COMPARABLE EFFICACY OF IBALIZUMAB IN COMBINATION WITH ONE OR TWO FULLY ACTIVE AGENTS

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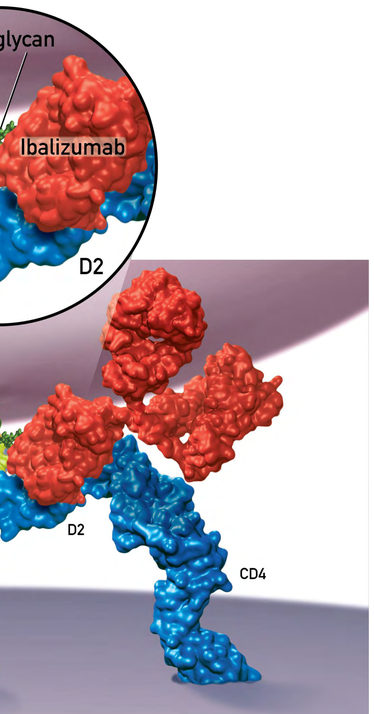
oduction

-acting humanized
oclonal antibody that blocks
cells. Unlike other antiretroviral
nformational epitope on the 2nd
ne CD4 receptor, away from
revents HIV from infecting
preserving normal

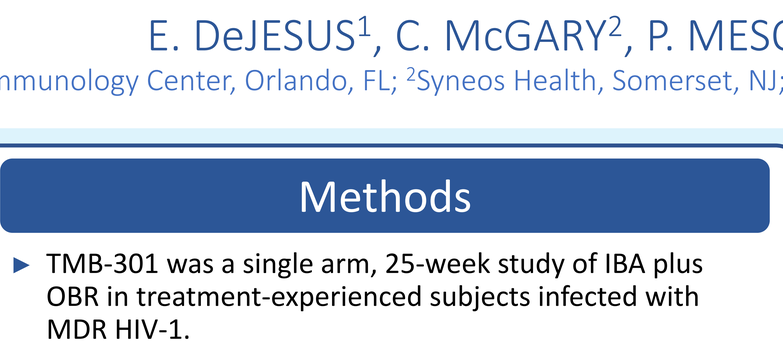
FDA in March 2018 for the
ion in heavily treatment-
multidrug resistant (MDR) HIV-1
rent antiretroviral (ARV) regimen.
ng-acting (non-daily) ARV and
cell rather than the virus.



Methods

- TMB-301 was a single arm, 25-week study of IBA plus OBR in treatment-experienced subjects infected with MDR HIV-1.
- Subjects receiving their current failing ARV therapy, or no therapy, were monitored during a 7-day control period. Thereafter, a loading dose of 2,000 mg of intravenous (IV) IBA was the only ARV agent added to their regimen for 7 days. An OBR with at least one additional sensitive agent was started 7 days after loading dose. IBA was continued at doses of 800 mg IV every 2 weeks through 25 weeks on study treatment.
- Eligible subjects (i.e. completed the 25-week TMB-301 study in the US and Puerto Rico) continued to receive IBA at 800 mg Q2W in study TMB-311 (Expanded Access) for up to 96 weeks.

STUDY DESIGN



*Patients transitioned to commercial drug when ibalizumab was approved

Results

BASELINE CHARACTERISTICS

Characteristic	OSS*=1	OSS=2
Number of patients	12	18
Median viral load (IQR)	64,550 copies/mL	20,350 copies/mL

Results (cont'd)

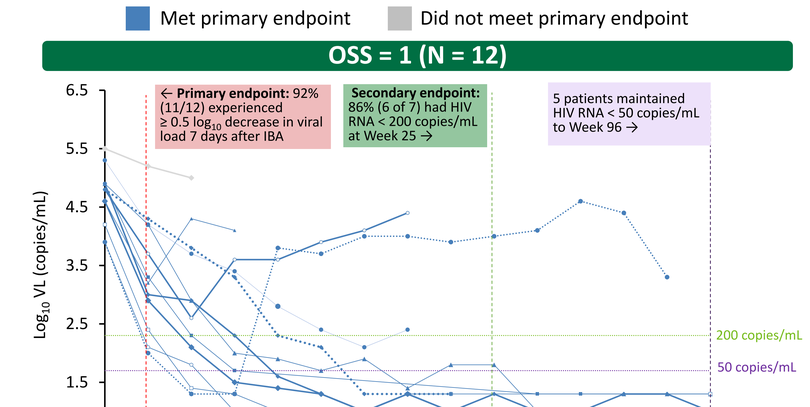
EFFICACY OUTCOMES

- A potent viral load reduction was observed with IBA functional monotherapy in patients with both one and two fully active agents.
- Patients receiving IBA in combination with both one and two fully active agents similarly maintained virologic suppression between Week 25 and 96.

	OSS = 1	OSS = 2
Primary endpoint (at Day 14)	**n = 12**	**n = 18**
≥ 0.5 $\log_{10}$ decrease in VL from BL	92%	72%
Secondary endpoints (at Week 25)	**n = 7***	**n = 16***
Mean change in VL ($\log_{10}$ copies/mL) from BL	–3.3	–2.3
VL < 50 copies/mL	71%	56%
VL < 200 copies/mL	86%	69%
≥ 0.5 $\log_{10}$ decrease in VL from BL	86%	100%
Outcomes (at Week 48)	**n = 6***	**n = 13***
Mean change in VL ($\log_{10}$ copies/mL) from BL	–2.8	–2.5
VL < 50 copies/mL	83%	69%
Outcomes (at Week 96)	**n = 5***	**n = 12***
Mean change in VL ($\log_{10}$ copies/mL) from BL	–3.3	–2.4
VL < 50 copies/mL	100%	75%

BL, baseline; VL, viral load.
*Values reflect percentages from patients who completed endpoint of interest.

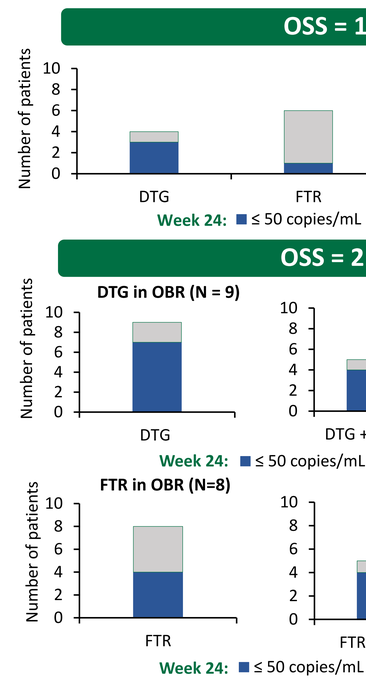
VIRAL LOAD – BASELINE TO WEEK 96



Results

FULLY ACTIVE

- Among patients receiving IB OBR, 3 out of 4 patients wit with OSS = 2 achieved VL <



- The majority of patients rec achieved virologic suppressi active DTG.

First Fully Active Agent	Second Fu
DTG	
DTG	
DTG	
DTG	
TFV	
TFV	
TFV	
ENF	
RPV	
MVC	