema; DME, diabetic macular edema; DRSS, Diabetic Retinopathy Severity Score; IAI, intravitreal aflibercept injection; NPDR, nonproliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy; PRN, pro re nata.

Proportion of Patients with ≥2-step Improvement in DRSS from Baseline



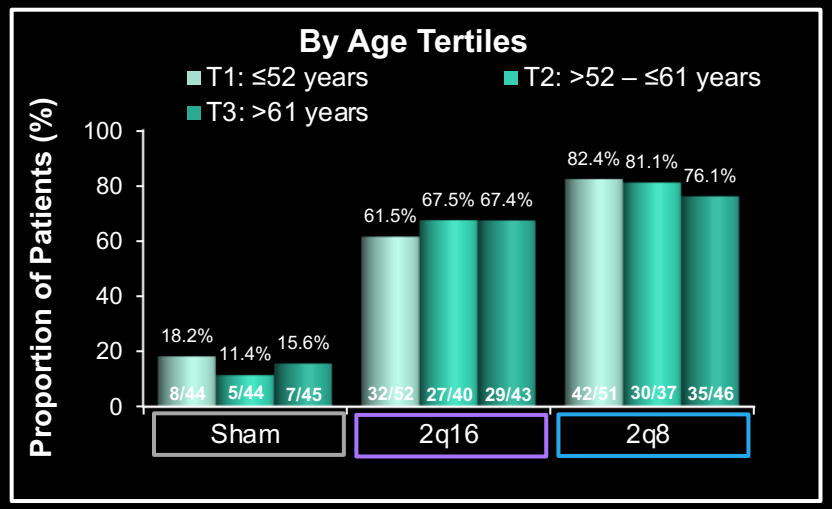
Through week 52 in PANORAMA, ocular AEs occurring in >10% of eyes treated with sham, 2q16, and 2q8 were conjunctival hemorrhage (5.3%, 11.9%, and 17.2%, respectively) and DME (24.1%, 5.9%, and 9.0%, respectively)

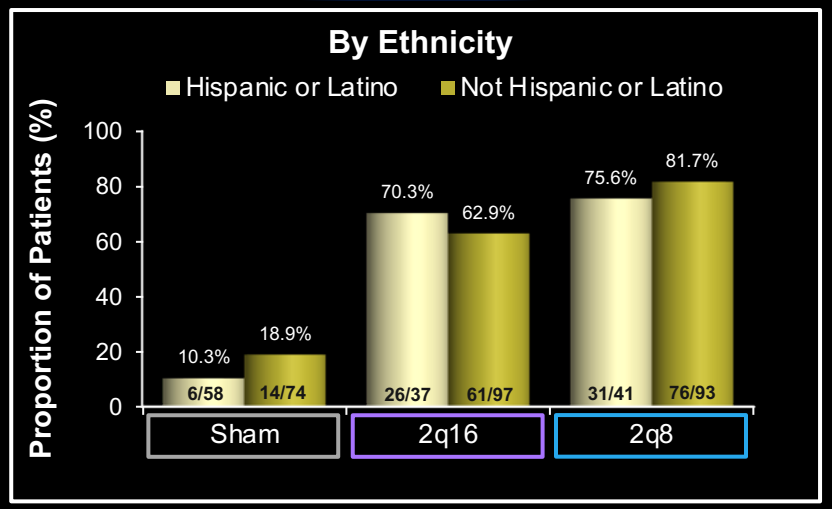
Sham n = 133, 2q16 n = 135, 2q8 n = 134. †Independent reading center review of investigator PRN decisions suggests under-treatment during year 2.

