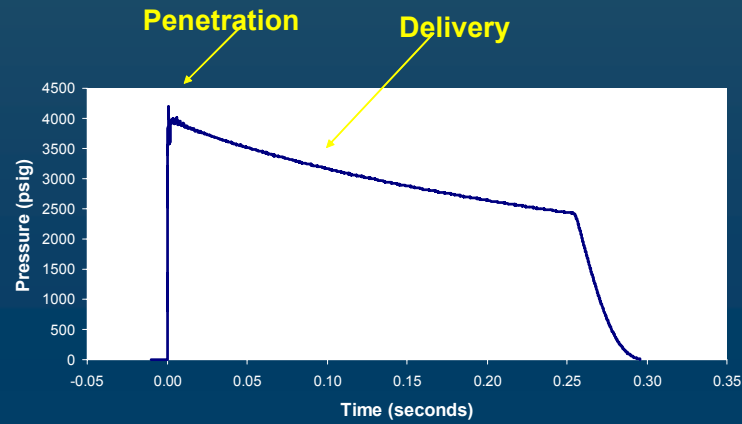


# Needle-free Administration of Enfuvirtide with Biojector 2000 demonstrates bioequivalence to standard needle administration

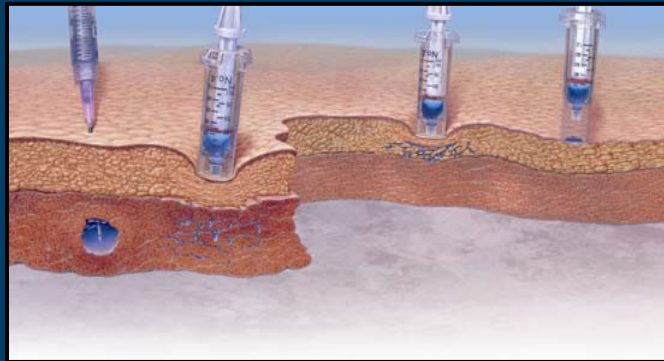
<sup>1</sup>True, AL, <sup>1</sup>Zhang, Y, <sup>2</sup>Chiu, Y-Y, <sup>1</sup>DeMasi, R, <sup>2</sup>Patel, I, <sup>3</sup>Stout, R, <sup>1</sup>Miralles, D.  
<sup>1</sup>Trimeris, Inc., Durham, NC, <sup>2</sup>Roche, Inc., Nutley, NJ, <sup>3</sup>Bioject, Inc., Portland, OR

## Background

### B2000 Pressure Profile (#2 syringe, 0.50 ml dose):



## Injection Placement and Dispersion



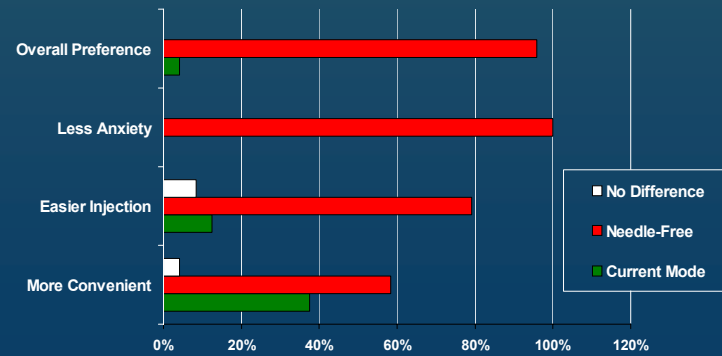
### Some advantages of needle-free technology:

- Improved dispersion, no rubbing needed.
- Consistent technique: Injection at same depth each time.
- Greater flexibility of injection site (1 handed delivery)
- Needle free
  - Attractive to patients with phobia to needles
  - IVDU
  - Decreased biohazard; biohazard elimination costs

### B2000 Preference Surveys

- **New York City Student Survey (N709)**
  - 85% preferred needle-free for next immunization
- **Oklahoma State Department of Health Survey**
  - 85% preferred needle-free
- **Multiple Sclerosis study**
  - 96% preference for needle-free

### Survey of 30 MS patients in US

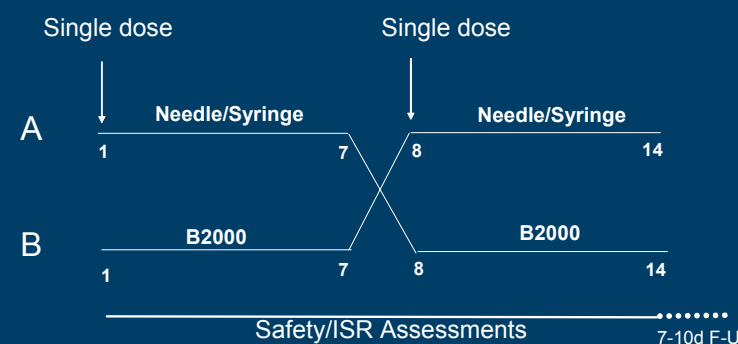


## Study T20-405

### Study T20-405 Objectives

- **Primary objectives:**
  - To determine the relative bioavailability of enfuvirtide after a single subcutaneous 1 mL 90 mg administration using two different devices: a 27 gauge needle/syringe or B2000 needle free Bioject system
- **Secondary objectives:**
  - To compare the safety and tolerability of single doses of the two injection devices.

