Results. 32% of patients with SUD is substantial. This enhanced coordination allows for potential cost savings to health systems.

Disclosures. Amber C. Streifel, PharmD, BCPS, Melinta (Advisor or Review Panel member) Monica K. Sikka, MD, FG2 (Scientific Research Study Investigator)

Table 3. Treatment Course Endpoints

| Endpoint | n (%)
|----------|---------|
| Lost to follow-up | 5 (19)
| 30-day readmission for any reason | 7 (13)
| 90-day readmission for any reason | 10 (19)
| Readmission due to infection recurrence or dolutabavuic adverse effects | 4 (8)
| Adverse reaction | 1 (2)

Conclusion. The OPAT-RN time required to coordinate outpatient DAL for patients with SUD is substantial. This enhanced coordination allows for potential cost savings to health systems.

Disclosures. Amber C. Streifel, PharmD, BCPS, Melinta (Advisor or Review Panel member) Monica K. Sikka, MD, FG2 (Scientific Research Study Investigator)

626. The Efficacy and Safety of Maintenance with Doravirine Plus Two NRTIs after Initial Suppression in Adults with HIV-1 in the DRIVE-FORWARD Clinical Trial: Results from the Study Extension through 192 Weeks
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Session: P-28. Clinical Trials

Background. DRIVE-FORWARD is a phase 3 trial with a completed double-blind period comparing doravirine (DOR) 100 mg with ritonavir-boosted darunavir (DRV/r) 800/100 mg, both administered with two nucleos(t)ide reverse transcriptase inhibitors (NRTIs; tenofovir and emtricitabine, or abacavir and lamivudine) and an ongoing open-label extension. At Week (W) 48, DOR demonstrated non inferior efficacy to DRV/r, with a superior lipid profile. Those results were sustained at W96. Here we present efficacy and safety results through W192.

Methods. Participants who completed the 96-week double-blind phase and met inclusion criteria were eligible to receive open-label DOR plus two NRTIs in a 96-week extension. Efficacy and safety at W192 were assessed in two groups: participants initially randomized to DOR and maintained on DOR (n=259) and those who switched from DRV/r (n=233).

Results. HIV-1 RNA < 50 copies/mL were maintained through W192 in 81.1% of participants who continued DOR and 80.7% of those who switched from DRV/r to DOR. The mean increase in CD4 T-cell counts from W96 to W192 was small (median 1.9 kg, Day 1 through W192); participants who switched to DOR had a small increase after W96 (median 1.5 kg), similar to the median weight gain in the base study (1.8 kg; DRV/r 0.7 kg).

Conclusion. Among participants who continued DOR in the DRIVE-FORWARD open-label extension, virologic suppression and favorable safety were maintained for an additional 96 weeks. Participants who switched from DRV/r to DOR maintained virologic suppression and demonstrated favorable safety for 96 weeks.

Table 1. DRIVE-FORWARD efficacy and safety outcomes at W192 in participants who entered extension (Weeks 96-192)

| Outcome | n (%) |
|---------|-------|
| Virologic suppression | 81.1 |
| Fasting LDL-cholesterol | 10.4 |
| Genotypic resistance to NRTIs | 1.0 |

Mean change (95% CI) Mean change (95% CI)

Conclusion. The OPAT-RN time required to coordinate outpatient DAL for patients with SUD is substantial. This enhanced coordination allows for potential cost savings to health systems.

Disclosures. Amber C. Streifel, PharmD, BCPS, Melinta (Advisor or Review Panel member) Monica K. Sikka, MD, FG2 (Scientific Research Study Investigator)

627. CURE ID as a Tool for Curating and Analyzing Drugs Used in COVID-19 Clinical Trials
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Session: P-28. Clinical Trials

Background. CURE ID is an internet-based data repository (https://cure.ncats.ofd.nih.gov/explore) developed collaboratively by FDA and NCATS/NIH. It is designed to capture real-world clinical outcome data to advance drug repurposing and to inform future clinical trials for infectious diseases with high unmet medical need. It also serves as a repository of clinical trials automatically pulled from https://clinicaltrials.gov into the CURE ID platform, where they were then manually curated, with the intention of keeping the infectious diseases community updated on the various clinical trials

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underway. The current study is a descriptive analysis of various therapeutics in clinical trials against COVID-19 on the CURE ID platform.