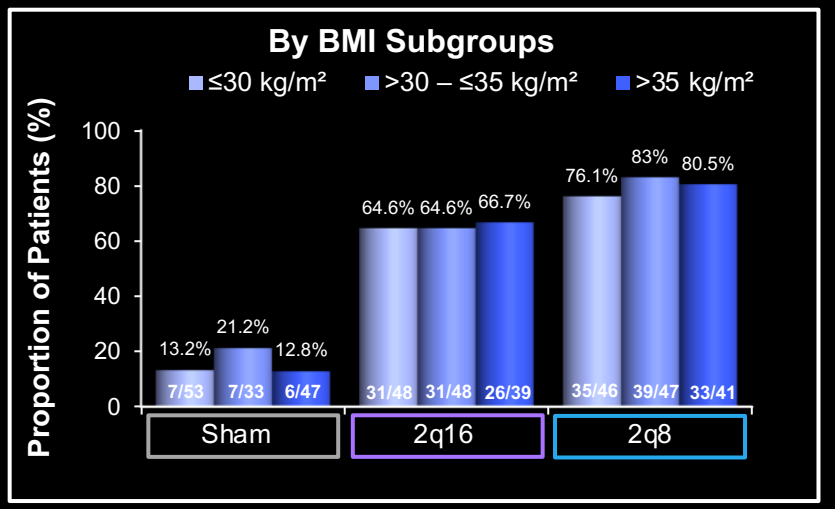
Post Hoc Analysis

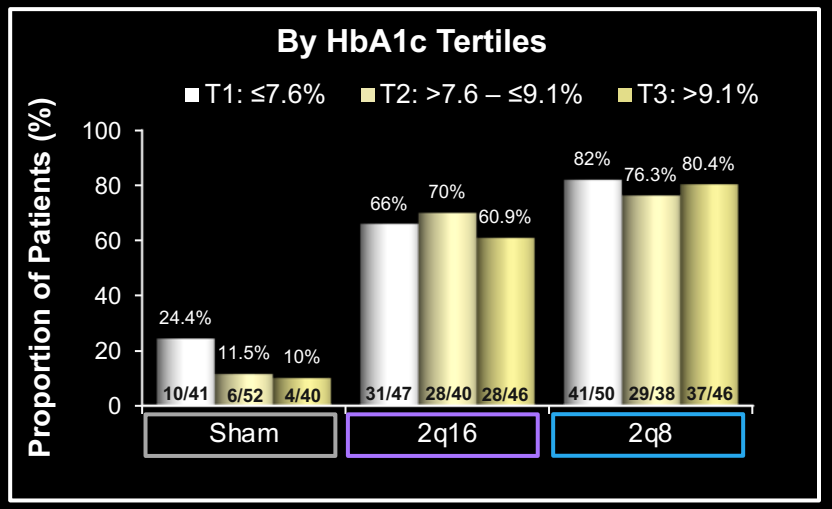
- **Objective**
  - To evaluate the difference in treatment effect between IAI and sham by baseline factors for the primary endpoint at weeks 52 and 100
- **Methods**
  - Difference in treatment effect across baseline factors was evaluated by Mantel-Haenszel weighting scheme adjusted by baseline DRSS stratification variable
  - Between-treatment group comparisons were evaluated by 2-sided Cochran-Mantel-Haenszel test adjusted by baseline DRSS stratification variable
  - Treatment-by-subgroup interactions were evaluated by logistic regression model using treatment, subgroup, treatment-by-subgroup interaction, and stratification variable as covariates
  - Last observation carried forward method was used to impute missing or non-gradable post-baseline data
  - For patients who received rescue treatment, data from the time rescue was given were censored

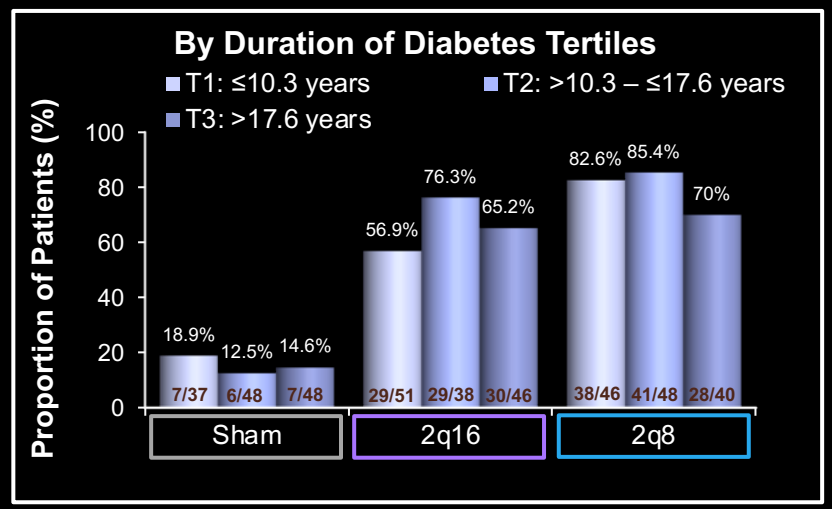
Proportion of Patients with ≥2-Step Improvement in DRSS From Baseline at Week 52

