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75. High Rates of Virologic Suppression with DTG/3TC in Newly Diagnosed Adults with HIV-1 Infection and Baseline Viral Load >500,000 c/mL: 48-Week Subgroup Analysis of the STAT Study

Charlotte-Paige M. Rolle, MD MPH[1]; Mezgebe Berhe, MD[2]; Tulika Singh, MD MS AAHIVS[3]; Roberto Ortiz, MD[4]; Anson K. Wurapa, MD[5];
Moti Ramgopal, MD FIDSA[6]; Dushyantha Jayaweera, MD, mrcog(uk), face[7];
Peter Leone, MD[8]; Jessica Matthews, BS[8]; Michael Cupo, Ph.D.[9];
Mark Underwood, PhD[8]; Kostas Angelis, PhD[10]; Brian Wynne, MD[8];
Deanna Merrill, PharmD, MBA, AAHIVP[8]; Christopher T. Nguyen, MD[8];
Jean A. van Wyk, MB,ChB[8]; Andrew Zolopa, MD[8]; [1]Orlando Immunology Center, Orlando, Florida; [2]North Texas Infectious Diseases Consultants, Dallas, TX; [3]University of California, Riverside, Palm Springs, CA; [4]Bliss Healthcare Services, Orlando, Florida; [5]Infectious Disease Specialists of Atlanta, Atlanta, GA; [6]Midway Specialty Care Centers, Fort Pierce, Florida; [7]University of Miami, Miami, Florida; [8]ViiV Healthcare, Chapel hill, North Carolina [9]GlaxoSmithKline, Collegeville, PA; [10]GSK, London, England, United Kingdom

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Background. The primary analysis of the STAT study demonstrated the feasibility, efficacy, and safety of using DTG/3TC as a first-line regimen in a test-and-treat setting through 24 weeks, with therapy adjustments for baseline resistance or hepatitis B virus (HBV) co-infection. Here we present secondary analyses through Week 48 of virologic outcomes in participants by baseline viral load (VL).

Methods. STAT is a single-arm study of treatment-naive adults with HIV-1 infection who initiated DTG/3TC ≤ 14 days after HIV-1 diagnosis without availability of screening/baseline laboratory results. If baseline testing indicated DTG or 3TC resistance, HBV co-infection, or creatinine clearance < 30 mL/min/1.73 m^2, then antiretroviral therapy (ART) was potentially adjusted and participants remained on study. Efficacy analyses included proportion of participants with HIV-1 RNA < 50 c/mL regardless of ART regimen at Week 48, among all participants (ITT-E missing = failure analysis) and among participants with available HIV-1 RNA data at Week 48 (observed analysis).

Results. Of 131 enrolled, DTG/3TC treatment was adjusted in 10 participants, and of those with available data (n=7), all (100%) achieved HIV-1 RNA < 50 c/mL at Week 48. At Week 48, 82% (107/131) of all participants (Figure 1) and 97% (107/110) of those with available data (Figure 2) achieved HIV-1 RNA < 50 c/mL. Of participants with baseline VL ≥ 500,000 c/mL, 89% (17/19) achieved HIV-1 RNA < 50 c/mL at Week 48; the remaining 2 withdrew from study. Of participants with baseline VL ≥ 1,000,000 c/mL, 90% (9/10) achieved HIV-1 RNA < 50 c/mL at Week 48 (Table); the remaining participant withdrew consent. Of the 17 participants with baseline VL ≥ 500,000 c/mL with available data through Week 48, 76% (13/17) achieved virologic suppression by Week 24. One participant with baseline VL ≥ 500,000 c/mL switched from DTG/3TC before the Week 48 assessment. Of the 9 participants with baseline VL

≥ 1,000,000 c/mL with available data through Week 48, most participants (8/9; 89%) were suppressed by Week 24.

Figure 1. Virologic outcomes at Week 48, overall and by baseline VL and CD4+ cell count: ITT-E missing = failure analysis.

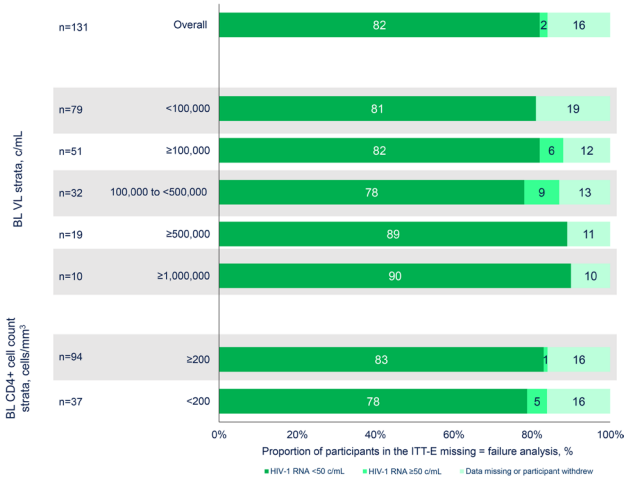

Figure 2. Virologic outcomes at Week 48, overall and by baseline VL and CD4+ cell count: observed analysis.