**Methods.** Using clinicaltrials.gov we selected those trials addressing therapeutics for COVID-19 and reviewed the drugs used, the current status of the trials, and the phases of development.

**Results.** As of 4 May 2021, we identified 2,154 clinical trials and 933 drugs from clinicaltrials.gov that met the inclusion criteria. Hydronychloroquine (n=251) was the most commonly investigated agent, followed by convalescent plasma (n=147), azithromycin (n=98), remdesivir (n=68), mesenchymal Stem Cells (n=63), tocilizumab (n=58), deferiprone (n=51), and favipiravir (n=41). At the time of our analysis, the majority (45%) of the clinical trials were in the recruiting phase, 12% were in the active phase, and 13% of the studies were completed. The majority (31%) of trials were in phase two, followed by phase three (21%) and phase one (10%). The vast majority of the agents were repurposed (92%), while only 8% of the agents were new molecular entities. Remdesivir was the only drug approved for marketing for treatment of certain patients with COVID-19 at the time of our analysis.

**Conclusion.** Several repurposed and novel drugs are being investigated to treat COVID-19 in clinical trials. CURE ID provides a broad view of the various drugs being researched and serves to keep the scientific community informed. Such a platform may help prevent duplication of efforts and help the scientific community with more coordinated research efforts and larger platform trials that can robustly answer scientific questions during a pandemic.

**Disclosures.** All Authors: No reported disclosures

628. Pharmacokinetics, Safety and Tolerability of Co-administration of Nacubactam and β-lactams after Multiple Doses in Japanese Healthy Subjects

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**Session:** P-28. Clinical Trials

**Background.** Increase of carbapenem-resistant Enterobacteriaceae (CRE) is a serious problem in the clinical setting and drugs which can treat patients with CRE are still limited. Nacubactam (OP0995) is a novel diazbicyclooctane-type β-lactamase inhibitor and being developed as a standalone drug to be co-administered with cefepime or aztreonam.

**Methods.** A randomized, double-blind multiple dose study of nacubactam in co-administration with cefepime (Cohort 1) or aztreonam (Cohort 2) in Japanese healthy subjects was performed to assess pharmacokinetics, safety, and tolerability of co-administrations of nacubactam and cefepime or aztreonam. In each cohort, 6 subjects received 3 g of nacubactam and 2 g of co-administrant drug (cefepime or aztreonam) and 2 subjects received placebo (saline) intravenously over 60 minutes, three times daily every 8 hours for 7 days. Plasma samples were collected and concentrations of each drug were analyzed by liquid chromatography-mass spectrometry (LC/MS/MS). Safety and tolerability assessments included treatment-emergent adverse events (TEAEs) and the evaluation of changes from baseline in safety laboratory test results, 12-lead electrocardiograms (ECGs), vital signs, and physical examinations.

**Results.** Profiles of Cmax,tmax,AUC0-τ,AUC0-∞ and t1/2 for nacubactam, cefepime and aztreonam are summarized in Table 1. Summary of Cmax,τ for nacubactam, cefepime and aztreonam are summarized in Table 2. Plasma concentrations of nacubactam, cefepime and aztreonam reached the steady-state by Day 4, and the mean accumulation ratios of Cmax, AUC0-∞ for nacubactam, cefepime and aztreonam on Day 7 to those of Day 1 were in the range 0.91 to 1.10. As for the safety, no serious adverse event was observed in this study. There was 1 TEAE (seborrhoeic dermatitis) leading to the discontinuation in 1 subject.

