SYMTUZA® (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide)
DIAMOND Study – Rapid Initiation

Study Overview[a]

DIAMOND

Phase 3, single-arm, open-label, multicenter, 48-week study

Evaluated the safety and efficacy of **D/C/F/TAF single-tablet regimen** in a **rapid initiation model** of care

Newly diagnosed, treatment-naïve, HIV-1–infected patients

N=109

Study Design[a,b]

Key Inclusion Criteria

- **Newly diagnosed** HIV-1 infection **≤2 weeks** from screening/baseline visit
- **ARV treatment-naive** except F/TDF for pre-exposure prophylaxis

Key Exclusion Criteria

- Certain known **opportunistic infections** or another AIDS-defining condition

D/C/F/TAF
800/150/200/10 mg QD

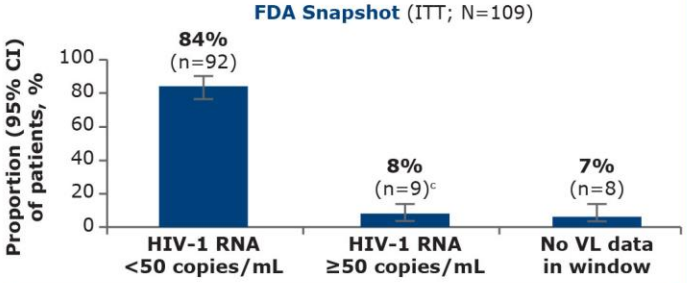
- **Day 1** Screening/baseline **Resistance testing**
- **Day 3** (+1 week) **Safety assessment** of baseline laboratory data
- **Week 4** (±1 week) **Review** baseline **resistance data**
- **Week 48** **Primary endpoint:** virologic response

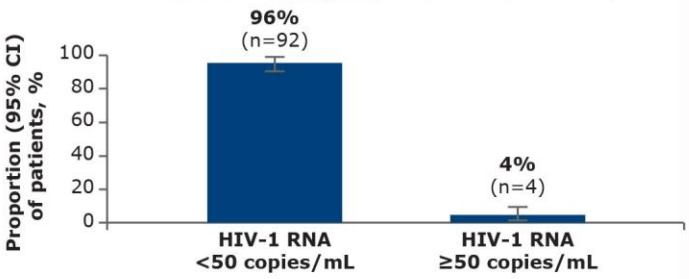
Patients received the **first dose** of D/C/F/TAF:

- **Within 24 hours** of screening/baseline visit
- **Before availability of results** from baseline safety and resistance laboratory tests

Efficacy

- The **primary endpoint** of **HIV-1 RNA <50 copies/mL** (FDA snapshot) **at week 48** was achieved by 84% of patients[a]





- Virologic response rates were similar across age, race/ethnicity, and HIV acquisition factor subgroups[d]
- No patients discontinued the study due to lack of efficacy or developed PDVF[a]

Safety and Tolerability[a]

- **Most AEs** were grade 1 or 2
- **Grade 1 and 2 treatment-related AEs** through week 48 were reported in 25% and 6% of patients, respectively
- **Grade 3 treatment-related AEs** through week 48 were reported in 2% of patients (n=2) and included:
  - Allergic dermatitis
  - Nausea (resolved with no changes to study treatment dosing)
- **One patient discontinued due to AEs** (grade 3 allergic dermatitis, grade 2 pyrexia, and grade 2 lip swelling; the AEs were considered study drug-related and all resolved after discontinuation of study treatment)
- **No serious or grade 4 treatment-related AEs** were observed
- Most common (≥2% of patients) **grade ≥2 ADRs** through week 48:
  - Diarrhea (2%)
  - Nausea (2%)
  - Rash (4%)
- **Grade 3 and 4 laboratory abnormalities** (≥2% of patients):
  - Increased AST (5%)
  - Increased ALT (3%)
  - Increased bilirubin (3%)

Header sections within the image contain hyperlinks to related sections within the document.

