Cutoff for Baseline Phenotypic Sensitivity to VH3810109 (N6LS) Did Not Impact Occurrence of Confirmed Virologic Failure in the Phase 2b EMBRACE Study

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Background

The EMBRACE study looks at a new HIV-1 treatment for adults with an undetectable viral load on successful antiretroviral therapy. It tests an antibody called VH3810109 (also known as N6LS) which works by attaching to a key part of the virus and stopping it from getting into human cells. The aim is to offer a treatment that doesn't need to be taken as often as current medicines, and to find out if the way the virus reacts to this antibody at the start affects how well the treatment works in the long run.

What treatment was studied here?

Researchers studied N6LS, an antibody that can block HIV-1 from entering human cells. The treatment is given either into a vein (intravenous) or under the skin (subcutaneous). People in the study got this treatment every 4 months, which is less often than many other HIV treatments. They also received monthly injections of another medicine called cabotegravir, an existing antiretroviral treatment. This combination is meant to keep HIV suppressed in adults with virus sensitive to N6LS.

What was the purpose of this study?

The study wanted to find out if the virus's first reaction to the antibody, and the amount of antibody in the body, affected the chances of the virus starting to make copies of itself again. This is important for deciding if N6LS could be a good treatment for HIV-1.

Who took part in the study and how was the treatment studied?

The study included 125 adults aged 18 to 70, all of whom had HIV-1 that was well controlled (shown by undetectable levels of virus in their blood). Everyone had been on

stable HIV treatment for at least 6 months and did not have active hepatitis B. Participants were split into 3 groups, 1 group receiving treatment into a vein, a second group receiving treatment under the skin, and the third receiving daily tablets. A special test checked how sensitive the virus was to the antibody.

What are the research findings?

The study found that 72% of participants had virus that was sensitive to N6LS. Of those who had sensitive virus, how sensitive the virus was to N6LS varied. Most people had suppressed virus: 96% in the intravenous group and 88% in the subcutaneous group. Only 4 people had confirmed virologic failure (meaning the virus started to make copies of itself again). There were no strong links between the characteristics of participants at the start of the study and how sensitive the virus was. The main goal was to monitor virologic failure, which when it occurred, wasn't found to be connected to how sensitive the virus was or how much antibody there was in the body.

What does this mean for people with HIV?

For people with HIV, N6LS could help keep the virus suppressed with less frequent medication. This might make life easier by reducing the need for daily pills. The low rate of virologic failure and high rates of viral suppression suggest N6LS could be a reliable treatment option for managing HIV.

Conclusions

The EMBRACE study shows that N6LS can keep the virus under control for most people. There was no link between virologic failure and how sensitive the virus was or between levels of N6LS in the blood, which suggests that it may be a reliable treatment option. However, more research is needed to understand why some people still experience virologic failure.

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