

FUZEON® (BOSS) Biojector

Roche Labs Protocol ENF-407/ML19849: FUZEON® Biojector® 2000 Open-Label Safety Study (BOSS)

Purpose: This is an 8-week open-label study to collect safety and patient satisfaction data on the use of enfuvirtide when administered using the B2000 needle-free jet injection and reconstitution system. To compare injection site signs and symptoms associated with ENF injection on needle/syringe (NS) versus B2000 needle-free injection device (NFID).

About the study: Subjects will be randomized 2:1 to either the B2000 needle-free injection device (NFID) or standard needles and syringe. Patients randomized to needle and syringe will initiate the NFID at Week 4 and remain on the NFID through the end of the study.

Required:

- Be a current FUZEON® user (uninterrupted ≥ 2 weeks prior to screening) or a former FUZEON® user (discontinued for ≥ 1 week prior to screening and deemed to benefit from needle-free administration of FUZEON®)
- Be willing to use the standard 27G ½” needle and syringe for injections through Week 4 if randomized to needle and syringe (NS)
- Female patients of childbearing potential must have a negative serum or urine pregnancy test during screening for eligibility, a negative pregnancy test 24 hours prior to first dose of study drug, and must agree to use a reliable form of effective contraception in addition to a barrier method for the duration of the study and for 30 days after the last dose of the study drug
- Male patients must agree to use a reliable form of contraception for the entire duration of the study

Not Allowed:

- Evidence of active, untreated opportunistic infections or unexplained temperature which is greater than or equal to 101.3°F for seven consecutive days, within 30 days prior to the screening. Patients who are on a stable anti-infective treatment or prophylaxis regimen are allowed in the study.
- Evidence of alcohol and/or substance abuse within one year of entry that would result in the patient being unreliable in fulfilling the conditions of the study
- Patients naïve to FUZEON®
- Patients who are unable to self-inject or who do not have a reliable caregiver to administer injections.

Study Location:

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