

Please contact us if you would like more details on any of these studies.

- For non-COVID studies, you can contact our outreach coordinator Dan Berner at 415 476 4082 ext 556 or [daniel.berner@ucsf.edu](mailto:daniel.berner@ucsf.edu)
- For COVID outpatient studies, please email [CovidResearchSFGH@ucsf.edu](mailto:CovidResearchSFGH@ucsf.edu) or (415) 806-8554

**STUDIES FOR **HIV INFECTED** PATIENTS:**

- ❖ **NOW OPEN - DORAVIRINE FOR PEOPLE WITH EXCESSIVE WEIGHT GAIN ON INTEGRASE INHIBITORS AND TENOFOVIR ALAFENAMIDE (THE DO-IT STUDY, A5391)** Phase 4, three arm, open label randomized study randomizing people living with HIV to stay on current INSTI based ART vs change to the NNRTI doravirine with Truvada (TDF/FTC) vs doravirine with Descovy (TAF/FTC) for 48 weeks. Eligibility includes BMI  $\geq 27.5$ , unintentional weight gain of  $> 10\%$  in the 1-3 years after starting an integrase inhibitor (bictegravir, raltegravir, dolutegravir), and suppressed HIV VL for at least 48 weeks.
- ❖ **COMING SOON- HIV CURE STRATEGY STUDY: IL-15 SUPERAGONIST N-803 GIVEN WITH OR WITHOUT IV BROADLY NEUTRALIZING ANTIBODIES (bNAbs) (A5386)** People living with HIV with a suppressed viral load for at least 2 years will receive the subcutaneous IL-15 superagonist every 3 weeks for 8 injections, and will be randomized to bNAbs infusion ( 10-1074 and VRC-7-523LS) administered twice after confirming susceptibility to these antibodies. Participants will undergo an analytic treatment interruption with ART stopped at week 30, for up to 24 weeks.
- ❖ **ENROLLING: OBSERVATIONAL STUDY FOR PEOPLE WITH PERSISTENT LOW LEVEL VIREMIA DESPITE EFFECTIVE ART (A5321)** This observational study will enroll those on an uninterrupted fully active ART regimen, with at least two HIV-1 RNA values 20-1500 copies/mL within the previous 24 months, at least one HIV-1 RNA value 20-1500 copies/mL within the previous 12 months, and no values  $>1500$  copies/mL within the previous 12 months. Enrollees will undergo a number of observational assessments including questionnaires, neuropsychiatric testing, and evaluation of blood, hair, and spinal fluid.
- ❖ **ENROLLING INJECTABLE CABOTEGRAVIR+RILPIVIRINE FOR INDIVIDUALS WHO HAVE BEEN NON-ADHERENT TO ORAL ART (A5359):** Phase III study of ART experienced individuals with HIV RNA  $>200$  and evidence of ART non-adherence and no evidence of cabotegravir or rilpivirine resistance. All participants will receive oral ART x 24 weeks with conditional economic incentives to attain HIV suppression. Those who are suppressed at 24 weeks will be randomized to IM CAB+RIL every 4 weeks (after an oral lead-in) vs continued oral ART for 48 weeks.
- ❖ **ENROLLING: ONE MONTH OF LATENT TB TREATMENT WITH INH/RIFAPENTINE FOR HIV+ INDIVIDUALS TAKING DOLUTEGRAVIR (A5372)** This is a drug interaction study which will evaluate the pharmacokinetics of dolutegravir during one month of LTBI treatment with INH/Rifapentine. An additional 50 mg dose will be given daily in the first phase of the study.

Participants will have two separate days (day 0 and day 28) with intensive PK evaluations, conducted in a clinical research center

- ❖ **COMING SOON: CMV TREATMENT WITH ORAL LETERMOVIR IN PEOPLE WITH HIV AND ASYMPTOMATIC CMV (ACTG 5383)** Phase 2 randomized open label placebo controlled study of 48 weeks of letermovir, an oral antiviral active against CMV, in people living with HIV. The goal of the study is to look at the impact of CMV treatment on inflammation and detectable CMV. Inclusion criteria include age  $\geq 40$ , HIV suppressed on ART, and CMV IgG (+) – serology can be tested as part of the study if not known.
- ❖ **COMING SOON: CMV VACCINATION FOR PEOPLE LIVING WITH HIV AND CMV AB (+) (ACTG 5355)** Phase 2, double blind, placebo controlled study evaluating a novel CMV Vaccine (Modified Vaccinia Ankara) for people with HIV and CMV antibody (+) without active CMV disease. CMV Ab status can be evaluated during screening if status is unknown. The goal of the study is to understand the safety, immune response and impact on inflammation. Inclusion criteria include current CD4 > 250, nadir  $\geq 100$ , and HIV virologically suppressed on ART.

#### **STUDIES FOR PREVENTION OF SEXUALLY TRANSMITTED DISEASES**

- ❖ **ENROLLING DoxyPEP:** Phase IV study of doxycycline taken as a single 200 mg dose within 24-72 hours after condomless sexual contact. Eligible individuals must be a man who has sex with men or a transgender woman, living with HIV or taking/starting HIV PrEP, with a history of gonorrhea, chlamydia or syphilis in the past year. Participants will be randomized 2:1 to receive open label doxycycline or continued standard of care for 12 months of follow-up. Contact 415-939-4543 (Living with HIV, enrolled at ZSFG) or 415-855-0402 (PrEP patients, enrolled at SF City clinic) Also see website: <https://depts.washington.edu/doxypepstudy/>

#### **STUDIES FOR COVID-19**

- ❖ **ENROLLING OUTPATIENT TREATMENT FOR RECENT COVID INFECTION (ACTIV-2)** : Phase 2/3 platform trial of treatments for outpatients with newly diagnosed COVID. Currently providing a single infusion of monoclonal antibodies vs. placebo for people with a diagnosis of COVID and symptom onset of less than 8 days. Includes multiple additional agents including oral therapy, inhaled interferon, IM monoclonal antibody, subQ monoclonal antibody, and bovine serum albumin. Safe transportation will be provided for patients during the isolation time period. More information available at [www.riseabovecovid.com](http://www.riseabovecovid.com) and call/text (415) 806-8554 (English/Spanish) or

#### **VIRAL HEPATITIS STUDIES:**

- ❖ **ENROLLING Acute HCV treatment with 4 weeks of glecaprevir/pibrentasvir (HIV (+) or HIV uninfected) (ACTG 5380):** Individuals with acute HCV will receive open label G/P x 4 weeks. Those who fail to attain an SVR12 will have the option to take study-provided retreatment. Acute HCV defined as
  - new ALT of  $\geq 5x$  ULN or  $>250U/L$  if prior normal ALT or  $\geq 10x$  ULN or  $>500 U/L$  if baseline ALT abnormal or not available, OR

- detectable HCV RNA with prior neg HCV Ab and undetectable HCV RNA in past 6 months (if no prior HCV infection)
- detectable HCV RNA with prior undetectable HCV RNA in past 6 months (if prior known HIV infection)
- 

❖ **ENROLLING** **HBV Vaccination for prior HBV vaccine non-responders who are living with HIV (ACTG 5379)**: Adults living with HIV who have prior HBV vaccination without protective HBV S Ab titers (>10 mIU/ml) will be randomized 1:1 to receive HBV vaccination with HEPLISAV-B or Energix-B, and response to vaccination will be evaluated. The arm for those who have never received HBV vaccination has now been closed

❖ **COMING SOON: Several studies evaluating HBV cure strategies in HBV mono-infected individuals on suppressive NRTI therapy.** More information forthcoming