• OB-002 is a small recombinant protein (69 amino acid residues) analog of RANTES/CCL5, a natural ligand of the CCR5 receptor.

• OB-002 is currently under development by Orion Biotechnology for both HIV prevention & cancer indications. Topical OB-002 prevents vaginal transmission of SHIV in a non-human primate (NHP) model of HIV infection. (Veazey & al. JID 2009)

• OB-002 is best-in-class, based on functional inhibition potency, compared to other CCR5 antagonists (Maraviroc and Lenolinil/PRO-140; Figure 1A). These data are supported by strong anti-HIV potency (human PBMC, Figure 1B) & efficacy (NHP vaginal challenge; Figure 1C) data.

• In this Phase I clinical trial, we sought to characterize the safety, acceptability, and pharmacokinetic profile of a gel formulation of OB-002 (OB-002H). The study was conducted in two parts: a single-dose vaginal/rectal application (Part 1) and a randomized placebo-controlled multiple-dose vaginal application (Part 2).

• In Part 1, 12 participants were allocated to either Cohort A1 (vaginal application; N=6 women) or Cohort B1 (rectal application; N=3 women, N=3 men).

• In Part 2, 18 female participants were allocated to either Cohort A2 (N=3) or Cohort A3 (N=15). Participants of Cohort A2 received open label OB-002H gel and Cohort A3 were randomised in a 2:1 ratio to either OB-002H (N=10) or placebo (N=5) vaginal gel application.

• The gel formulation of OB-002 was safe, well tolerated. Product-related genital adverse events were mild (Grade 1) or moderate (Grade 2) and transient.

• In Part 1, one participant experienced Grade 2 hyperkalemia which was deemed not to be related to product use.

• In Part 2, seven TEAEs were reported to be related to product use, including genital burning sensation, vulvovaginal pruritus, and vaginal discharge (all Grade 1) and vulvar disorder (Grade 2).

• Serum concentration of OB-002 was below the limit of quantification in all analysed samples at each time point, indicating that there was no systemic absorption of the gel.

• The majority of the feedback related to acceptability profile of the gel’s consistency, feeling, and lubrication was positive.

• The majority of participants confirmed their willingness to use the gel against HIV, pregnancy, or both.

• In Part 2, 18 female participants were allocated to either Cohort A2 (N=3) or Cohort A3 (N=15). Participants of Cohort A2 received open label OB-002H gel and Cohort A3 were randomised in a 2:1 ratio to either OB-002H (N=10) or placebo (N=5) vaginal gel application.

• The gel formulation of OB-002 was safe, well tolerated, and product-related genital adverse events were mild (Grade 1) or moderate (Grade 2) and transient.

• The majority of participants expressed satisfaction with the product and the intent to use an OB-002H gel for prevention of HIV infection if the gel was available.

• There was no evidence of systemic absorption of OB-002 following single or multiple vaginal/rectal OB-002H gel administration.

• Further trials will be necessary to evaluate the safety and pharmacokinetic profile of rectal administration, as well as the optimal dosage for rectal and vaginal administration of OB-002H.

Figure 1 (A) Functional inhibition assay in vitro; OB-002 potency (0.2 nM) is 13-fold higher than that of Maraviroc (2.6 nM) & 28-fold higher than that of PRO-140/Leronlimab (5.6 nM). (B) HIV replication assay; OB-002 showed potency consistently higher than that of Maraviroc. (C) Positive SHIV protection in NHPs; OB-002 is fully efficacious against vaginal SHIV challenge in macaques.