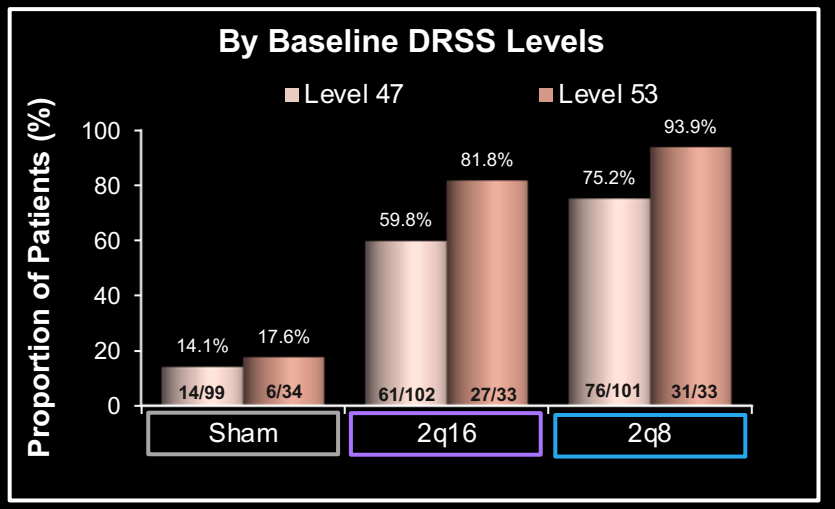






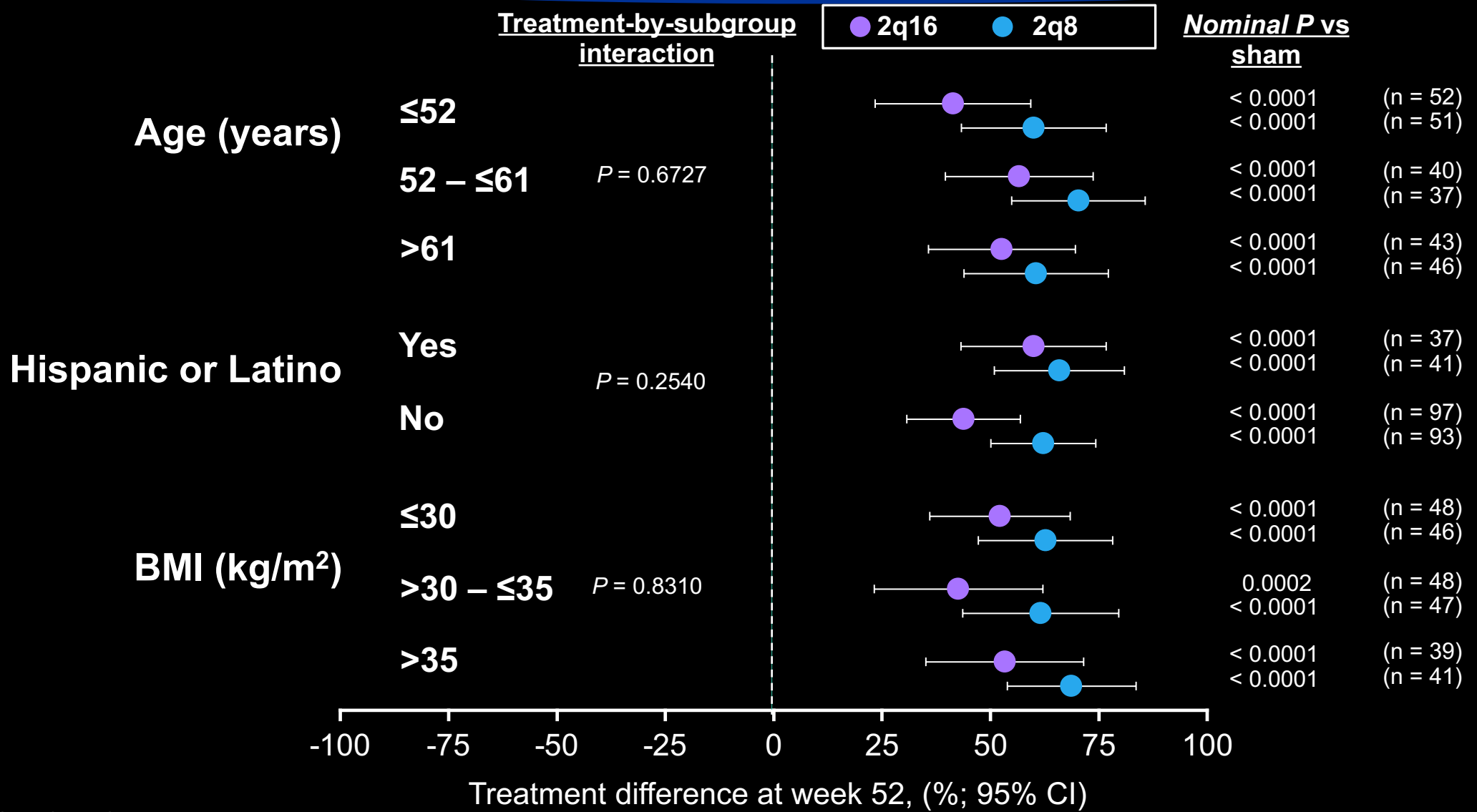






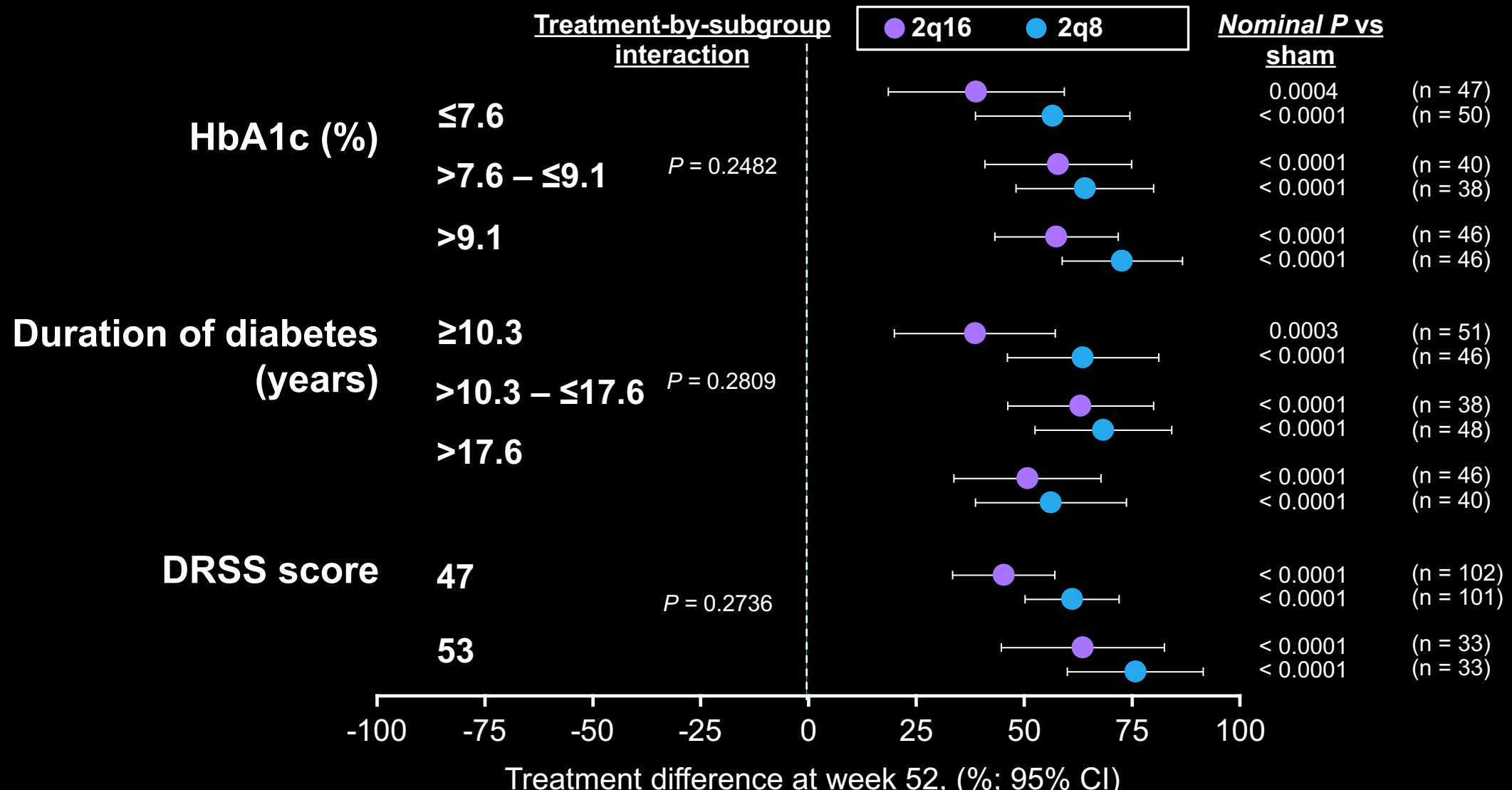
n = 133 for sham except for n = 132 in ethnicity, n = 135 for 2q16 except for n = 133 in HbA1c and n = 134 in ethnicity, n = 134 in 2q8 except n = 131 in the ethnicity analysis.
BMI, body mass index; T, tertile; HbA1c, glycated hemoglobin.

