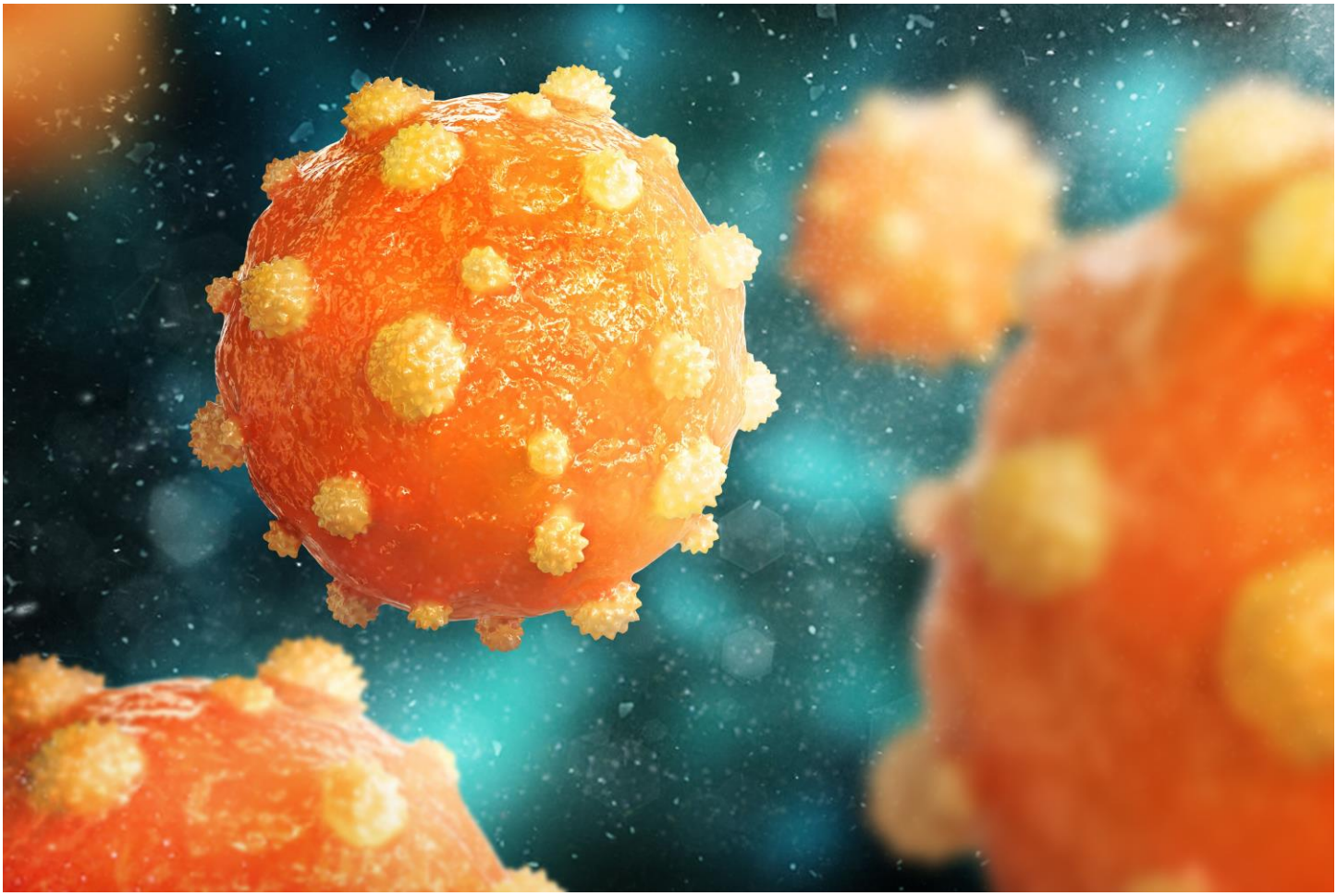
FDA Approves Expanded Indication for Tenofovir Alafenamide as Hepatitis B Treatment

