Fostemsavir

Investigational Treatment. This treatment has NOT been approved by the FDA.

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Drug Summary

Fostemsavir is an investigational attachment inhibitor with a unique mechanism of action. It is a prodrug of temsavir, which binds to HIV envelope glycoprotein 120 (gp120), thereby preventing viral attachment to the host CD4 cell surface receptor. In the absence of effective binding of HIV gp120 with the host CD4 receptor, HIV does not enter the host cell. Because fostemsavir has a novel mechanism of action, the drug should have full activity against HIV strains that have developed resistance to other classes of antiretroviral medications. In a phase 2b study of treatment-experienced individuals, fostemsavir appeared to be well tolerated. Phase 3 studies are ongoing.

Key Clinical Trials

In an open-label, proof of concept study, antiretroviral-naïve or -experienced adults received 8 days of oral fostemsavir monotherapy (with or without ritonavir); participants had a significant decline in HIV RNA levels and low rates of side effects [AI438-006]. A phase 2b trial enrolled treatment-experienced adults with HIV infection and randomized study subjects to one of four doses of fostemsavir (400 mg twice daily, 800 mg twice daily, 600 mg once daily, or 1200 mg once daily) or to ritonavir-boosted atazanavir; participants in each arm also received raltegravir 400 mg twice daily and tenofovir DF 300 mg once daily [AI438-011]. There were approximately 50 individuals in each arm. Through 24 weeks of treatment, virologic efficacy and tolerability were similar in the fostemsavir groups and the boosted atazanavir group: 80% of participants in the fostemsavir 400 mg twice daily group, 69% in the 800 mg twice daily group, 76% in the 600 mg once daily group, and 72% in the 1200 mg once daily group had HIV RNA level below 50 copies/mL, as compared to 75% in the boosted atazanavir group. Rates of adverse events and discontinuations due to adverse events were also similar in the various groups. After 48 weeks, all the fostemsavir groups were consolidated and were given fostemsavir 1200 mg once daily for the remainder of the study; after 96 weeks of treatment, 61% of individuals taking fostemsavir plus raltegravir plus tenofovir DF had HIV RNA below 50 copies/mL as compared to 53% of those taking boosted atazanavir plus raltegravir plus tenofovir DF.

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