Abbreviations: AE, adverse event; ADR, adverse drug reaction; AIDS, acquired immunodeficiency syndrome; ALT, alanine aminotransferase; ARV, antiretroviral; AST, aspartate aminotransferase; CI, confidence interval; D/C/F/TAF, darunavir/cobicistat/emtricitabine/tenofovir alafenamide; FDA, Food and Drug Administration; F/TDF, emtricitabine/tenofovir disoproxil fumarate; HIV-1, human immunodeficiency virus type 1; ITT, intention-to-treat; PDVF, protocol-defined virologic failure; QD, once daily; RNA, ribonucleic acid; VL, viral load.

[a]Huhn (2019). [b]Huhn (2019) suppl. [c]Three patients discontinued due to protocol-defined safety stopping rules. [d]Anderson (2019).

SUMMARY

- Major human immunodeficiency virus (HIV) treatment guidelines committees have endorsed rapid or same-day antiretroviral therapy (ART) initiation to increase the proportion of patients who achieve and maintain viral suppression, decrease risk of transmission to their sexual partners, and increase engagement in care.[2–4]
- The DIAMOND study was a phase 3, single-arm, open-label, multicenter study to evaluate the safety and efficacy of SYMTUZA in newly diagnosed, HIV-1 infected, treatment-naïve patients in a rapid initiation model of care over 48 weeks.[1]
    - At week 48, in the intention-to-treat (ITT) population, 92 of 109 (84%) patients achieved viral load (VL) <50 copies/mL (FDA snapshot).
    - At week 48, using an observed analysis (missing=excluded), 92 of 96 (96%) patients achieved VL <50 copies/mL; the remaining 4 patients all had VL <200 copies/mL.

BACKGROUND

- Major HIV treatment guidelines committees have endorsed rapid or same-day ART initiation to increase the proportion of patients who achieve and maintain viral suppression, decrease risk of transmission to their sexual partners, and increase engagement in care.[2–4]
- The World Health Organization (WHO) strongly recommends that rapid ART initiation (defined as within 7 days of diagnosis) should be offered to all people living with HIV (PLWHIV) following a confirmed HIV diagnosis and clinical assessment, and ART initiation should be offered on the same day to people who are ready to start.[2]
- The IAS-USA Treatment Guidelines recommend ART initiation within 7 days of diagnosis, including on the day of diagnosis or first clinic visit, if the patient is ready and there is no evidence of an opportunistic infection that might affect the timing of treatment initiation.[3]
- The Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents recommends initiating ART immediately (or as soon as possible) after HIV diagnosis in order to increase the uptake of ART and linkage to care, decrease the time to viral suppression for individual patients, and improve the rate of virologic suppression among persons with HIV. Rapid ART initiation also has the potential to reduce the time during which people with newly diagnosed HIV can transmit HIV. Use of a rapid ART initiation strategy is supported by randomized controlled trials that were performed in resource-limited settings outside of the United States and observational trials in the United States that included both immediate initiation of ART (on the day of diagnosis) and rapid ART initiation (within days or weeks of diagnosis). The results from some of these studies are discussed further within the guidelines.[4]

CLINICAL DATA

DIAMOND STUDY

The DIAMOND study was a phase 3, single-arm, open-label, multicenter study to evaluate the safety and efficacy of SYMTUZA in newly diagnosed, HIV-1 infected, treatment-naïve patients in a rapid initiation model of care over 48 weeks (N=109).[1]

Study Design/Methods

- Eligible patients were enrolled and started on a single-tablet regimen (STR) consisting of SYMTUZA (darunavir [DRV] 800 mg, cobicistat [COBI] 150 mg, emtricitabine [FTC] 200 mg, and tenofovir alafenamide [TAF] 10 mg) orally once daily within 24 hours of the screening/baseline visit and before results of the baseline safety and resistance laboratory tests were available.
- All patients were from the United States.
- Key inclusion criteria:

