Long-term Safety and Impact of Immune Recovery in Heavy Treatment-Experienced Adults Receiving Fostematin for up to 5 Years in the BRIGHTE Study

Josep M. Libe,1 Judith A. Aberg,2 Sharon Walmsley,3 Juan Velez,4 Carlos Zela,5 Brenda Crabtree Ramirez,4 Bronagh Shepherd,6 Rimi Shah,7 Andrew Clark,8 Allan R. Tenorio,9 Amy Pierce,10 Fangfang Du,10 Bo Li,10 Marcia Wang,11 Silvén Chabrias,12

1Hospital Universitario Germans Trias i Pujol, Barcelona, Spain; 2Hospital of Medicine at Mount Sinai, New York, NY, USA; 3University Health Network, Toronto, ON, Canada; 4Fundación Valle del Llano, Cali, Valle de Cauca, Colombia; 5Hospital of Medicine, Buenos Aires, Argentina; 6Department of Infectology, Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Mexico City, Mexico; 7QSK, Brandford, UK; 8VIII Healthcare, Brandford, UK; 9VIII Healthcare, Durham, NC, USA; 10GSK, Collegeville, PA, USA; 11VIII Healthcare, Brandford, CT, USA

Key Takeaways
- The BRIGHTE study, heavily treatment-experienced (HTE) adults treated with fostemsavir (FTR) + optimized background therapy (OBT) experienced durable virologic responses through Week 240,
- IRIS was reported in 8 (2%) participants; 3 events were classified as SAEs (recurrent mycobacterial infestations),
- Among participants with baseline CD4+ T cell count ≥200/mm³, 5 (15%) had CD4+ T cell count ≥50/mm³ at any time,
- No SAEs occurred more frequently in the Non-directed Cohort than in the Non-directed Cohort,
- Non-directed Cohort randomized participants had an increased rate of all-cause mortality compared to the Non-directed Cohort randomized participants,
- Data from this study supports the continued use of fostemsavir for up to 5 years in HTE adults who are otherwise unable to form a suppressive response to subsequent salvage therapy.

Introduction
- Infections and HIV-1/HIV-2 disease progression are governed by the majority of grade 3-4 adverse events (AEs), serious AEs (SAEs), and deaths, likely reflecting the severity of immune compromise.
- After Week 48, there were no new AIDS-defining events reported among HTE adults with any exposed regimen (CD4+ T cell count >200/mm³ at any time during the analysis period).
- These findings highlight the importance of initiating salvage regimens before the development of advanced disease, whenever possible.

Methods
- This randomized, open-label, multicenter, 3-arm trial investigated the safety and efficacy of fostemsavir (FTR) + optimized background therapy (OBT) in HTE adults with ≥200/mm³ CD4 T cell count.
- Participants were randomized at entry to 1 of 3 treatment arms: (i) FTR-OBT-directed regimen, (ii) FTR-OBT non-directed regimen, or (iii) FTR-OBT non-directed regimen.
- Participants with baseline CD4+ T cell count ≥200/mm³ were randomized 1:1:1 to the 3 randomization arms using an interactive voice response system.
- Use of ART was allowed during the study period.

Results
- Participants who were randomized to the randomization cohorts experienced treatment-emergent AEs (TEAEs) in 288 (93%), 120 (98%), and 142 (97%) of participants in the FTR-OBT-directed, FTR-OBT non-directed randomized, and FTR-OBT non-directed non-randomized groups, respectively.
- The most common AEs were upper respiratory infection (68%), diarrhea (42%), and dizziness (32%).
- Data from this study supports the continued use of fostemsavir for up to 5 years in HTE adults who are otherwise unable to form a suppressive response to subsequent salvage therapy.

Conclusions
- These findings highlight the importance of initiating salvage regimens before the development of advanced disease, whenever possible.
- This study was funded by ViiV Healthcare. The authors thank all BRIGHTE clinical trial participants and their families and all investigators and study sites for their important contributions.

References
This content was acquired following an unsolicited medical information enquiry by a healthcare professional. Always consult the product information for your country, before prescribing a ViiV medicine. ViiV does not recommend the use of our medicines outside the terms of their licence. In some cases, the scientific Information requested and downloaded may relate to the use of our medicine(s) outside of their license.