Treatment Difference for Proportions with ≥2-Step DRSS Improvement at Week 52: By Demographics

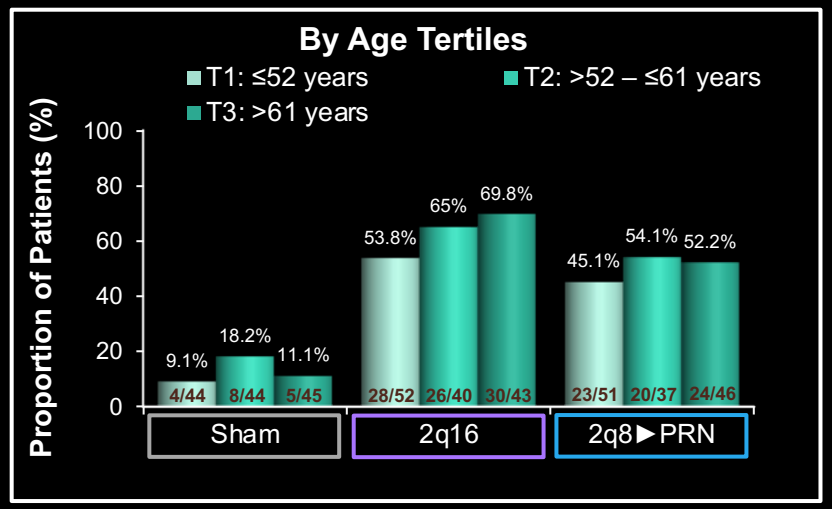


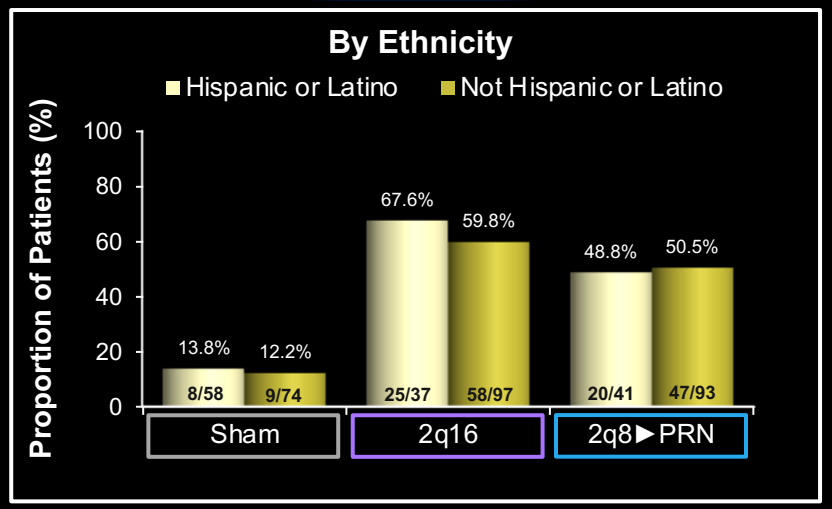
CI, confidence interval.

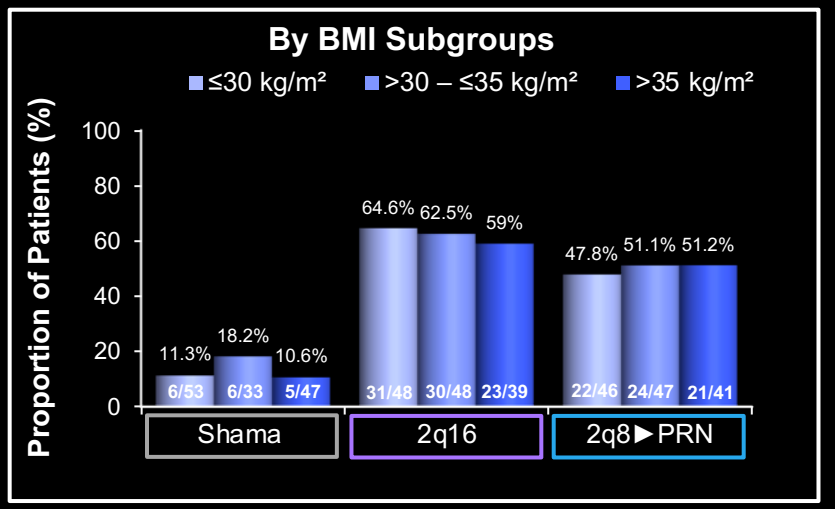
Treatment Difference for Proportions with ≥2-Step DRSS Improvement at Week 52: By Disease Characteristics