    - Newly diagnosed with HIV-1 within 2 weeks of the screening/baseline visit
    - Antiretroviral (ARV) treatment-naïve, except for the use of TDF/FTC for pre-exposure prophylaxis
- Key exclusion criteria:
    - Certain known opportunistic infections or another acquired immunodeficiency syndrome (AIDS)-defining condition that in the investigator's judgment would increase the risk of morbidity/mortality
    - Certain clinically relevant renal and hepatic conditions
- Investigators reviewed screening/baseline laboratory findings as results became available; patients not meeting pre-defined safety or resistance stopping rules continued treatment.
    - Screening/baseline safety laboratory findings were evaluated on day 3 (±1 week), with the following stopping criteria (retesting of abnormal screening/baseline safety laboratory values was allowed once):
        - Estimated glomerular filtration rate (eGFR) <50 mL/min
        - Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) ≥2.5 times the upper limit of normal (ULN)
        - Serum lipase ≥1.5 times the ULN
        - Positive pregnancy test for women of childbearing potential
        - Laboratory results that the investigator believed should result in discontinuation of study medication
        - Active hepatitis C infection that requires immediate treatment or is expected to require treatment during the study with agents not compatible with SYMTUZA
    - Resistance was evaluated at week 4 (± 7 days) based on predicted genotypic sensitivity. Patients who did not show full sensitivity to all drugs were to be discontinued (with the exception of M184I/V).
- **Primary endpoint:** VL <50 copies/mL (FDA snapshot) at week 48
- Other endpoints:
    - VL <50 or <200 copies/mL (using an observed algorithm)
    - Absolute CD4+ cell count at screening/baseline and week 48
    - Discontinuations due to protocol-defined safety stopping rules, adverse events (AEs), adverse drug reactions (ADRs), and laboratory abnormalities
    - HIV Treatment Satisfaction Questionnaire status version (HIVTSQs) results at weeks 4, 24, and 48
    - Treatment adherence[5]
- Resistance testing was performed at screening/baseline.
- Post-baseline samples were eligible for resistance testing in patients with VL values ≥400 copies/mL and protocol-defined virologic failure (PDVF), defined as one of the following:
    - Virologic nonresponse: VL <1 $\log_{10}$ reduction from baseline and ≥400 copies/mL at the week 12 visit (confirmed within 2-4 weeks)
    - Virologic rebound: at any visit, after achieving confirmed consecutive VL <50 copies/mL, a rebound to ≥50 copies/mL (confirmed within 2-4 weeks) or, at any visit, a >1 $\log_{10}$ increase in VL from nadir (confirmed within 2-4 weeks)
- Subgroup analyses conducted included age, race, ethnicity, acute (HIV-1 antibody negative and VL positive/p24 positive) or early infection (HIV-1 antibody positive and suspected infection ≤6 months before screening), HIV acquisition factor, time from diagnosis to enrollment, baseline viral load (VL), and baseline CD4+ count.[1,6–9]

Results

Baseline Characteristics

- There were 109 patients enrolled in the study.[1]

- Baseline characteristics are provided below (see Table: Baseline Characteristics). Overall, 25% had VL ≥ 100,000 copies/mL and 21% had CD4+ <200 cells/uL.
- Among patients with genotypic data at screening/baseline, all patients had full genotypic susceptibility to darunavir and tenofovir. Two patients had emtricitabine RAMs (M184I/V) (see Table: HIV-1 Genotype at Screening/Baseline).
- Overall, 97 (89%) patients completed the study. By week 48, 12 (11%) patients had discontinued (4 lost to follow-up, 3 due to protocol-defined safety stopping rules, 2 for other reasons [patient incarceration and switch to another ARV due to SYMTUZA food requirements], 1 withdrawal of consent, 1 protocol violation, 1 due to AEs).
- Among the 12 patients who prematurely discontinued, 10 enrolled >48 hours after diagnosis.[7]
- No patients discontinued due to resistance stopping rules.
- 5 patients met safety stopping rules criteria; all had confirmed elevations in AST or ALT ≥2.5 times the ULN identified at the screening/baseline visit (ie, prior to SYMTUZA administration).
    - 3 of these patients discontinued according to the protocol and 2 remained in the study based on clinical assessment by the investigator and agreement of the sponsor.
    - Transaminases normalized after screening/baseline in all 5 patients.

