

## Additional Analyses for VivaGel® BV Efficacy in Prevention of Recurrent BV (rBV)

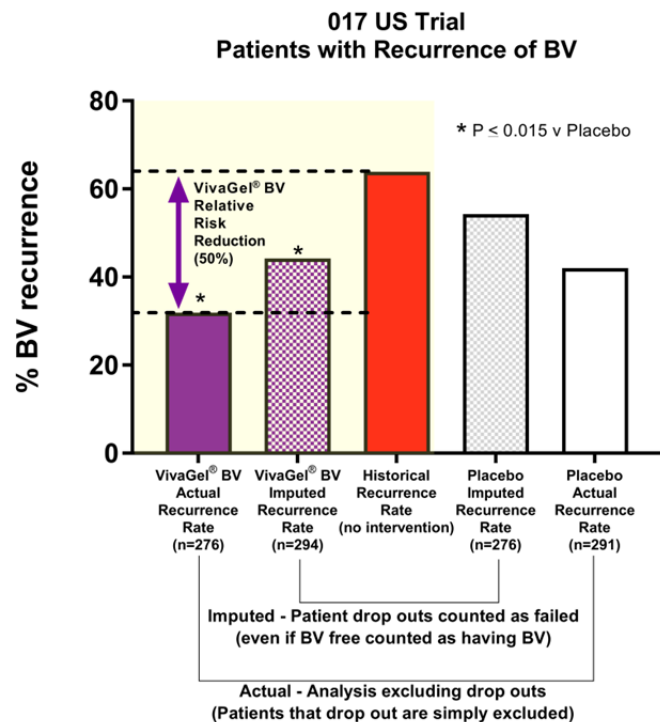
**Primary Efficacy Endpoint:** Recurrence of BV at or by the Week 16 visit (measured by 3 of 4 Amsel Criteria)

**Figure a: 017 US Trial:**

The rate of BV recurrence at or by week 16 in the VivaGel® BV group (Imputed Recurrence Rate<sup>1</sup>) was 44.2% ( $P=0.015$  v Placebo which was 54.3%).

When looking at Actual Recurrence Rate<sup>2</sup>, the rate of BV recurrence at or by week 16 in the VivaGel® BV group was even lower at 31.9% ( $P=0.014$  v Placebo which was 42%).

The Relative Risk Reduction (%) in the VivaGel® BV Actual Recurrence group compared to the Historical Recurrence Rate<sup>3</sup> was 50%

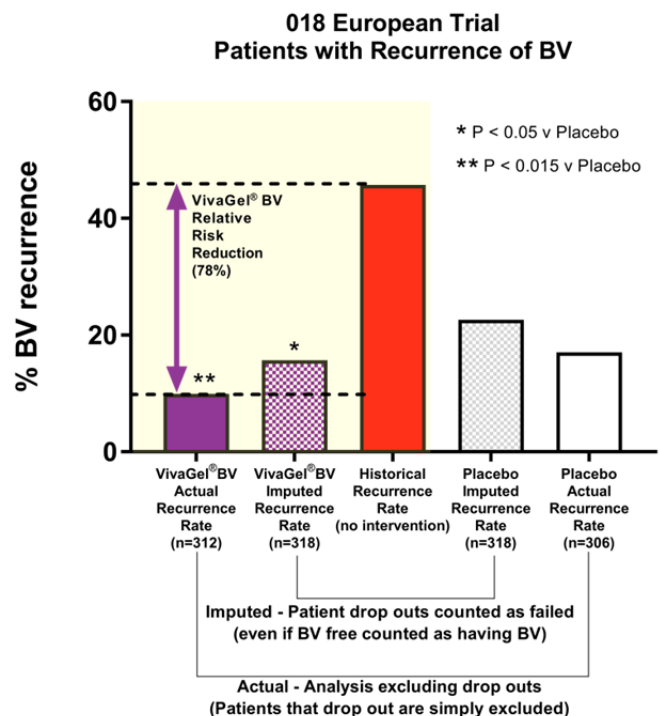


**Figure b: 018 European Trial (Full Analysis).**

The rate of BV recurrence at or by week 16 in the VivaGel® BV group (Imputed Recurrence Rate) was 15.7% ( $P<0.05$  v Placebo which was 22.6%).

When looking at Actual Recurrence Rate, the rate of BV recurrence at or by week 16 in the VivaGel® BV group was even lower at 9.9% ( $P<0.015$  v Placebo which was 17%).

The Relative Risk Reduction (%) in the VivaGel® BV Actual recurrence group compared to the Historical Recurrence Rate was 78%



<sup>1</sup> Imputed Recurrence Rate (where patient drop-outs are counted as failures)

<sup>2</sup> Actual Recurrence Rate (where dropouts are not included in the analysis)

<sup>3</sup> 16 week Historical Recurrence Rate (the rate of recurrence that would have been expected in this population in a 16 week period if they did not have a prevention therapy)