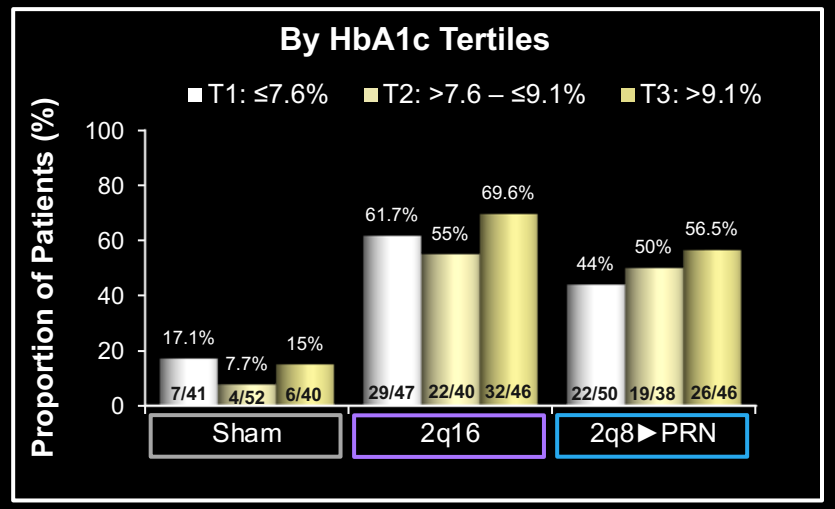


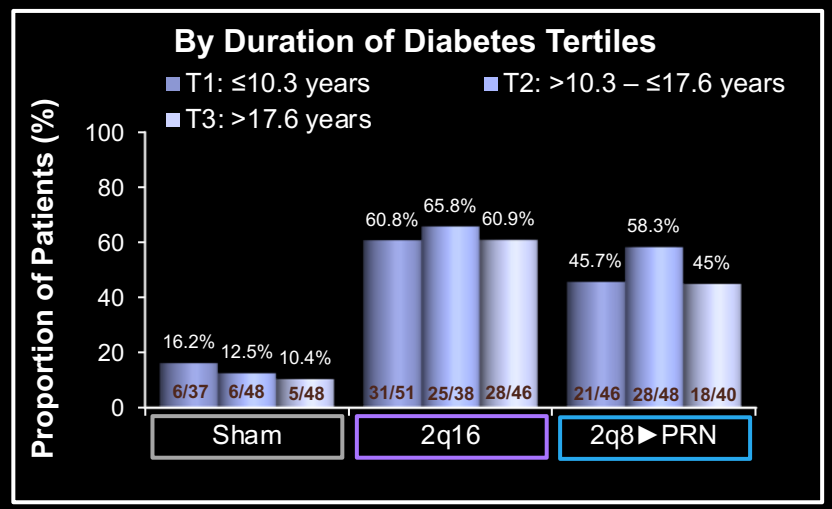
Proportion of Patients with ≥2-Step Improvement in DRSS From Baseline at Week 100

