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## What's up with ART? Latest studies in HIV treatment

OAB0202

Prior M184V/I and multiple prior virological failures have no impact on the efficacy of switching HIV+ adults to DTG/3TC through 96Wks in SOLAR-3D

G. Blick<sup>1</sup>, E. Cerreta<sup>1</sup>, G. Mancini<sup>1</sup>, A. Cosenza<sup>1</sup>, L. Fang<sup>2</sup> <sup>1</sup> Health Care Advocates International, Stratford, United States, <sup>2</sup> Pharstat Inc., Raleigh, United States

Background: DTG/3TC is approved for virologically suppressed HIV+ adults switching from stable ART with no prior DTG or 3TC resistance or prior virologic/treatment failure. SOLAR-3D prospectively evaluated the ability of DTG/3TC to maintain virologic suppression in adults switched in the setting of prior and current M184V/I and multiple virologic failures.

Methods: SOLAR-3D is a prospective, open-label, comparative 96-week study of HIV-1+ adults virologically suppressed for  $\geq 6$  mos, with  $\geq 3$  prior ART and prior virologic failures, enrolled from May 2019-April 2020 and stratified by history of prior M184V/I. There were no exclusions for prior INSTI use, any CD4, prior M184V/I, or 3TC-associated mutations detected at BL by proviral DNA NGS. Primary and Secondary Efficacy Endpoints: participants with PCR  $\geq 50$  at Wk48 and 96, resp. by FDA snapshot (ITT-E and PP). Additional Secondary Endpoints: PCR  $< 50$  at Wk48 and 96 (ITT-E, PP), incidence of AEs and discontinuation due to CVF (PCR  $\geq 50$  followed by PCR  $> 200$ ).

Results: 100 adults switched to DTG/3TC, n=50 with historical/prior M184V/I (n=15 with current M184V/I by proviral DNA NGS) and n=50 without prior M184V/I. Those with prior M184V/I had more prior virologic failures (n[IQR]:9[7-13]v4[3-5], p<0.001) and longer median duration HIV (28.4v15.5yrs, p<0.001), were older, and had lower nadir CD4, longer ART duration, and longer duration PCR<50c/ mL. Median time on DTG/3TC was 137wks for both groups. At Wks 48 and 96, no difference in efficacy

was observed in those with prior M184V/I compared to those without prior M184V/I:

- Primary Endpoint: PCR $\geq$ 50c/mL, n[%]: Wk48: 1[2]v3[6], ITT-E (2.1v6.4, PP); Wk96: 2[4]v1[2], ITT-E (4.6v2.2, PP);
- Secondary Endpoint: PCR<50, n[%]: Wk48: 46[92] v44[88], ITT-E (97.9v93.6, PP); W96: 42[84.0]v44[88.0], ITT-E (95.5v97.8, PP);
- Viral blips  $\geq$ 50 at Wk96 (2v1) re-suppressed at followup. No CVF were observed in either group;
- At Wk96, no differences regarding PCR TND (<20), viral blips, AEs, or discontinuations were observed;
- Baseline Proviral DNA NGS demonstrated M184V/I was no longer present in 64.4% of those with prior M184V/I

Conclusions: Through 96wks, SOLAR-3D, the largest prospective trial evaluating DTG/3TC switch in individuals with prior 3TC-associated mutations, confirms prior history/current presence of M184V/I doesn't impact the efficacy of switching virologically suppressed HIV+ adults with multiple prior virologic failures.