Rukobia OK’d for Resistant HIV

The novel attachment inhibitor led to viral suppression in 60% of people with extensive prior treatment.

September 28, 2020 By Benjamin Ryan

The Food and Drug Administration (FDA) has approved ViiV Healthcare’s Rukobia (fostemsavir) for people with HIV that is resistant to numerous antiretrovirals (ARVs). In particular, the drug-—a new type of entry inhibitor—was green-lit for those who have used many previous ARVs and whose current regimen is not working due to drug resistance, personal inability to tolerate the medications or safety problems.

Rukobia’s approval was based on findings from a Phase III clinical trial that included people who had taken numerous ARVs over time and who had HIV that was resistant to multiple drugs. They were treated with Rukobia plus an ARV regimen designed to work as well as possible. Sixty percent were able to achieve an undetectable viral load within two years. Rukobia also led to a substantial rise in CD4 cells during that time. The treatment was generally safe and well tolerated.

“The FDA’s approval of Rukobia, the first-ever attachment inhibitor, marks a significant milestone in the treatment of HIV patients with heavy treatment experience,” says longtime HIV physician Anthony Mills, MD, CEO of the Men’s Health Foundation in Los Angeles. “While most patients living with HIV are thriving on current therapies, patients with long and complex treatment histories may develop strains of the virus that are difficult to fight.”

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http://beta.docker.poz.com/article/rukobia-okd-resistant-hiv