Here are open studies that may be of interest, including a newly open HIV study for patients with **weight gain on integrase inhibitors**, ongoing doxycycline **postexposure prophylaxis study to reduce STI's in men who have sex with men** and studies of **CMV vaccination as well as CMV oral therapy in HIV**.

Our **outpatient COVID treatment study** is now OPEN again for those **at higher risk of progression** to severe disease and provides an open label active comparator of the Regeneron monoclonal antibodies. Prior COVID vaccination is not exclusionary. More information below. 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 Berrner at 415 476 4082 ext 556 or daniel.berrner@ucsf.edu
- For COVID outpatient studies, please email CovidResearchSFGH@ucsf.edu or (415) 806-8554

Please email Dan or me if you would like to be taken off this list.

Thanks, Annie
415 476 4082 ext 130
Annie.luetkemeyer@ucsf.edu

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 ≥ 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.

- ***NOW OPEN***- **SWITCH STUDY: MONTHLY CABOTEGRAVIR INJECTION PLUS IV bNAbs FOR PEOPLE WITH WELL CONTROLLED HIV (A5357)** Single arm, Phase II open-label switch study to assess the safety and effectiveness of monthly IM Cabotegravir combined with every 8 weeks IV bNAbs (VRC07-523LS) given for up to 48 weeks. Eligibility includes stability on 3 drug ART regimen with VL < 50 for at least 2 years (one blip permitted), CD4 >350, no history of prior virologic failure, and no active HBV infection. Participants will be tested for susceptibility to the bNAbs during screening

- **ENROLLING - 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 bNAb 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 ≥ 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 ≥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 enrolling patients diagnosed with COVID within 10 days and symptom onset of less than 7 days who are at HIGHER risk for disease progression. Those at higher risk include:
  1) not fully vaccinated with one or more risk factors including age >65, or HTN, CAD, COPD, BMI >35, diabetes, ongoing immunosuppression, HIV with CD4 < 200 *or*
  2) Fully vaccinated with one of the following: chemotherapy, hematologic malignancy, untreated HIV with CD4<200, combined 1o immunodeficiency, on immunosuppressants (including prednisone 20 gm/day for > 14d, mycophenolate, rituximab)
  Participants will randomized to open label investigational IV polyclonal antibody (SAB) vs an active comparator of IV REGN monoclonal antibody infusion. Safe transportation will be provided for patients during the infectious time period. More information available at www.riseabovecovid.com and call/text (415) 806-8554 (English/Spanish).

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 ≥ 5x ULN or >250U/L if prior normal ALT or ≥ 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)
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- **ENROLLING HBV Vaccination for prior HBV vaccine non-responders who are living with HIV (ACTG 5379):** Adults living with HIV who have had 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