The FDA has approved a supplemental new drug application for tenofovir alafenamide (Vemlidy; Gilead Sciences Inc) at a once daily 25 mg tablet for chronic hepatitis B virus (HBV) infection in pediatric patients aged 6 years and older who weigh at least 25 kg and have compensated liver disease, according to a press release. Tenofovir alafenamide is a targeted prodrug of tenofovir that was approved by the FDA for the treatment of chronic HBV in adults in 2016 and the treatment of HBV in pediatric patients aged 12 and older in 2022.[1]



Tenofovir alafenamide is recommended at the preferred first-line treatment for adults with chronic HBV with compensated liver disease in guidelines by the American Association for the Study of Liver Disease and the European Association for the Study of the Liver.[1]

"Chronic hepatitis B can have a significant and lasting impact on the health of children. If left untreated, hepatitis B can lead to liver cirrhosis and liver cancer," Chaun-Hao Lin, MD, associate professor of clinical pediatrics at the Krek School of Medicine at the University of Southern California, said in the press release. "As a clinician, I am well aware of the critical importance of promptly treating this disease to

avoid possible complications and liver damage. The clinical trial demonstrated that tenofovir alafenamide may represent an effective treatment option for children as young as 6 years old affected by this chronic disease."[1]

The approval is supported by data from a phase 2 clinical trial (Trial 1092; NCT02932150), which compared tenofovir alafenamide 25 mg compared to the placebo in 18 individuals who were aged 6 to less than 12 years of age and were either treatment naïve or treatment experienced, according to the press release. Investigators found that individuals in both groups who switched to tenofovir alafenamide in the open-label part of the study after week 24 had increases in the rates of virological suppression through week 96, both overall and within the children and adolescent subgroups.[1]

About The Trial

Trial Name: Study of Tenofovir Alafenamide (TAF) in Children and Teen Participants With Chronic Hepatitis B Virus Infection

ClinicalTrials.gov ID: NCT02932150

Sponsor: Gilead Sciences

Completion Date (Estimated): October 2029

Trial 1092 is an ongoing, phase 2 study in children and adolescents with 4 different cohorts pertaining to weight, according to the clinical trial information. Written informed consent is obtained from the child and parent/legal guardian. All individuals have documented chronic HBV for 6 months or more and had an estimated creatinine clearance of 80 mL/min/1.73m^2 of more.[2]

In the patient population, the most common adverse events included nasopharyngitis, headache, COVID-19, pyrexia, diarrhea, upper respiratory tract infection, cough, respiratory tract infection viral, and upper abdominal pain.[1]

"The expanded indication for [tenofovir alafenamide] for the treatment of children as young as 6 years old is a testament to the safety, tolerability and efficacy profile of this therapy," Frank Duff, MD, senior vice president of Virology Therapeutic Area Head at Gilead Sciences, in the press release. "Effective and tolerable options for children require our best science and a dedicated focus."[1]

According to the press release, tenofovir alafenamide includes a boxed warning indicating post-treatment severe acute exacerbation of hepatitis B.[1]

References

1. FDA Expands Indication for Gilead's Vemlidy (Tenofovir Alafenamide) to Treat Chronic HBV Infection in Pediatric Patients as Young as Six. News release. Gilead. March 28, 2024. Accessed March 28, 2024. https://www.gilead.com/news-and-press/press-room/press-releases/2024/3/fda-expands-indication-for-gileads-vemlidy-tenofovir-alafenamide-to-treat-chronic-hbv-infection-in-pediatric-patients-as-young-as-six
2. Study of Tenofovir Alafenamide (TAF) in Children and Teen Participants With Chronic Hepatitis B Virus Infection. ClinicalTrials.gov Identifier: NCT02932150. Updated February 06, 2024. Accessed March 28, 2024. https://clinicaltrials.gov/study/NCT02932150

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