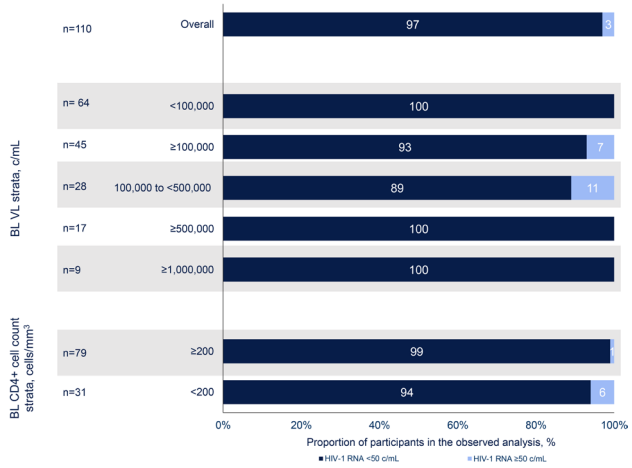

Table. Viral Load by Study Visit Among Participants with Baseline HIV-1 RNA ≥1,000,000 c/mL

		HIV-1 RNA (c/mL) by study visit							
Participant	Baseline CD4+ cell count	Baseline	Week 1	Week 4	Week 8	Week 12	Week 24	Week 36	Week 48
A	410	68,706,840	518,812	9781	NA	90,912	NA*	—	—
B	128	13,987,640	123,843	1682	297	493	191/ 157 / 302	124	63 / 48
C	613	5,794,931	98,499	96	<40	<40	<40	<40	<40
D	534	5,034,556	33,293	304	<40	<40	<40	NA	<40
E	464	2,592,169	1046	115	<40	<40†	<40	<40	<40
F	387	2,319,328	19,210	122	<40	52	<40	<40	<40
G	532	2,252,702	6241	136	48	42	<40	NA	<40
H	671	1,981,995	8373	245	<40	<40	<40	<40	<40
I	56	1,291,792	2618	222	147	71	<40	<40	<40
J	94	1,013,606	8646	725	242	185	<40	<40	<40

Values after / denote viral load at retesting. Green denotes virologic suppression on DTG/3TC; light green denotes virologic suppression on modified ART (see footnote).
NA, not available.
*Participant confirmed many missed doses before Week 12 and withdrew consent due to incarceration. †Participant switched to DRV/COBI/FTC/TAF on Day 92 (Week 12) due to AE (rash); participant switched again to BIC/FTC/TAF on Day 113 (Week 12) due to a different rash.

Conclusion. These data provide evidence for the efficacy and feasibility of using DTG/3TC as a first-line regimen in a test-and-treat setting, including among participants with very high baseline VL.

Disclosures. **Charlotte-Paige M. Rolle, MD MPH**, **Gilead Sciences** (Grant/Research Support, Scientific Research Study Investigator, Speaker's Bureau)**Janssen Infectious Disease** (Scientific Research Study Investigator, Advisor or Review Panel member)**ViiV Healthcare** (Grant/Research Support, Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau) **Tulika Singh, MD MS AAHIVS**, **Gilead** (Grant/Research Support, Advisor or Review Panel member)**ViiV** (Grant/Research Support, Advisor or Review Panel member, Speaker's Bureau) **Moti Ramgopal, MD FIDSA**, **Abbvie** (Scientific Research Study Investigator, Speaker's Bureau)**Gilead** (Consultant, Scientific Research Study Investigator, Speaker's Bureau)**Janssen** (Consultant, Scientific Research Study Investigator, Research Grant or Support, Speaker's Bureau)**Merck** (Consultant, Scientific Research Study Investigator)**ViiV** (Consultant, Scientific Research Study Investigator, Speaker's Bureau) **Dushyantha Jayaweera, MD, mrcog(uk), face**, **Gilead** (Research Grant or Support)**Janssen** (Research Grant or Support)**viiv** (Research Grant or Support) **Peter Leone, MD**, **viiv healthcare** (Employee) **Jessica Matthews, BS**, **ViiV Healthcare** (Employee) **Michael Cupo, Ph.D.**, **GlaxoSmithKline** (Employee) **Mark Underwood, PhD**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Kostas Angelis, PhD**, **GSK** (Employee, Shareholder) **Brian Wynne, MD**, **ViiV Healthcare** (Employee, Shareholder, I have shares in GSK, the part owner of ViiV) **Deanna Merrill, PharmD, MBA, AAHIVP**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Christopher T. Nguyen, MD**, **ViiV Healthcare** (Employee) **Jean A. van Wyk, MB,ChB**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Andrew Zolopa, MD**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee)

76. Effects of the "Undetectable = Untransmittable" ("U=U") Educational Campaign on Treatment Outcomes and Perceptions among People Living with HIV in North American Countries

Frank Spinelli, MD[1]; Bruce Richman, JD[2]; Patricia De Los Rios, MSc[1];
Benjamin Young, MD, PhD[1]; Marvelous Muchenje, BSW, MSc. in Global Health[1];
Nicolas Van de Velde, PhD[1]; Chinyere Okoli, PharmD, MSc, DIP[1]; [1]ViiV Healthcare, Sag Harbor, NY; [2]Prevention Access Campaign, New York, New York

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Background. The educational campaign "Undetectable = Untransmittable" (U=U) began in 2016 to improve the well-being of people living with HIV (PLHIV) and recalibrate HIV-related social norms. As medical practice can vary by region, we examined reports from PLHIV in North American countries to identify if the campaign affected healthcare provider (HCP) communication of U=U and if positive health outcomes differed by U=U-informed status or country.

Methods. Data were collected from the 2019 Positive Perspectives survey of PLHIV in Canada (n=120), Mexico (n=63), and the United States (US; n=400) and stratified by country. Outcomes were self-rated mental and sexual health ("Good"/"Very good"), viral suppression, and sharing of HIV status. Treatment perceptions were also assessed.