

FOR IMMEDIATE RELEASE

Tuesday, February 26, 2019

Media Contact:

Alexis Sexton, AIDS Clinical Trials Group (ACTG)

<u>ASexton@mednet.ucla.edu</u>

868-603-2946 (office); 310-267-4895 (cell)

ACTG PRESENTS NEW RESEARCH ON HIV AND TB, CO-MORBIDITIES, TREATMENT PARADIGMS, AND CURE AT CROI 2019

The <u>AIDS Clinical Trials Group (ACTG)</u>, the world's largest and longest-established HIV research network, funded by NIAID at the U.S. NIH, will make 11 oral and 19 poster presentations at <u>CROI 2019</u> (Seattle, March 4-7). Several have the potential to influence clinical practice and guidelines for care.

"For more than 30 years, the ACTG has been at the forefront of research to treat HIV and its coinfections and comorbidities," said ACTG Chair Judith Currier, M.D., MSc of the University of California Los Angeles. "These studies represent the breadth of ACTG investigations and offer important insights into the treatment of MDR-TB, how to approach antiretroviral treatment in resource-limited settings, and strategies to address chronic complications of HIV."

Highlights of ACTG presentations at CROI 2019 by topic include the following:

Tuberculosis:

* 84LB. QT EFFECTS OF BEDAQUILINE, DELAMANID OR BOTH IN MDR-TB PATIENTS: THE DELIBERATE TRIAL (ACTG 5343; CROI Oral Abstract Session 7: TB: From Contact to Cure and Beyond; Wednesday, March 6, 10:00 am – 12:00 pm) *Kelly Dooley et al.* (kdooley1@jhmi.edu) (presenting *Gary Maartens. gary.maartens@uct.ac.za*)

* FEATURED ON THE WEDNESDAY, MARCH 6 OFFICIAL CROI PRESS CONFERENCE

Bedaquiline and delaminid, the first two novel medications for MDR-TB to be developed in decades, generated extensive excitement when released. However, there is a lingering concern about overlapping toxicities with the two medications, specifically prolongation of the QT interval. This abstract resolves the debate.

82. EARLY BACTERICIDAL ACTIVITY OF HIGH-DOSE ISONIAZID AGAINST MULTI DRUG RESISTANT TB (ACTG 5312 (CROI Oral Abstract Session 7: TB: From Contact to Cure and Beyond; Wednesday, March 6, 10:00 am – 12:00 pm) *Kelly Dooley et al.* (<u>kdooley1@jhmi.edu</u>)

High-dose isoniazid (INH) 10-15 mg/kg was left off the World Health Organization guidelines for multidrug-resistant TB recently, due to lack of data about bacteriocidal killing against TB with typical patterns of INH resistance. This abstract provides pivotal data that could impact guidelines.

78. POTENTIAL CONCERN FOR TIMING OF DMPA INJECTION AMONG WOMEN TREATED FOR HIV AND TB (ACTG 5338; CROI Oral Abstract Session 7: TB: From Contact to Cure and Beyond; Wednesday, March 6, 10:00 am – 12:00 pm) *Rosie Mngqibisa et al.* (*mnqqibisa @ecarefoundation.com*)

Injectable depot medroxyprogesterone acetate (DMPA) is an important hormonal contraceptive for women in resource-limited settings, but we don't know how it interacts with rifampin-based TB therapy. This study provides the first answers about the drug-drug interactions between DMPA and RIF based TB therapy among women on efavirenz-based ART.

Cure, Persistence, and Inflammation:

26. MULTI-DOSE IV ROMIDEPSIN: NO INCREASE HIV-1 EXPRESSION IN PERSONS ON ART, ACTG A5315 (CROI Oral Abstract Session 2: Strategies for HIV Cure; Tuesday, March 5, 10:00 am – 12:00 pm) Deborah McMahon et al. (mcmahond@pitt.edu)

* FEATURED ON THE TUESDAY, MARCH 5 OFFICIAL CROI PRESS CONFERENCE

The histone deacetylase inhibitor Romidepsin (RMD) could help in efforts to reverse HIV latency, if the drug induced HIV expression from cells. Unfortunately, this trial showed that RMD did not induce HIV expression among patients on ART as had been hoped.

37 LB. SAFETY, TOLERABILITY AND IMMUNOLOGIC ACTIVITY OF RUXOLITINIB ADDED TO SUPPRESSIVE ART (ACTG 5366 (CROI Oral Abstract Session 3: Noncommunicable Diseases in Treated HIV; Tuesday, March 5, 10:00 am – 12:00 pm) *Vincent Marconi et al.* (<u>vcmarco@emory.edu</u>)

Ruxolitinib (RUX) is a Janus kinase (Jak) inhibitor that reduces biomarkers of systemic inflammation in people without HIV and has some activity in the laboratory on reducing persistence in ex-vivo models. This abstract provides important new insights on whether RUX can safely reduce the persistent inflammation seen in people living with HIV, even when on suppressive ART.