**Conclusion.** In conclusion, no remarkable change in pharmacokinetics was observed in each drug with multiple concomitant administration for 7 days and safety and tolerability of co-administrations of nacubactam and cefepime or aztreonam were confirmed. Based on these results, nacubactam is currently under further development.

**Disclosures.** All Authors: No reported disclosures

629. High Efficacy of Bictegravir/Emitructitabine/Tenofovir Alafenamide (B/F/TAF) in African American Adults Including Those with Preexisting Resistance, Viral Blips, and Suboptimal Adherence

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**Session:** P-28. Clinical Trials

**Background.** BRAVE-2020 demonstrated the efficacy of switching to bictegravir/emitritcitanb/tenofovir alafenamide (B/F/TAF) among African American adults with suppressed HIV through Week (W) 48 (Figure 1). We present resistance, viral blips, adherence, and virologic outcomes through W72.

Figure 1. BRAVE-2020 study design (phase 3, randomized, open-label, multicenter USA), active-controlled study) and virologic suppression at weeks 24 and 48.

**Results.** 489 participants received B/F/TAF and had ≥1 post-switch HIV-1 RNA measurement. Baseline genotypic data from cumulative historical and/or proof-of-concept trials were available for 96% (468/489) in protease/reverse transcriptase and 93% (453/489) in integrase. Preexisting NNRTI-R, PI-R, and certain INSTI-R (R185T/Y, L100I/V, Y181C/I, 243I, 248H/ F, 265G, 276L, 326L, and 327L) were observed. Preexisting drug resistance was assessed with historical genotypes and retrospective baseline proviral DNA genotyping. Adherence was calculated by pill count. Viral blips (transient HIV-1 RNA ≥50 copies/mL) and outcomes based on last available on-treatment HIV-1 RNA were assessed.

**Methods.** Enrollment criteria permitted NNRTI resistance (-R), PI-R, and certain INSTI-R (R185T/Y allowed). K562/F1N. ≥3 Hydroxymeth analog mutations [TAMs], or T69 insertion excluded) and excluded known primary INSTI-R. Preexisting drug resistance was assessed with historical genotypes and retrospective baseline proviral DNA genotyping. Adherence was calculated by pill count. Viral blips (transient HIV-1 RNA ≥50 copies/mL) and outcomes based on last available on-treatment HIV-1 RNA were assessed.

**Conclusion.** Virologic suppression was maintained through W72 of B/F/TAF treatment, including those with preexisting resistance, viral blips, and suboptimal adherence. Continued HIV suppression and absence of treatment-emergent resistance demonstrate the efficacy of B/F/TAF in African Americans regardless of adherence or preexisting resistance to NNRTIs, PIs, or non-tenofovir NRTIs.

**Disclosures.** Kristen Andreata, MSc, Gilead Sciences, Inc (Employee, Shareholder) Michelle L. D’Antoni, PhD, Gilead Sciences (Employee, Shareholder). Gilead Sciences, Inc. (Employee, Shareholder) Ayiapp Parvangan, MS Computational Biology, Gilead Sciences, Inc (Employee, Shareholder) Ross Martin, PhD, Gilead Sciences, Inc (Employee, Shareholder) Christiana Blair, MS, Gilead Sciences, Inc, (Employee, Shareholder) Sean E. Collins, MD, MS, Gilead Sciences, Inc (Employee, Shareholder) Kirsten L. White, PhD, Gilead Sciences, Inc (Employee, Shareholder)

630. Emergence of Colistin Resistance in the OVERCOME Trial: Impact of Combination Therapy with Meropenem

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**Conclusion.** Virologic suppression was maintained through Week 2 of B/F/TAF treatment, including those with preexisting resistance, viral blips, and suboptimal adherence. Continued HIV suppression and absence of treatment-emergent resistance demonstrate the efficacy of B/F/TAF in African Americans regardless of adherence or preexisting resistance to NNRTIs, PIs, or non-tenofovir NRTIs.

**Disclosures.** All Authors: No reported disclosures