Baseline Characteristics[1]

	SYMTUZA N=109
Median age (range), years	28 (19-66)
Male, n (%)	95 (87)
Race, n (%)	
White	65 (60)
Black/African American	35 (32)
Other	9 (8)
VL, n	108[a]
Median (range), copies/mL	38,700 (19[b]-144,000,000)
≥100,000 copies/mL, n (%)	27 (25)
CD4+ cell count, n	108[a]
Median (range), cells/µL	369 (7-1082)
<200 cells/µL, n (%)	23 (21)
Median (range) time from diagnosis to screening/baseline, days	5 (0-14)
Enrolled within 48 hours of diagnosis, n (%)	34 (31)
Duration of infection, n	108[b]
Acute infection, n (%)[c]	13 (12)
Early infection, n (%)[d]	43 (40)
Chronic infection, n (%)[e]	34 (32)
Unknown, n (%)	18 (17)

Abbreviations: HIV-1, human immunodeficiency virus type 1; VL, viral load.
[a]One patient had missing values due to a shipping error of the screening/baseline samples.
[b]One patient was HIV-1 negative (false positive fourth generation test).
[c]Acute infection was defined as HIV-1 antibody negative and VL positive/p24 positive.
[d]Early infection was defined as HIV-1 antibody positive and suspected infection ≤6 months prior to screening/baseline.
[e]Chronic infection was defined as HIV-1 antibody positive and suspected infection >6 months prior to screening/baseline.

HIV-1 Genotype at Screening/Baseline[1]

	SYMTUZA N=102[a]
Genotypic susceptibility, n (%)	
Darunavir	102 (100)
Emtricitabine	100 (98)
Tenofovir	102 (100)

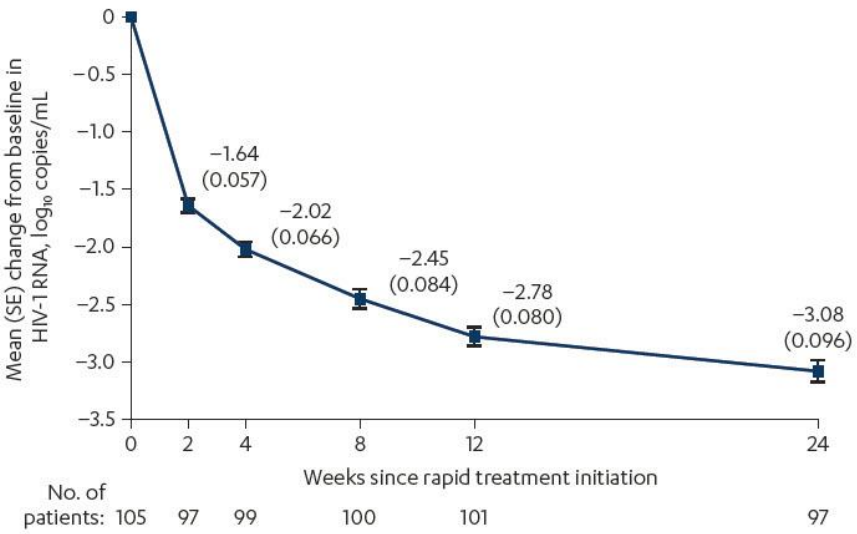
All PIs	97 (95)
All NRTIs	98 (96)
All NNRTIs	80 (78)
All INIs	97 (95)
≥1 RAM, n (%)	
Primary PI	5 (5)
Secondary PI	100 (98)
Darunavir	0
Emtricitabine	2 (2)
M184M/I	1 (<1)
M184M/V	1 (<1)
Tenofovir	0
NNRTI[b]	28 (28)
K103N	11 (11)
Primary INI	0
Secondary INI	5 (5)
T97T/A	3 (3)
T97A	2 (2)

Abbreviations: HIV-1, human immunodeficiency virus type 1; INI, integrase inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; RAM, resistance-associated mutation; VL, viral load.
[a]Genotypes were not available for 7 patients due to being unable to amplify (ie, low VL, reduced viral fitness, compromised sample collection/handling, primer incompatibility).
[b]Individual NNRTI RAMs are only shown for those occurring in ≥10% of patients.

