Questions raised about promising HIV vaccine trial results

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NEW YORK The excitement over data from a late-stage clinical trial of an HIV vaccine regimen may have been premature, according to published reports.

Last month, Sanofi-Aventis announced results of a trial of a vaccine regimen comprising its ALVAC HIV vaccine and VaxGen's AIDSVAX B/E in 16,000 men in Thailand. Results showed that when combined, the two vaccines reduced the risk of HIV infection by 31.2%. That rate, while modest, was statistically significant, Sanofi said at the time.

But according to reports, a press conference showed only initial analysis of the data. Further analysis showed lower rates of protection and evidence that the results were not statistically significant, and some scientists have criticized the presentation of the data as misleading.

Nick Saraniti, CEO and director of operations of Fort Lauderdale, Fla.-based specialty pharmacy Commcare Pharmacy, is also skeptical. He noted that the results indicate patients who took the vaccine contracted HIV 31.2% less than those who didn't, but the question remained as to whether they were also 31.2% less exposed to the virus.

"Realistically, it doesn't put them much closer to a vaccine than they were two years ago," Saraniti told *Drug Store News*. "It gives us the hope to keep trying."