

Treatment Study Updates

Annual Meeting

18 June 2018



IMPAACT Treatment Studies: Closed to Accrual

Study	Title	Status	Population
P1097	Raltegravir Pharmacokinetics and Safety in Neonates	Closed to accrual (April 2018) <i>Closed to follow-up expected in August 2018</i>	Pregnant women with HIV and their infants
P1090	A Phase II/III Open-Label Trial to Evaluate the Safety, Tolerability, PK & Antiviral Activity of Etravirine in Antiretroviral Treatment-Experienced HIV-1 Infected Infants and Children, ≥2 Months to <6 Years	Closed to Accrual (October 2017) <i>Closed to follow-up expected in July 2023</i>	Children living with HIV (2 months to <6 years of age)

IMPAACT Treatment Studies: Pending, Open to Accrual, and Enrolling

Study	Title	Status	Population
IMPAACT 2017 (MOCHA)	Phase I/II Study of the Safety, Acceptability, Tolerability, and Pharmacokinetics of Oral and Long-Acting Injectable Cabotegravir and Long-Acting Injectable Rilpivirine in Virologically Suppressed HIV-Infected Children and Adolescents	Pending <i>Open to accrual expected by September 2018</i>	Adolescents living with HIV
IMPAACT 2014	Phase I/II Trial of the Pharmacokinetics, Safety and Efficacy of Doravirine (MK-1439) and Doravirine/ Lamivudine/ Tenofovir Disoproxil Fumarate (MK-1439A) in HIV-1-infected Children and Adolescents	Open to accrual <i>First enrollment expected June 2018</i>	Children living with HIV (12 to <18 years of age)
IMPAACT 2007	Phase I Safety & Pharmacokinetics of Maraviroc in HIV-1-Exposed Neonates at Risk of Acquiring HIV-1 Infection	Enrolling, 15 of 72 (21%)	Neonates exposed to HIV perinatally

IMPAACT Treatment Studies: In Development

Study	Title	Status	Population
IMPAACT 2026	Pharmacokinetic Properties of Antiretroviral, Anti-Tuberculosis, Contraceptive and Related Drugs During Pregnancy and Postpartum	Protocol Version 1.0 expected in November 2018	Pregnant and postpartum women and their infants
IMPAACT 2019	Phase I/II Study of the Pharmacokinetics, Safety, and Tolerability of Abacavir / Dolutegravir / Lamivudine in HIV-1-Infected Children Less than 12 years of Age	Protocol Version 1.0 expected in August 2018	Children living with HIV (2 to <12 years of age)

IMPAACT Treatment Studies: Proposals

Study	Title	Population
CS 5012 (CAP 521)	A Phase I Trial to Evaluate the Safety and Pharmacokinetics of Dolutegravir in HIV-1 Exposed Neonates at Risk of Acquiring HIV-1 Infection	Neonates exposed to HIV perinatally
CS 5016 (CAP 531)	Vedolizumab therapy in older perinatally-infected children who initiated early antiretroviral treatment	Children living with HIV (7 to 16 years of age)
CS 5018 (CAP 534)	Feasibility and acceptability of long acting injectable (LAI) ARV medications in non-adherent HIV+ youth	Youth living with HIV (13 to <24 years of age)
CAP 538	Open-label, randomized, non-inferiority study to evaluate maintenance of antiviral efficacy and safety of DTG + RPV in ART-experienced, virologically suppressed, HIV-1-infected children from 6 to <18 years of age and weighing at least 17 kg	Children living with HIV (6 to <18 years of age)

Thank you!

- Check the IMPAACT website for study updates
- Contact us for any questions or ideas about new studies (or problems that need studies!)

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