Efficacy

- Mean (standard error [SE]) VL decreased from baseline to week 24 by 3.08 (0.096) log_{10} copies/mL (n=97) (see Figure: Change from Baseline in Log_{10} HIV-1 RNA Over Time [Observed]).[10]

Change from Baseline in Log_{10} HIV-1 RNA Over Time (Observed)[10]



- At week 48, in the ITT population, 92 of 109 (84%) patients achieved VL <50 copies/mL (FDA snapshot).[1]
  - 9 patients (8%) had VL ≥50 copies/mL.
  - 8 patients (7%) had no VL data.
  - Virologic response rates were similar across age, race, ethnicity, and HIV acquisition factor subgroups.[1,6]

- At week 48, using an observed analysis (missing=excluded), 92 of 96 (96%; 95% confidence interval [CI]: 90-98) patients achieved VL <50 copies/mL; the remaining 4 patients all had VL <200 copies/mL.
    - VL <200 copies/mL was achieved by 85 of 102 (83%) patients at week 12, 96 of 98 (98%) patients at week 24, and 100 of 100 (100%) patients at week 36.
    - Virologic response rates were similar across age, race, ethnicity, and HIV acquisition factor subgroups.[1,6]

Virologic Response (VL <50 copies/mL) at week 48 by subgroups[1,8]

Population	FDA Snapshot-ITT (N=109)	Observed Analysis (N=96)
	VL <50 copies/mL, n/N (%)	
Overall	92/109 (84)	92/96 (96)
Acute Infection	10/13 (77)	10/11 (91)
Early Infection	37/43 (86)	37/38 (97)
Time from diagnosis to enrollment, days[a]		
0-1	21/23 (91)	21/22 (96)
1-2	10/11 (91)	10/10 (100)
2-3	3/4 (75)	3/3 (100)
3-7	32/38 (84)	32/34 (94)
7-14	26/33 (79)	26/27 (96)
Baseline VL, copies/mL[a,b]		
≥100,000	19/27 (70)	19/22 (86)
<100,000	72/81 (89)	72/73 (99)
Baseline CD4+ cell count, cells/μL[a,b]		
≤200	17/23 (74)	17/19 (90)
>200	74/85 (87)	74/76 (97)
Age, years		
18-25	32/38 (84)	32/32 (100)
26-50	50/58 (86)	50/52 (96)
>50	10/13 (77)	10/12 (83)
Gender		
Women	9/14 (64)[c]	9/10 (90)
Men	83/95 (87)	83/86 (97)
Race/ethnicity		
White	55/65 (85)	55/58 (95)
Black/African American	29/35 (83)	29/30 (97)
Other	8/9 (89)	8/8 (100)
Hispanic	42/48 (88)	42/44 (95)
Non-Hispanic	50/61 (82)	50/52 (96)

Abbreviations: FDA, Food and Drug Administration; ITT, intention-to-treat; VL, viral load.
[a]Differences in virologic response rates (FDA snapshot-ITT) across subgroups were largely driven by early study discontinuation.
[b]One participant had missing values due to a shipping error of the screening/baseline samples.
[c]Among the 5 women who did not achieve VL <50 copies/mL at Week 48, 1 had VL=77 copies/mL at Week 48, 1 had VL ≥50 copies/mL at early discontinuation, and 3 did not have data in the window.

