

Study Factsheet

Protocol Number: 213500

SOLAR Study Purpose

The SOLAR study is a randomized, multicenter, active-controlled, parallel-group, non-inferiority, open-label study evaluating the efficacy, safety, and tolerability of injected long-acting cabotegravir (CAB LA) plus long-acting rilpivirine (RPV LA) in HIV-1 infected adults who are virologically suppressed. The study is designed to demonstrate the non-inferior antiviral activity of CAB LA + RPV LA administered every 2 months (Q2M) compared to Biktarvy (BIK) administered orally once daily for 12 months.

The SOLAR study is part of the overall objective to develop a two-drug long-acting injectable regimen that has the potential to offer improved treatment convenience, compliance, and quality of life for individuals living with HIV.

Key Eligibility Criteria

A patient may be eligible for the study, if he or she:

- Is aged 18 years or older (or ≥ 19 where required by local regulatory agencies)
- Is on the uninterrupted current regimen of BIK for at least 6 months prior to Screening with an undetectable HIV-1 viral load for at least 6 months prior to Screening
- Has documented evidence of plasma HIV-1 RNA measurements < 50 c/mL in the 6 months prior to Screening

Study Medications

Cabotegravir (CAB) is a potent integrase inhibitor that possesses attributes that allow formulation and delivery as a long-acting (LA) parenteral product. Rilpivirine (RPV) is a diarylpyrimidine derivative and a potent non-nucleoside reverse transcriptase inhibitor (NNRTI) with in vitro activity against wild type HIV-1 and select NNRTI-resistant mutants. Intramuscular administration of a two-drug combination therapy with CAB LA plus RPV LA may offer a better tolerability and resistance profile, as well as improved adherence and treatment satisfaction in virologically suppressed patients.

Study Design

Approximately 654 adult HIV-1 infected patients who are on the stable ARV regimen BIK will be randomized 2:1 to either be switched to the CAB LA + RPV LA regimen or continue BIK through 12 months. The study will continue with an Extension Phase after Month 12.

