**THE FIRST-IN-HUMAN TRIAL OF PC-1005 (MIV-150 AND ZINC ACETATE IN A CARRAGEEAN GEL)**

Barbara A. Friedland1, Craig J. Hoesley2, Marlena Plagianos3, Shimin Zhang4, Elena Hoskin5, Mohcine Alamri1, Natalia Teleshova1, José A. Fernández-Romero3, Thomas M. Zdowsky1, George W. Creasy3

1Population Council, New York, NY; 2University of Alabama, Birmingham, AL; 3Population Council, Center for Biomedical Research, New York, NY; 4Population Council, Washington, DC

**BACKGROUND**

PC-1005 is a promising multipurpose prevention technology (MPT) in development that is active against 3 non-curable STIs: HIV, herpes simplex virus (HSV), and human papillomavirus (HPV); and is designed for vaginal and rectal use.

PC-1005 is composed of: MIV-150, a potent NNRTI, not used for HIV therapy; zinc acetate, a selective antiviral agent generally recognized as safe (GRAS) by the US FDA; and carrageenan (CG), a gelling agent derived from seaweed (also GRAS) with excellent antiviral activity against HPV.

**METHODS**

Design: Randomized (4:1), placebo-controlled, double-blind trial (RCT); preceded by 3-day open-label (OL) run-in, PC-1005 only (Figures 1 and 2)

Population: Healthy, sexually abstinent women, aged 19–49 at one US site: University of Alabama, Birmingham (UAB)

Regimen: 4 ml PC-1005 (or HEC placebo) gel inserted vaginally once daily for 14 days; doses 1, 8 and 14 in the clinic

Endpoints and assessments:

- **Safety:** Adverse events (AE), abnormal clinical or laboratory findings
- **PK:** MIV-150 and zinc PK parameters calculated using non-compartmental techniques and actual sampling times
- **Acceptability:** Self-administered questionnaire (Day 14); in-depth interview (Day 21)
- **Adherence:** Self-report and appicator count (Days 8 and 14)
- **PD:**
  - Antiviral activity against HIV, HSV-2 and HPV in CVL measured using cell-based assays
  - ECO values for CVL antiviral activity calculated using a dose-response inhibition analysis

**RESULTS**

Primary Outcomes

- **Safety:**
  - There were no SAEs or early discontinuations for AEs.
  - Of the 18 AEs recorded, most were mild (n=13) and/or unrelated (n=9) and similar across groups (data not shown).
  - No significant abnormalities were observed in clinical, lab or pathology results.

PK of MIV-150 (Table 2, Figure 4)

- MIV-150 was absorbed systemically at low levels with no accumulation detected.

**CONCLUSIONS**

- PC-1005 gel used vaginally for 14 days was well-tolerated, with low systemic absorption of MIV-150 and measurable HIV and HPV antiviral activity in CVL.

- These results warrant continued development of PC-1005 as a viable MPT for vaginal or rectal prevention of HIV/STIs.

**FOR MORE INFORMATION**

For more information please contact Barbara Friedland at bfriedland@popcouncil.org

This work was made possible by the generous support of the American people through the United States Agency for International Development (USAID) Cooperative agreement GPH-00-04-00010-00. These contents are the responsibility of the Population Council and do not necessarily reflect the views of USAID or the United States Government.