## Study Design



### Patient Disposition:

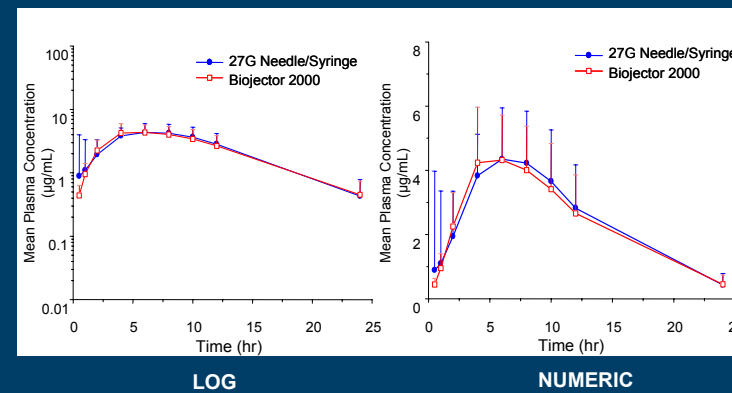
- **Safety population:** N = 27;
  - N=26 completed both injection periods (27 completed B2000, 26 completed needle/syringe)
  - One subject failed to complete study; removed by the sponsor after completion of the 1st dosing period due to a positive drug screen.

### Patient Demographics:

- **Median Age:** 48 years
- **Gender:** 81.5% Male, 18.5% Female
- **Race:** African American (51.9%), Hispanic (25.9%), Caucasian (22.2%)
- **Median BMI:** 24.8

## PK RESULTS

### Plasma Concentration-Time Profiles



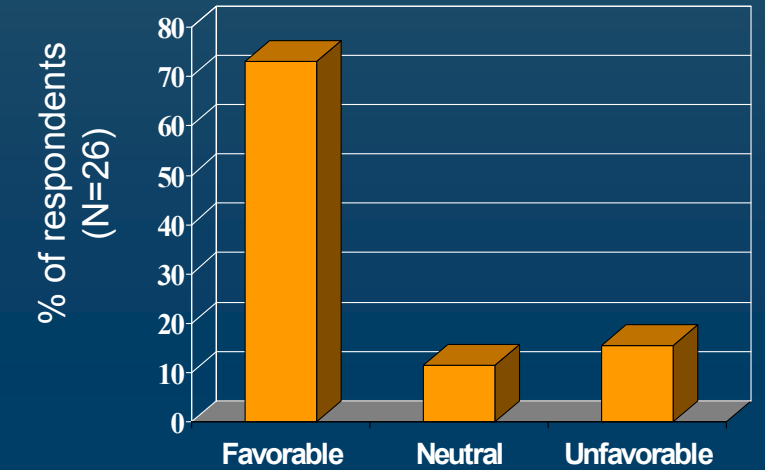
### Bioequivalence

Parameter (n=25)	Bioject (B)	Needle/Syringe (N)	Ratio (B/N)	90% CI (%)
$C_{max}$	4.42	4.64	0.95	84-109
$C_{12}$	2.42	2.50	0.97	86-109
$AUC_{0-24}$	56.7	57.3	0.99	93-105
$AUC_{0-\infty}$	56.9	57.6	0.99	93-104

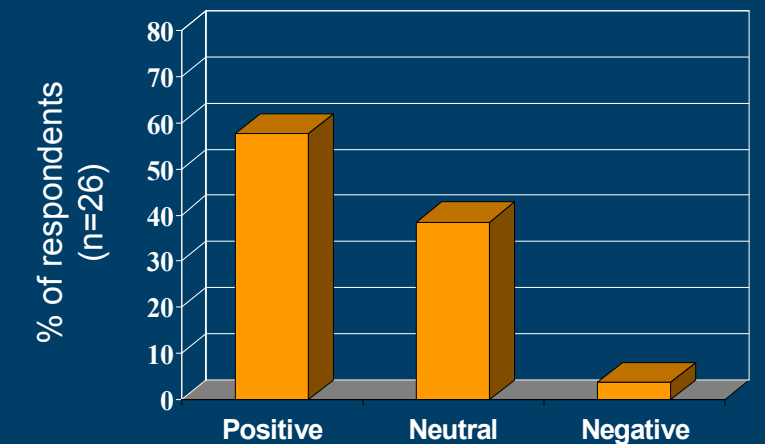
### SAFETY SUMMARY (B2000 and Needle/Syringe)

- No ISR > Grade 2 noted for any sign or symptom
- Majority of ISR occurred during injection through 24 hr post- injection
- No ISR present after 48 hr through 7-14 days post-injection
- No injection malfunctions (i.e. wet injections, leak back, incomplete dose delivered, etc.) noted

### What is your overall impression of the needle-free injection?



### Rate your experience with needle-free injection compared to the needle/syringe injection



## Conclusions

- $C_{max}$ ,  $C_{12}$ ,  $AUC_{0-24}$  and  $AUC_{0-\infty}$  were equivalent between needle/syringe and Bioject dosing devices
- Use of Bioject was well tolerated.
- The majority of patients had a positive overall impression of the B2000.
- Studies are needed to determine the long term tolerability of ENF when administered using the Bioject 2000 device.