- Both patients with baseline emtricitabine resistance due to M184I/V mutations had VL <50 copies/mL at week 4.
- No patients discontinued the study due to lack of efficacy or developed PDVF.
- The mean (SE) CD4+ cell count was 413 (24) cells/μL at screening/baseline and 628 (30) cells/μL at week 48.

Resistance

- Since no patient had PDVF, no patients were eligible for post-baseline resistance testing.

Safety

- Most AEs were grade 1 or 2 and there were no deaths (Table: Summary of AEs Through 48 Weeks).
- Among the most common ADRs, most were grade 1 (Table: Most Common ADRs [≥2% of Patients] Through 48 Weeks).
- No serious AEs or grade 4 AEs were related to SYMTUZA.
    - Rates of study drug-related AEs were lower in the black/AA subgroup vs. non-black/AA subgroup (17% vs 41%, respectively); however, sample sizes were notably small (n=35 vs. n=74, respectively).[9]
    - Rates of study drug-related AEs by baseline VL were higher in the ≥100,000 copies/mL subgroup compared to <100,000 copies/mL subgroup (n=11/27, 41% vs. n=24/81, 30%, respectively).[7]
    - Rates of study drug-related AEs by baseline CD4+ cell count were higher in the ≥200 cells/uL subgroup compared to the <200 cells/uL subgroup (n=33/85, 39% vs. n=3/23, 13%, respectively).[7]
    - Patients who were >50 years of age, women, and non-MSM had numerically lower rates of related AEs versus other subgroups.[6]
        - Age: 18-25y (n=14/38, 37%) vs. 26-50y (n=20/58, 34%) vs. >50y (n=2/13, 15%)
        - Gender: Men (n=34/95, 36%) vs. Women (n=2/14, 14%)
        - HIV acquisition factor: MSM (n=31/82, 38%) vs. Non-MSM (n=5/27, 19%)
- There were no cases of immune reconstitution inflammatory events and no discontinuations due to central nervous system, gastrointestinal, renal, or bone AEs.
- One patient discontinued due to AEs (grade 3 allergic dermatitis, grade 2 pyrexia, and grade 2 lip swelling; the AEs were considered study drug-related and all resolved after discontinuation of study treatment).
- Grade 3 and 4 laboratory abnormalities which occurred in ≥2% of patients included increased AST in 5 (5%) patients, increased ALT in 3 (3%) patients, and increased bilirubin in 3 (3%) patients.

Summary of AEs Through 48 Weeks[1]

AE, n (%)	SYMTUZA N=109	
	Overall	Related
AE	92 (84)	36 (33)
Serious AE	10 (9)	0
Grade 1 AE	30 (28)	27 (25)
Grade 2 AE	48 (44)	7 (6)
Grade 3 AE[a]	13 (12)	2 (2)
Grade 4 AE[b]	1 (<1)	0

Abbreviations: AE, adverse event.
[a]Two grade 3 AEs were considered related to study drug: allergic dermatitis (resolved after discontinuation of study treatment) and nausea (resolved with no changes to study drug dosing).
[b]Abdominal injury (grade 4, not related) secondary to motor vehicle accident (grade 3, not related).

Most Common ADRs (≥2% of Patients) Through 48 Weeks[1]

ADR, n (%)	SYMTUZA N=109	
	Any grade	≥Grade 2
Diarrhea	13 (12)	2 (2)
Nausea	13 (12)	2 (2)
Rash[a,b]	5 (5)	4 (4)
Vomiting	4 (4)	0
Fatigue	3 (3)	0

Abbreviations: ADR, adverse drug reaction.
[a]Pooled preferred terms of allergic dermatitis, dermatitis, rash, macular rash, maculo-papular rash, papular

rash, and pruritic rash.
[b]All rash AEs were grade 1 or 2, except for 1 that was grade 3.

