congenital anomalies, including neural tube defects. These data support the current HIV treatment recommendations for the use of raltegravir 400 mg twice daily in women of reproductive potential and during pregnancy.

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

887. High Rates of Virologic Suppression Achieved in HIV-1–Infected Adults Rapidly Starting Antiretroviral Therapy (ART) with the Single-Tablet Regimen (STR) of Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (D/C/F/TAF) 800/150/200/10 mg Regardless of Baseline Disease Characteristics: Week 48 Subgroup Analyses from the Phase 3 DIAMOND Trial

Gregory D. Huhn, MD1; Moti Ramgopal, MD1; Gordon Crofoot, MD1; Joseph Galte, Jr, MD2; Sarah Seydikaem, PharmD2; Patricia Cosker, PharmD2; Richard Bruce Simonson, BS2; Donghan Loo, PhD3 and Keith Dunn, PharmD3; 1The Ruth M. Rothstein CORE Center, Chicago, Illinois; 2Midway Immunology and Research Center, Fort Pierce, Florida; 3Crofoot Research Center, Houston, Texas; 4Therapeutic Concepts, Houston, Texas; 5Janssen Scientific Affairs, LLC, Titusville, New Jersey; 6Janssen Research & Development, LLC, Titusville, New Jersey

**Session:** 96. HIV Viral Suppression or Bust

**Thursday, October 3, 2019: 4:15 PM**

**Background.** Rapid initiation of ART requires that clinicians start therapy prior to having baseline laboratory Results. High rates of virologic suppression and retention were reported in the DIAMOND trial. Efficacy and safety are presented, according to baseline disease characteristics.

**Methods.** DIAMOND (ClinicalTrials.gov: NCT03227861), a phase 3, single-arm, open-label, prospective, multicenter study, assessed efficacy/safety of D/C/F/TAF in rapid initiation. Adults enrolled within 14 days of diagnosis and started D/C/F/TAF without baseline laboratory results; investigators reviewed results as they became available. Primary endpoint was virologic suppression (HIV-1 RNA < 50 copies/mL; intent-to-treat (ITT); Food and Drug Administration (FDA) snapshot) at Week 48. Virologic suppression <50 c/mL and <200 c/mL were also assessed via an observed analysis, excluding patients with missing data.

**Results.** Overall, 109 patients were enrolled; 25% had HIV-1 RNA ≥100,000 c/mL and 21% had CD4+ < 200 cells/μL (Table 1). 21% of patients started therapy within 24 hours of diagnosis. At Week 48, 84% and 88% of patients had HIV-1 RNA <50 c/mL and <200 c/mL (FDA snapshot), respectively. In the observed analysis, 96% and 100% of patients had HIV-1 RNA <100,000 c/mL and CD4+ >200 cells/μL were associated with numerically higher virologic suppression rates (ITT-FDA snapshot; Table 2). No patient discontinued due to lack of efficacy or met protocol-defined virologic failure (PDVF) criteria. In the observed analysis, virologic suppression rates were consistent across all subgroups; all patients were suppressed <200 c/mL at Week 48. One patient discontinued due to an adverse event (AE); incidences of grade 3/4 (10%) and serious (9%) AEs were low, with no serious AEs related to study drug and no deaths.

**Conclusion.** In the first phase 3 study of an STR in a rapid initiation model, no patients rapidly starting D/C/F/TAF discontinued therapy due to lack of efficacy or had PDVF through 48 weeks. High rates of virologic suppression were achieved and maintained with a variety of baseline characteristics, and treatment was safe and well tolerated, indicating D/C/F/TAF as a preferred ART option for patients rapidly starting treatment.

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

888. Impact of Mandatory Infectious Diseases Consult on All-cause In-patient Mortality and 30-Day Readmission in Patients with Severe Sepsis

Cindy Hou, DO, MA, MBA, FACOI1; Todd P. Levin, DO, FACOI, FIDSA2; Nikunj M. Vyas, PharmD1; BCPS; Stefanie Deangelo, BSN, MLA, RN, CMSRN1; Jean Klepka, BSN, BA, RN, CMSRN1 and Dawne Pietrowsicz, MSN, RN1; Jefferson Health - New Jersey, Voorhees, New Jersey

**Session:** 96. HIV Viral Suppression or Bust

**Thursday, October 3, 2019: 4:15 PM**

**Background.** Rapid initiation of ART requires that clinicians start therapy prior to having baseline laboratory Results. High rates of virologic suppression and retention were reported in the DIAMOND trial. Efficacy and safety are presented, according to baseline disease characteristics.

**Methods.** DIAMOND (ClinicalTrials.gov: NCT03227861), a phase 3, single-arm, open-label, prospective, multicenter study, assessed efficacy/safety of D/C/F/TAF in rapid initiation. Adults enrolled within 14 days of diagnosis and started D/C/F/TAF without baseline laboratory results; investigators reviewed results as they became available. Primary endpoint was virologic suppression (HIV-1 RNA < 50 copies/mL; intent-to-treat (ITT); Food and Drug Administration (FDA) snapshot) at Week 48. Virologic suppression <50 c/mL and <200 c/mL were also assessed via an observed analysis, excluding patients with missing data.

**Results.** Overall, 109 patients were enrolled; 25% had HIV-1 RNA ≥100,000 c/mL and 21% had CD4+ < 200 cells/μL (Table 1). 21% of patients started therapy within 24 hours of diagnosis. At Week 48, 84% and 88% of patients had HIV-1 RNA <50 c/mL and <200 c/mL (FDA snapshot), respectively. In the observed analysis, 96% and 100% of patients had HIV-1 RNA <100,000 c/mL and CD4+ >200 cells/μL were associated with numerically higher virologic suppression rates (ITT-FDA snapshot; Table 2). No patient discontinued due to lack of efficacy or met protocol-defined virologic failure (PDVF) criteria. In the observed analysis, virologic suppression rates were consistent across all subgroups; all patients were suppressed <200 c/mL at Week 48. One patient discontinued due to an adverse event (AE); incidences of grade 3/4 (10%) and serious (9%) AEs were low, with no serious AEs related to study drug and no deaths.

**Conclusion.** In the first phase 3 study of an STR in a rapid initiation model, no patients rapidly starting D/C/F/TAF discontinued therapy due to lack of efficacy or had PDVF through 48 weeks. High rates of virologic suppression were achieved and maintained with a variety of baseline characteristics, and treatment was safe and well tolerated, indicating D/C/F/TAF as a preferred ART option for patients rapidly starting treatment.

**Disclosures.** All Authors: No reported Disclosures.
OFID 2019:6 (Suppl 2)