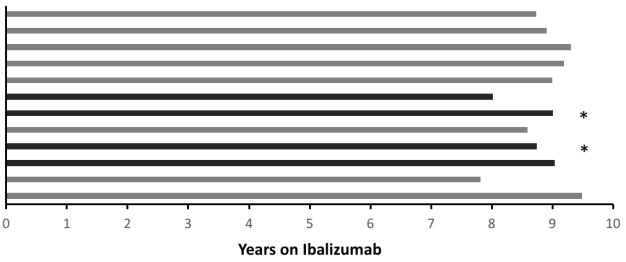
average of 8.9 years (range 8-9.5), during which 8/12 did not require addition of new ARVs to their OBR to maintain suppression.

Figure 1: duration of ibalizumab-based regimen is displayed for the 12 patients. Grey bars represent patients with no addition of new ARVs to OBR. Black bars represent patients with an addition to OBR. Asterisks represent addition of ritonavir only.



Conclusion. Data from 12 patients who received IBA for an average of 9 years validate the long-term efficacy and safety of IBA in TE patients. Importantly, for most patients, the durability of virologic response was maintained with minimal adjustments to the OBR. Altogether, these data demonstrate the contribution of IBA towards durable viral suppression in TE HIV patients with limited therapeutic options.

Disclosures. **William Towner, MD**, **Dynavax** (Research Grant or Support)**Gilead** (Grant/Research Support)**Merck** (Research Grant or Support)**Tai Med** (Research Grant or Support)**ViiV** (Research Grant or Support) **Edwin DeJesus, MD**, **Gilead Sciences** (Advisor or Review Panel member) **Colleen McGary, PhD**, **Theratechnologies** (Employee) **Mohammed Zogheib, PharmD, MPH**, **Theratechnologies** (Employee) **Steven Weinheimer, PhD**, **TaiMed Biologics USA** (Employee) **Pedro Mesquita, PhD**, **Theratechnologies, Inc.** (Employee)

1028. Long-term Follow-up After a Switch to Bictegravir, Emtracitabine, Tenofovir Alafenamide from Dolutegravir, Abacavir, Lamivudine

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Session: P-47. HIV: Treatment

Background. Bictegravir, emtricitabine and tenofovir alafenamide (B/F/TAF) is a guidelines-recommended single-tablet regimen (STR) for people living with HIV-1 (PLWH). Week (W) 48 primary endpoint results of this phase 3 study switching to B/F/TAF from dolutegravir (DTG), abacavir (ABC) and lamivudine (3TC) established the safety and efficacy of B/F/TAF. Here we report outcomes from an open-label (OL) extension of B/F/TAF.

Methods. Adults virologically suppressed on DTG, ABC, and 3TC were randomized 1:1 to switch to B/F/TAF once daily or continue their current regimen as a STR in a double blind (DB) manner. Unblinding occurred after the W48 primary endpoint, then participants received B/F/TAF in an OL extension while transitioning off the study. All participants who received B/F/TAF in the DB or OL phases are included in analyses. Efficacy was assessed as the proportion with HIV-1 RNA < 50 copies/mL at each study visit using missing=excluded (M=E) analysis, efficacy in in subgroups with pre-existing resistance was assessed using last observation carried forward. Safety was assessed by adverse events (AEs) and laboratory results.

Results. 563 participants were randomized and treated (282 B/F/TAF, 281 ABC/DTG/3TC); 524 (93%) completed the DB phase and received OL B/F/TAF; a total of 547 participants received B/F/TAF in DB and/or OL phases: 11% women, 21% Black, median age 47 yrs (range 21, 71). The median duration of B/F/TAF was 96 weeks (IQR 49-119). HIV-1 RNA < 50 c/mL was maintained in 99-100% at all timepoints (M=E) through a maximum of 168 weeks, including high efficacy in those with archived resistance (Table 1). No participant developed resistance to B/F/TAF. Study drug-related AEs occurred in 7% on B/F/TAF; most were grade 1; the most common was headache (1.6%). 7 (1%) participants had an AE leading to premature study drug discontinuation, only 1, headache, occurred in the OL phase. Estimated GFR and lipids were mostly stable with slightly increased LDL at W96; weight changes are noted at W48 and W96. (Table 2).

Table 1.

Table 1. Preexisting Resistance and B/F/TAF Efficacy

% (n/n)	All B/F/TAF	HIV-1 RNA < 50 copies/mL at Last Study Visit[b]
≥1 HIV-1 RNA measurement post B/F/TAF switch	545	98% (535/545)
Baseline resistance data available[a]	96% (522/545)	98% (512/522)
No primary resistance (PR, RT, IN)	69% (361/522)	98% (353/361)
Any primary resistance (PR, RT, IN)	31% (161/522)	99% (159/161)
NRTI resistance	9% (48/522)	98% (47/48)
M184V/I	3% (17/522)	100% (17/17)
Any TAM	7% (36/522)	97% (35/36)
1-2 TAMs	5% (28/522)	100% (28/28)
≥3 TAMs	2% (8/522)	88% (7/8)
NNRTI resistance	17% (88/522)	98% (86/88)
PI resistance	10% (54/522)	98% (53/54)
INSTI resistance	3% (16/522)	100% (16/16)
T97A	2% (12/522)	100% (12/12)

a. Baseline data derived from cumulative historical and/or proviral genotypes
b. Outcomes determined by last on-treatment observation carried forward analysis through the end of study

Table 2.

Table 2. Changes from baseline after switching to B/F/TAF

	All B/F/TAF (n=547)	DTG/ABC/3TC* (n=281)
Median (Q1, Q3) change in eGFR, mL/min		
Week 48 (n=482)	2 (-5, 10)	-2 (-9, 5)
Week 96 (n=281)	2 (-5, 9)	--
Median (Q1, Q3) change in fasting lipids Week 48 (n=468)		
Total cholesterol, mg/dL	-3 (-18, 13)	2 (-17, 18)
LDL cholesterol, mg/dL	2 (-12, 18)	2 (-14, 14)
HDL cholesterol, mg/dL	-1 (-6, 3)	0 (-4, 6)
Total Cholesterol:HDL ratio	0.0 (-0.4, 0.4)	0.0 (-0.5, 0.4)
Triglycerides, mg/dL	-3 (-31, 24)	3 (-21, 30)
Median (Q1, Q3) change in fasting lipids Week 96 (n=269)		
Total cholesterol, mg/dL	2 (-13, 17)	--
LDL cholesterol, mg/dL	12 (-4, 27)	--
HDL cholesterol, mg/dL	-1 (-7, 4)	--
Total Cholesterol:HDL ratio	0.1 (-0.3, 0.6)	--
Triglycerides, mg/dL	1 (-31, 29)	--
Median (Q1, Q3) change in body weight, kg		
Week 48 (n=482)	1.5 (-0.4, 3.8)	0.8 (-1.5, 2.7)
Week 96 (n=282)	2.3 (0.0, 5.1)	--

*Data from participants randomized to DTG/ABC/3TC is from the double-blind phase

Conclusion. Extended follow-up to the study of switching to B/F/TAF from DTG/ABC/3TC, demonstrates continued high rates of virologic suppression with no resistance and excellent safety and tolerability of B/F/TAF through a maximum of 168 weeks for treatment of PLWH.

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