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

<u>Primary Efficacy Endpoint:</u> 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 Rate¹) was 44.2% (P=0.015 v Placebo which was 54.3%).

When looking at Actual Recurrence Rate², 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 Rate³ was 50%

Patients with Recurrence of BV 80 * P ≤ 0.015 v Placebo % BV recurrence 60 VivaGel® BV Relative Risk 40 20 0 VivaGel[®] BV VivaGel[®] BV Historical Placebo Actual Imputed Recurrence Imputed ecurrence Actual Recurrence Rate Recurrence (no intervention) Rate (n=291) Rate (n=276) (n=294)(n=276) Imputed - Patient drop outs counted as failed (even if BV free counted as having BV) Actual - Analysis excluding drop outs (Patients that drop out are simply excluded)

017 US Trial

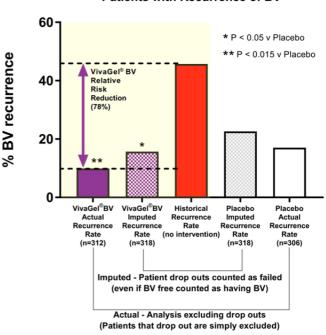
Figure b: 018 European Trial (Full Analysis).

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%

018 European Trial Patients with Recurrence of BV



¹ Imputed Recurrence Rate (where patient drop-outs are counted as failures)

 $^{^{2}}$ Actual Recurrence Rate (where dropouts are not included in the analysis)

³ 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)