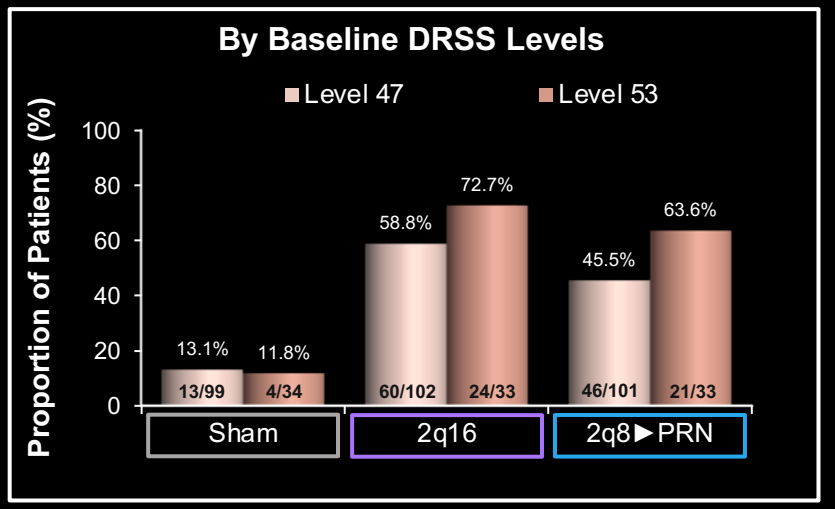






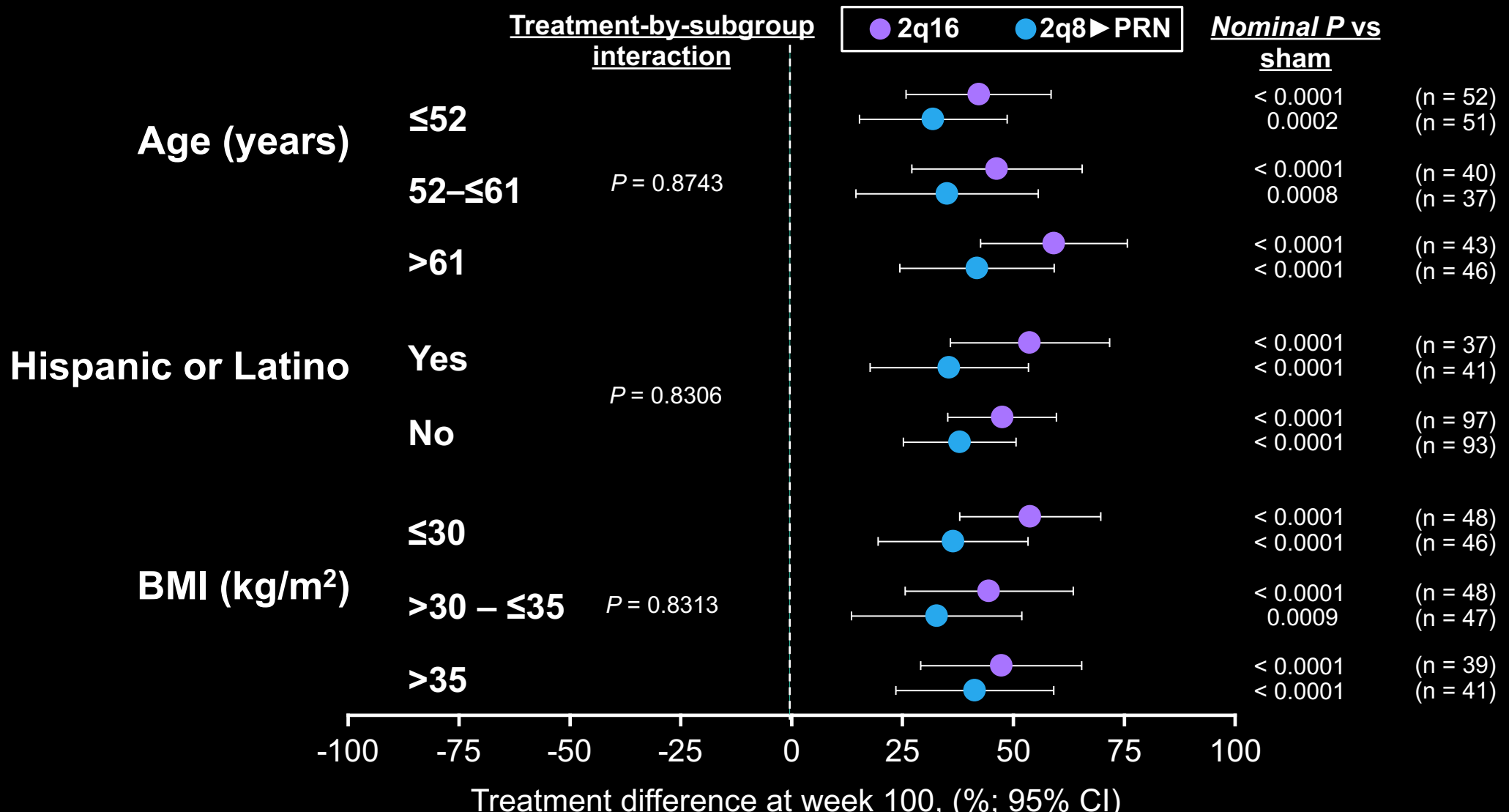




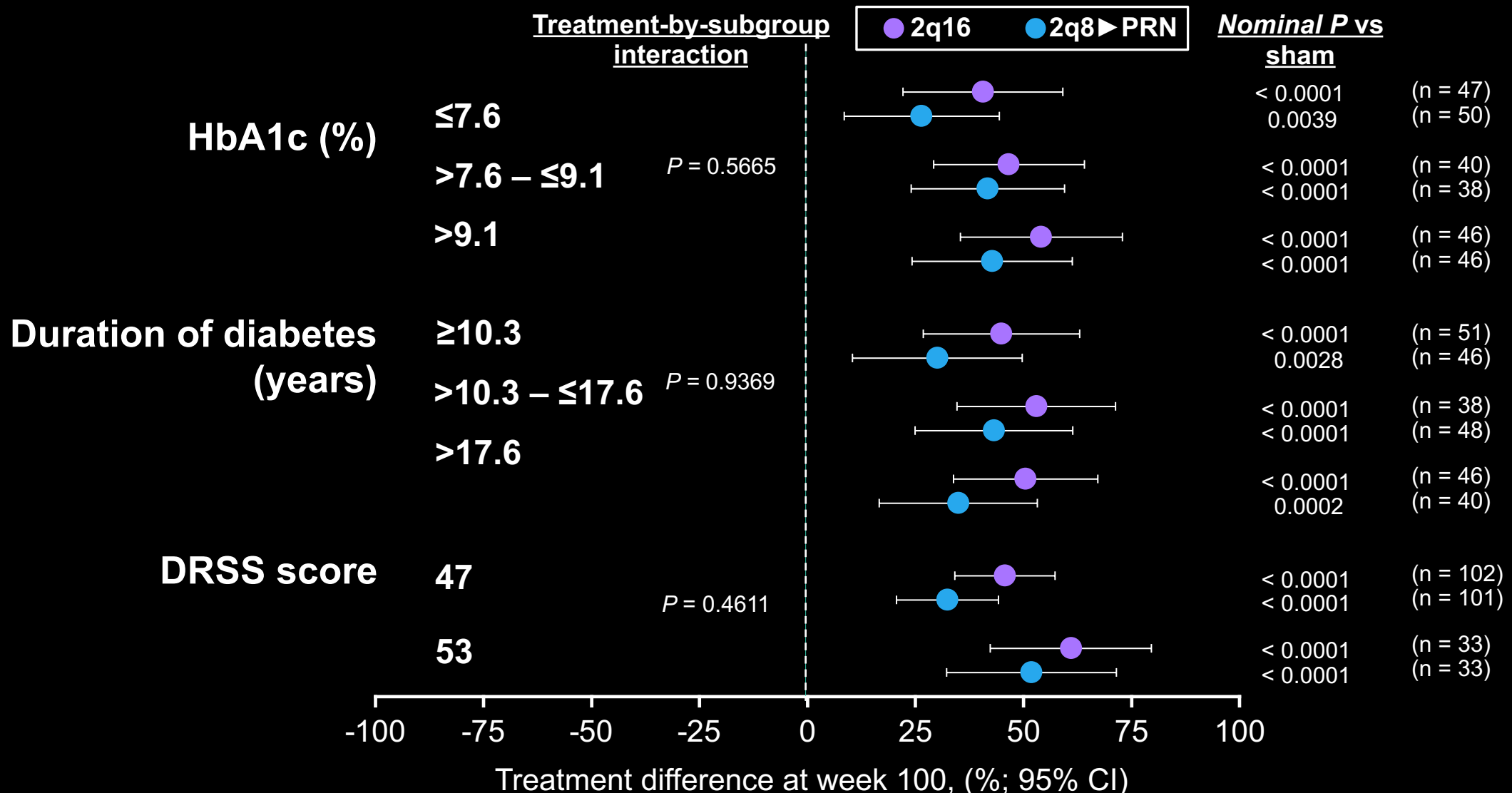


n = 133 for sham except for n=132 in ethnicity, n = 135 for 2q16 except for n = 133 in HbA1c and n = 134 in ethnicity, n = 134 2q8▸PRN except for n = 131 in ethnicity analysis.

Treatment Difference for Proportions with ≥2-Step DRSS Improvement at Week 100: By Demographics



Treatment Difference for Proportions with ≥2-Step DRSS Improvement at Week 100: By Disease Characteristics



Conclusions

- This post hoc analysis found no treatment-by-subgroup interactions across selected baseline factors in patients with moderately severe to severe NPDR at both weeks 52 and 100
- Greater proportions of eyes treated with IAI had a ≥2-step DRSS improvement from baseline compared with sham across all selected demographics and disease characteristics, in eyes with moderately severe to severe NPDR