IMPAACT 2017 (MOCHA)

Study Overview/Summary

IMPAACT 2017, also known as MOCHA (More Options for Children and Adolescents), is a Phase I/II, multi-center, open-label, non-comparative study of oral cabotegravir (CAB), long-acting injectable CAB (CAB-LA), and long-acting injectable rilpivirine (RPV-LA) in virologically suppressed children and adolescents living with HIV-1 who are 12 to less than 18 years. The study is taking place in Botswana, South Africa, Thailand, Uganda, and the United States.

Adherence to daily oral antiretrovirals can be difficult for adolescents managing HIV. The combined regimen made up of long-acting CAB and RPV injectable antiretrovirals is a promising new therapy that has been made available to adults living with HIV and could make adhering to antiretrovirals and managing HIV much easier for adolescents. The MOCHA study aims to provide data to extend the use of this long-acting antiretroviral regimen to adolescents living with HIV.

The MOCHA study is designed to confirm the dose and evaluate the safety, tolerability, acceptability, and pharmacokinetics of CAB when given as oral tablets and of both CAB and RPV when given as long-acting intramuscular injections in adolescents living with HIV. Although both oral CAB and oral RPV are used in the study, only oral CAB is being evaluated because oral RPV (Edurant®) is already approved for this study population. The combined regimens of both oral CAB and oral RPV followed by CAB-LA + RPV-LA are already approved for adults living with HIV-1 who are virologically suppressed (Cabenuva®).

There are two sequential cohorts in the study. In Cohort 1, study participants are assigned to receive either CAB or RPV and retain their pre-study ART regimens. Cohort 1 starts with a 4 to 6-week oral lead-in phase followed by a 12-week injection phase in which participants receive a total of either 2 or 3 injections, each administered four weeks apart. In Cohort 2, study participants receive both CAB + RPV and discontinue their pre-study ART regimens. Cohort 2 also has an oral lead-in phase over a 4 to 6-week. During the injection phase in Cohort 2, participants receive both CAB-LA + RPV-LA intramuscular injections over a 92-week period and injections are administered every eight weeks. Participants discontinuing study product injections in either Cohort 1 or Cohort 2 will be followed for an additional 48 weeks to evaluate tolerability and acceptability, and characterize long-term safety and washout PK.

Parents/caregivers of adolescent participants in the United States are also enrolled to take part in a single in-depth qualitative interview to contribute to the evaluation of tolerability and acceptability of the study drugs.

Findings presented at CROI 2022 were based on interim data collected through Week 16 from 23 participants enrolled to Cohort 1 who received either oral CAB or oral RPV followed by 3 injections of either CAB-LA or RPV-LA; and 10 parents/caregivers who completed an in-depth interview. Results are described below.

CROI 2022 Study Results

Findings presented at CROI 2022 are based on interim data collected through Week 16, from 23 participants enrolled in the U.S. to Cohort 1 who received either oral CAB or oral RPV followed by three injections of either CAB-LA or RPV-LA; and ten parents/caregivers who completed an in-depth interview. Results are described below.

1. CAB-LA and RPV-LA, when given individually and with a background ART regimen, are well-tolerated and achieve targeted pharmacokinetic concentrations in these adolescents.
2. No new or unanticipated safety concerns were identified. Of the injection site reactions which occurred, all were Grade 1 or 2, and none led to treatment discontinuation.
3. Adolescents and their parents/caregivers found the long-acting injection formulation and the single injectable study drug to be acceptable.

The study will continue to evaluate the safety, tolerability, acceptability, and pharmacokinetics of oral CAB, CAB-LA, and RPV-LA. These interim results and future results from the MOCHA study are expected to support expanded options of treatment formulations for children and adolescents living with HIV-1 to improve adherence and treatment satisfaction.