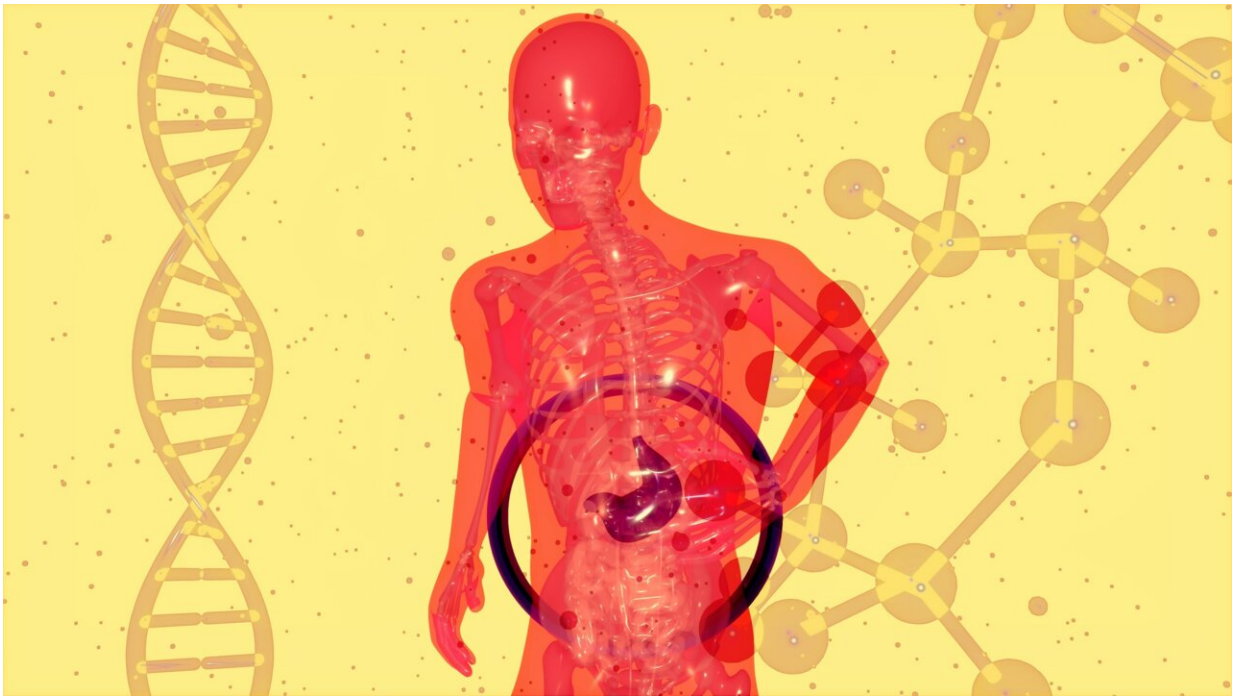


Clinical trial results suggest potential new treatment for primary biliary cholangitis

November 16 2023, by Liam Connolly



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An international clinical trial involving UC Davis Health suggests the investigational drug Elafibranor is a potential novel treatment for patients with the rare, autoimmune disease primary biliary cholangitis. Results from the clinical trial showed significant improvements in biomarkers of disease progression. Patients also reported positive outcomes.

The [results of the clinical trial](#) were published in *The New England Journal of Medicine*. They were also presented by Christopher Bowlus, chief of Gastroenterology and Hepatology at UC Davis Health, at [The Liver Meeting](#), hosted by the American Association for the Study of Liver Diseases.

Primary biliary cholangitis is a disease that damages the bile ducts that run through the liver and can lead to [liver failure](#).

"When managing primary biliary cholangitis our first goal is to effectively control the disease progression which can lead to liver failure," Bowlus said. "The results from this trial provide compelling evidence that Elafibranor has the potential to achieve this goal, with evidence of a highly significant treatment benefit that is associated with improved clinical outcomes."

ELATIVE clinical trial

Data from the phase three trial called ELATIVE showed more than half of [patients](#) treated with Elafibranor achieved the study's primary endpoint of biochemical response. This was defined as having normal bilirubin concentrations alongside a substantial decrease in alkaline phosphatase levels, maintained below a particular threshold. Only 4% of those who got the placebo met these criteria.

Elafibranor also normalized alkaline phosphatase levels in 15% of treated patients, compared to none in the placebo group.

In addition, the study assessed itching, a common symptom of primary biliary cholangitis, using a quality-of-life questionnaire. The 52-week data on the quality-of-life questionnaire favored Elafibranor over the placebo.

In terms of safety, the study found that Elafibranor was well-tolerated with an adverse event profile that was like the placebo group. Common side effects included [abdominal pain](#), diarrhea, nausea and vomiting.

"Based on the [clinical data](#), Elafibranor has the potential to improve treatment for our patients living with primary biliary cholangitis by both effectively managing the disease progression and improving the burden of symptoms," said Bowlus.

What is primary biliary cholangitis?

Primary biliary cholangitis is a disease that affects the bile ducts that run through the liver. It slowly degrades those [bile ducts](#), making it harder for bile to flow through. Bile backs up inside the liver, which damages the tissues. Scar tissue gradually replaces healthy tissue and eventually leads to [liver](#) failure.

Although it affects both sexes, primary biliary cholangitis primarily affects women and people assigned female at birth by a ratio of 10-to-1. At this time, there are no approved treatments available that can effectively manage both [disease progression](#) and life-impacting symptoms.

More information: Kris V. Kowdley et al, Efficacy and Safety of Elafibranor in Primary Biliary Cholangitis, *New England Journal of Medicine* (2023). [DOI: 10.1056/NEJMoa2306185](https://doi.org/10.1056/NEJMoa2306185)

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