131. SIROLIMUS REDUCES T CELL CYCLING AND IMMUNE CHECKPOINT MARKER EXPRESSION, ACTG A5337 (CROI Oral Abstract Session 12: HIV/SIV and the Immune System: An Intimate Dance; Thursday, March 7 10:00 am – 12:00 pm) *Timothy Henrich et al.* (Timothy.Henrich@ucsf.edu)

This abstract shows that continuous use of oral sirolimus, an mTOR inhibitor, modulates CCR5 expression and markers of cell cycling. Safety of this approach is still being evaluated, however.

Cognitive Function, Obesity and Long-Term HIV Infection:

128. CARDIOVASCULAR RISK SCORES PREDICT LONGITUDINAL COGNITIVE FUNCTION IN OLDER PLHIV (ACTG 5322; CROI Oral Abstract Session 11: Suppressive ART and the CNS: Switches, Outcomes, and Biomarkers; Thursday, March 7 10:00 am – 12:00 pm) *Felicia Chow et al.* (*felicia.chow@ucsf.edu*)

Addressing neurocognitive decline in people living with HIV requires targets for intervention. This study shows that the established baseline 10-year cardiovascular risk score predicts longitudinal cognitive function in people living with HIV - and may provide clinicians with new insights into opportunities to optimize both heart health and brain health.

129. OBESITY IS INDEPENDENTLY ASSOCIATED WITH COGNITIVE DECLINE IN HIV (ACTG 5322; CROI Oral Abstract Session 11: Suppressive ART and the CNS: Switches, Outcomes, and Biomarkers; Thursday, March 7 10:00 am – 12:00 pm) *Jeremiah Perez* et al. (perez@sdac.harvard.edu)

Much remains to be learned about what contributes to neurocognitive decline in persons living with HIV, and how to prevent or reverse it. In the ACTG 5322 (HALIO) study, both greater age and obesity were independently associated with neurocognitive decline.

This is just one of the many important ACTG abstracts at CROI 2019 highlighting the impact of obesity in HIV disease, including:

- 669. RISK FACTORS FOR EXCESS WEIGHT GAIN FOLLOWING SWITCH TO INTEGRASE INHIBITOR-BASED ART (ACTG 5322, ACTG 5001; Themed Discussion Session 08, Weight Gain During ART, Wednesday, March 6, 1:30 pm) Jordan Lake et al. (Jordan.E.Lake @uth.tmc.edu)
- 673. THE IMPACT OF WEIGHT GAIN AND SEX ON IMMUNE ACTIVATION FOLLOWING INITIATION OF ART (NWCS 407; Themed Discussion Session 08, Weight Gain During ART, Wednesday, March 6, 1:30 pm) Sarah Bares et al. (sara.bares@unmc.edu)
- 384. SEX AND OBESITY ARE ASSOCIATED WITH RESIDUAL VIREMIA IN ART-SUPPRESSED INDIVIDUALS (ACTG 5321; Poster Session P-E09; Mechanisms of Persistence; Thursday, March 7, 2:30 pm) Joshua Cyktor. et al. (jcc114@pitt.edu)
- 681. CHANGES IN FAT DENSITY AFTER ART INITIATION (NWCS 450; Poster Session P-N3: Adipose Tissue Density and Biology; Thursday, March 7, 2:30 pm) Jordan Lake et al. (Jordan.E.Lake@uth.tmc.edu)

Antiretroviral therapy:

52. PHARMACOGENETICS WORSENS AN ADVERSE ANTIRETROVIRAL-HORMONAL CONTRACEPTIVE INTERACTION (ACTG 5316; CROI Oral Abstract Session O-05: Strange Bedfellows: STIs, Contraception, and Trials of HIV Testing, Tuesday, March 5 10:00 am – 12:00 pm) David Haas et al. (david.haas@vanderbilt.edu)

We already know that efavirenz influences the levels of the birth control products etonogestrol and ethinyl estradiol in injectable implants. This important study looks at whether there are genetic traits we can screen for that influence that interaction.

518. IMPORTANT SEX DIFFERENCES IN OUTCOMES FOR INDIVIDUALS PRESENTING FOR THIRD LINE ART (ACTG 5288; Themed Discussion Session TD-04: Women with HIV: Are Outcomes Different? Tuesday, March 5, 1:30 pm) *Catherine Godfrey et al. (cgodfrey @niaid.nih.gov)*

This study looked at how to treat people living with HIV on failing 2nd-line ART in low- and middle- income countries. This abstract explores the very important topic of sex differences in safety and outcomes for men and women in that large study.

496. QUALITY OF LIFE AND ADHERENCE AS PREDICTORS OF SECOND-LINE ART VIROLOGICAL FAILURE (ACTG 5373; CROI Poster Session P-H3, Virologic Failures: To Second Line and Beyond, Wednesday, March 6, 2:30 pm). *Thiago Torres et al.* (*thiago.torres@ini.fiocruz.br*)

Can quality of life influence adherence when switching to a new regimen? If so, providers can help patients with adherence by focusing more on their overall quality of life.

499. PREDICTORS OF VIROLOGIC OUTCOME WHILE CONTINUING A PI-BASED ART REGIMEN IN ACTG A5288. (CROI Poster Session P-H3, Virologic Failures: To Second Line and Beyond, Wednesday, March 6, 2:30 pm). *Robert Salata et al. (ras7@case.edu)*

This important presentation provides further evidence of the factors that lead to better or worse outcomes for people failing 2nd line therapy in low- and middle-income countries.

###