Patient-Reported Outcomes - HIVTSQs

- Total treatment satisfaction scores were high and consistent at all time points during the study.[1]
- Mean total treatment satisfaction scores (range: 0-60):
  - Week 4 (n=103): 56.5
  - Week 24 (n=100): 57.9
  - Week 48 (n=96): 57.9
- At week 48, a majority of patients reported they were satisfied (score of 5 or 6) with their treatment (97%), satisfied (score of 5 or 6) with any side effects of their present treatment (88%), and that they would recommend (score of 5 or 6) their present treatment to someone else with HIV (98%). Patient responses to select HIVTSQs questions at week 48 (n=96):
  - Question 1 – How satisfied are you with your current treatment? (6=very satisfied and 0=very dissatisfied)
    - 6: 88.5%
    - 5: 8.3%
    - 3: 2.1%
    - 1: 1.0%
  - Question 3 – How satisfied are you with any side effect of your present treatment? (6=very satisfied and 0=very dissatisfied)
    - 6: 74.0%
    - 5: 13.5%
    - 4: 9.4%
    - 3: 2.1%
    - 2: 1.0%
  - Question 9 – Would you recommend your present treatment to someone else with HIV? (6=yes, I would definitely recommend the treatment and 0=no, I would definitely not recommend the treatment)
    - 6: 92.7%
    - 5: 5.2%
    - 4: 1.0%
    - 3: 1.0%

Treatment Adherence[5]

- Cumulative treatment adherence was defined based on pill count and evaluated at weeks 4, 8, 12, 24, 36, and 48.
  - Adherence was calculated by visit from baseline to week 48 and cumulatively through week 48 as the following: (actual amount taken/amount to be taken) x 100%.
  - Treatment adherence (by pill count) was analyzed descriptively and defined as the following:
    - Adherent (level of adherence >95%)
    - Suboptimally adherent (level of adherence ≤95%)
  - Adherence was also evaluated by patient self-report using a 4-day recall period.
- Predictors of suboptimal adherence were assessed according to intrinsic versus extrinsic factors.
  - Predictors included: baseline body mass index, Centers for Disease Control disease classification, current alcohol use, current drug use, current nicotine use, education,

employment, ethnicity, gender, has insurance, housing situation, marital status, race, social support, and time from diagnosis to start of the study.

- Mean adherence through week 48 overall (as measured by pill count) was 95% (median: 99%).
- Adherence rates for patients with acute or early infection were similar to those in the overall population (mean: 95%).
- The proportions of patients who met specific adherence thresholds at each time point during the study are shown in Table: Adherence Over Time According to Pill Count.

Adherence Over Time According to Pill Count[5]

Adherence, n (%)	Week 4 (n=109)	Week 8 (n=97)	Week 12 (n=97)	Week 24 (n=98)	Week 36 (n=99)	Week 48 (n=96)
>95	91 (83)	82 (85)	77 (79)	75 (77)	75 (76)	63 (66)
>80% to ≤95%	13 (12)	12 (12)	17 (18)	16 (16)	17 (17)	25 (26)
>65% to ≤80%	1 (1)	3 (3)	1 (1)	4 (4)	2 (2)	4 (4)
>50% to ≤65%	0	0	0	2 (2)	3 (3)	3 (3)
≤50%	4 (4)	0	2 (2)	1 (1)	2 (2)	1 (1)

- SYMTUZA virologic response (VL <50 copies/mL) at week 48 by cumulative adherence subgroup was as follows:
  - FDA snapshot (ITT):
    - ≤95% adherence subgroup: 81% (30/37)
    - >95% adherence subgroup: 86% (62/72)
  - Observed analysis:
    - ≤95% adherence subgroup: 100% (30/30)
    - >95% adherence subgroup: 94% (62/66)
- In a univariate analysis of intrinsic and extrinsic factors associated with suboptimal adherence, only current drug use, current nicotine use, and being of female gender were significantly associated with suboptimal adherence.
- In a separate multivariate analysis, only current nicotine use remained as a significant predictor of suboptimal adherence.

LITERATURE SEARCH

A literature search of MEDLINE®, EMBASE®, BIOSIS Previews®, and DERWENT® (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 12 September 2023.

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