Introduction

- Fosterasaki (Fukuzaki et al.), an oral prod of the first-in-class attachment inhibitor temsavir, is approved for the treatment of HIV-1-infected adults with treatment-experienced (TEx) adults who are otherwise ineligible for a combo regimen. TEx adults are those who are unable to form a suppressive antiretroviral regimen due to resistance prior to initiation, advanced HIV disease, immune compromise, and toxicity issues with antiretroviral drugs may have already played a role in limiting treatment options.

Safety and tolerability are particularly important for HIV TEx individuals because prior intolerance, advanced HIV disease, immune compromise, and toxicity issues with antiretroviral drugs may have already played a role in limiting treatment options.

- Fosterasaki has few drug-drug interactions and can be administered with most drugs prescribed for the management of HIV. Fosterasaki is associated with no new dose adjustment.

- Fosterasaki was well tolerated in prior clinical studies conducted in participants with mild-to-severe hepatic impairment

- Since fostemavir represents a novel class of antiretroviral agents, it is important to assess the long-term safety profile in the indicated population.

Objectives

- To summarize the safety experience, through the Week 96 data cutoff, of HIV TEx adults who received fostemavir-based antiretroviral therapy as participants in the phase 3 BRIGHTE trial.

Methods

- **Study Design**
  - **BRIGHTE** is an ongoing phase 3 study evaluating twice-daily fostemavirus 600 mg plus OBT in HIV TEx adults failing antiretroviral therapy with limited treatment options (Figure 1).

- **Study Population**
  - All Week 96 safety data were obtained before the SARS-CoV-2 pandemic
  - To summarize the safety experience, through the Week 96 data cutoff, of HIV TEx adults who received fostemavir-based antiretroviral therapy as participants in the phase 3 BRIGHTE trial.

- **Safety Assessments**
  - Safety assessments comprised monitoring of adverse events (AEs), clinical laboratory tests, vital signs, and in participants who were previously suppressed.
  - None of these reports were associated with loss of virologic suppression in participants who were previously suppressed.

- **7 participants were discontinued from the study for meeting protocol-specified QTc prolongation stopping criteria**

- Events associated with IRIS included progressive multifocal leukoencephalopathy, atypical mycobacterial infection, CNS lesions, cryptococcal meningitis, pneumococcal pneumonia, immune reconstitution diseases, and cerebral toxoplasmosis.

Conclusions

- Cumulative safety findings through the Week 96 interim analysis of the BRIGHTE trial are consistent with expectations for this HTE population with high rates of advanced HIV disease and multiple comorbidities.

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- The safety and tolerability profile of fostemavir is favorable in the intended-use population.