MTN-004

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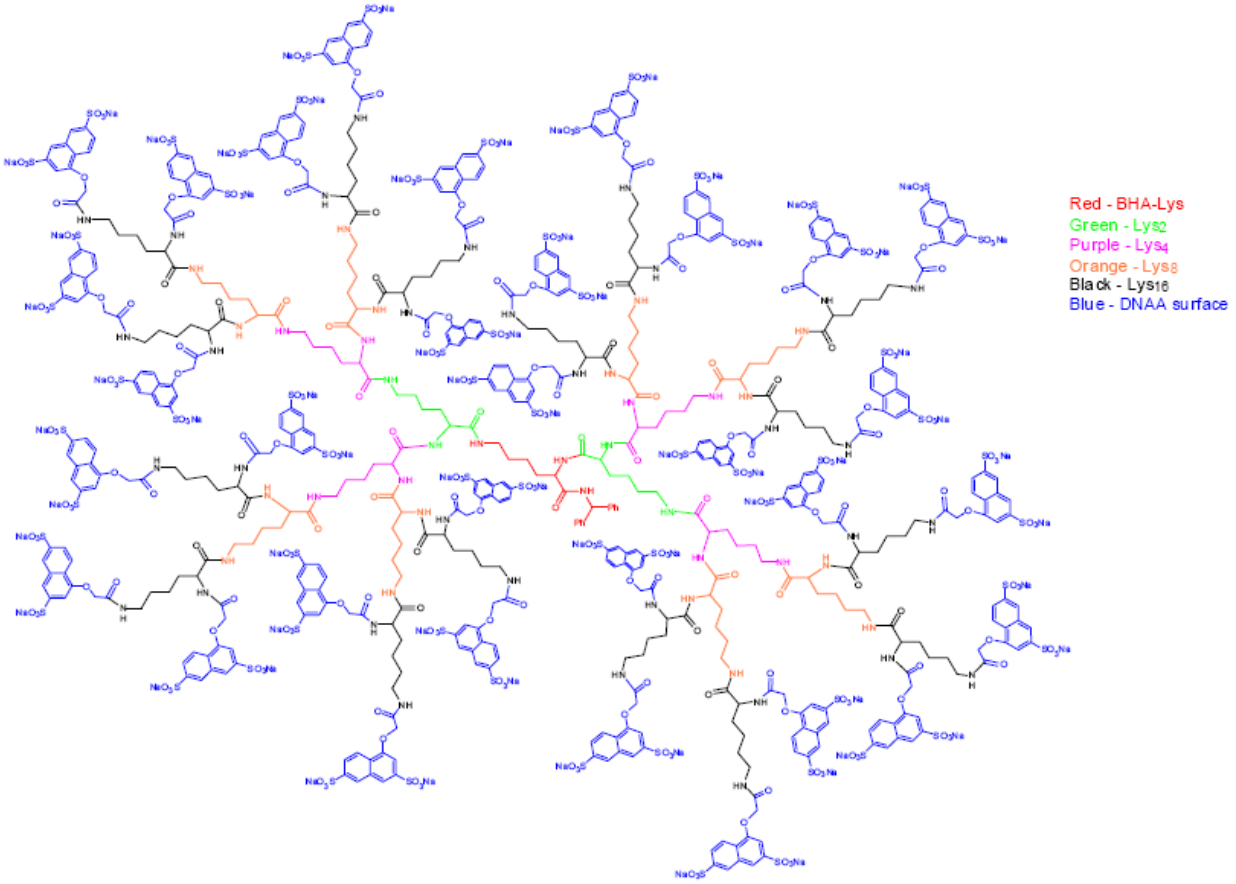
MTN Annual Meeting

Arlington, April 2008

SPL7013 (VivaGel™)



SPL7013 (VivaGel™)

- Polylysine dendrimer molecule
- Activity against HSV-2 and HIV-1

Clinical Program	
Study	Status
Starpharma Phase 1 safety	Completed
DMID / STI-CTG Phase 1 safety	Completed
Penile safety	Completed
MTN-004 Phase 1 safety	Paused
Phase 1 rectal safety	Development

MTN-004 Design

- Phase 1, double blind, randomized, controlled comparison with 14 days of twice daily exposure to 3% w/w SPL7103 Gel or placebo gel in HIV-uninfected sexually active women

Arm	Description	N	Frequency
1	SPL7013 Gel	20	BID (14 days)
2	Placebo Gel	20	BID (14 days)

MTN-004 Sites

Student Health Center
University of South Florida
Tampa, Florida
Site PI: Diane Straub MD MPH

Maternal Infant Study Center (CEMI)
University of Puerto Rico
Medical Science Campus
San Juan, Puerto Rico
Site PI: Irma Febo MD

Primary Objective

- To assess the safety of 3% w/w SPL7013 Gel when administered for 14 consecutive days on the vulvar and cervicovaginal mucosa of healthy sexually active HIV-negative women aged 18-24 years

Secondary Objectives

- To assess the **adherence** to a short-term regimen of 3% w/w SPL7013 Gel among healthy sexually-active HIV-negative women aged 18-24 years
- To evaluate product **acceptability** among healthy sexually-active HIV-negative women aged 18-24 years
- To assess the effect of a twice daily short-term regimen of 3% w/w SPL7013 Gel on the **vaginal microflora** of healthy sexually-active HIV-negative women aged 18-24 years

Exploratory Objectives

- Determine the pattern of cytokine chemokine, innate immune factor changes,
- Determine the extent of SPL7013 absorption into the blood following the completion of product dosing

Primary Endpoints

- Abnormal genital symptoms judged by the Investigator to be possibly, probably, or definitely related to product use
- Abnormal pelvic exam findings, including colposcopic findings, judged by the Investigator to be possibly, probably, or definitely related to product use
- Grade 3 or higher laboratory values (as defined by the DAIDS Toxicity Tables) for hematology, liver function, creatinine level and coagulation judged by the Investigator to be possibly, probably, or definitely related to product use
- Adverse experiences judged by the Investigator to be possibly, probably, or definitely related to product use

MTN-004 Study Design

Activity	Screen 1	Screen 2	Enroll	Phone Call (D2)	Week 1	Week 2	Week 3
Consent							
Screening	X	(X)					
Safety bloods	X	(X)	X		X	X	
Pelvic exam			X		X	X	X
Colposcopy			X			X	
PK			X			X	
Behavioral			X			X	
Vag culture			X		X	X	X
Innate factors			X		X	X	X

MTN-004 Amendment

- Add third arm to study:
  - VivaGel™ (N=18)
  - VivaGel™ placebo (N=18)
  - Universal placebo (N=18)
- Remove applicator dye test

MTN-004 Timelines

Activity	Due Date	Status
Protocol development	November 2006	Completed
IRB Submission	January 2007	Completed
Screening and enrollment	August 2007	Completed
Study Pause	October 2007	Completed
Review of STI-CTG data	April 2008	Pending
Submit amendment	May 2008	Pending
Restart study	Q3 2008	Pending
Study completion	Q3 2009	Pending