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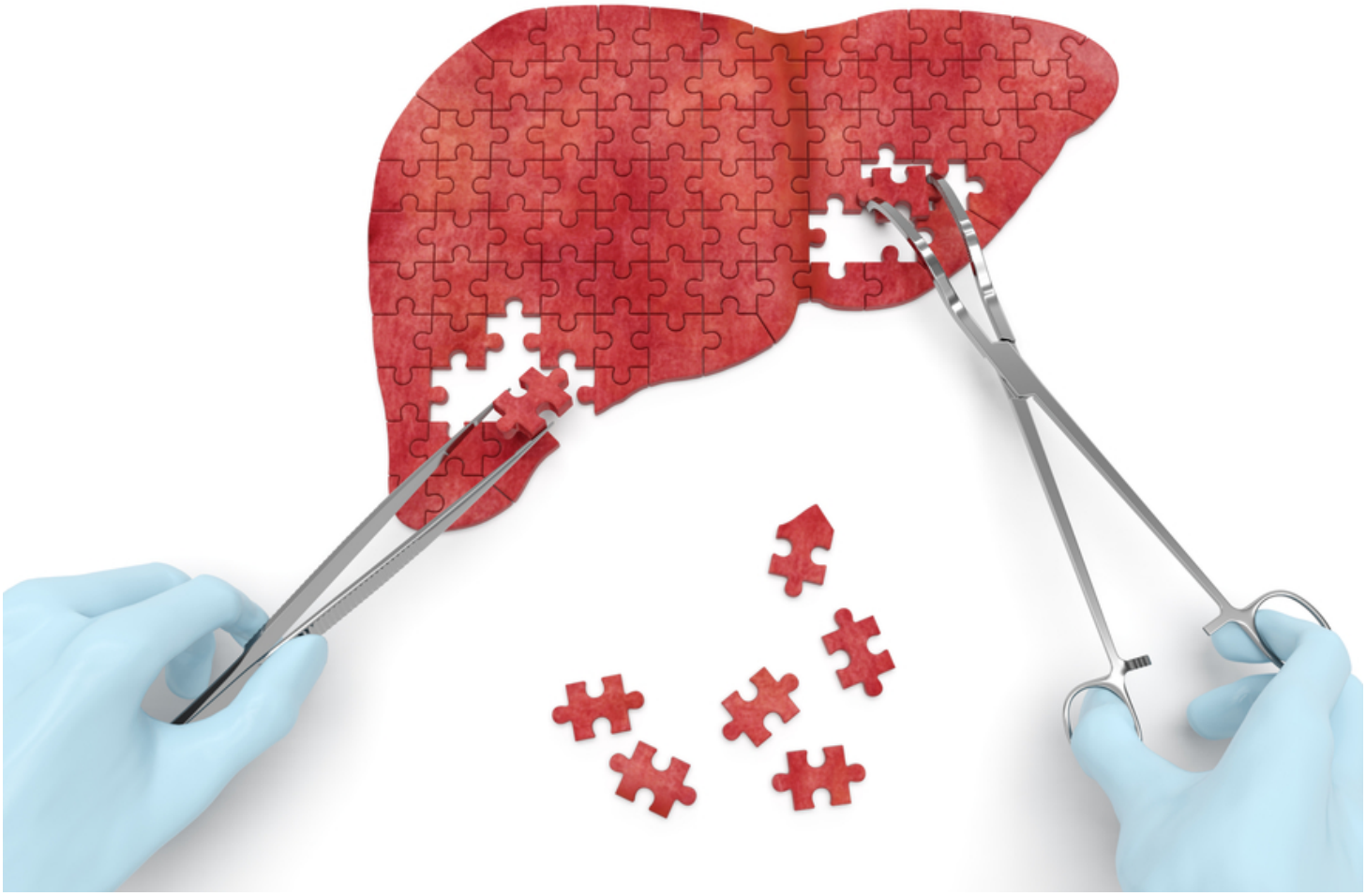
Biotech

Akero's NASH drug cuts liver fat in phase 2, but COVID-19 may delay full data

by Amirah Al Idrus | Mar 31, 2020 11:05am



The company plans to report topline data, including safety and tolerability, laboratory measures such as levels of the liver enzyme ALT, and biopsy in the second quarter of this year, but is unsure if the COVID-19 pandemic will affect its ability to collect biopsies. (Getty Images/Aksabir)

Two years ago, Akero Therapeutics licensed a diabetes drug from Amgen in hopes that it could move the needle in fatty liver disease. Now, it looks like that bet is starting to pay off—the company unveiled phase 2a data showing the drug **beat placebo** at reducing liver fat in patients with nonalcoholic steatohepatitis (NASH).

The company plans to report topline data, including safety and tolerability, laboratory measures such as levels of the liver enzyme ALT, and biopsy in the second quarter of this year. It is about halfway through collecting biopsies from 50 patients whose liver fat decreased by at least 30% but is unsure how much longer the process will take.

“The extent to which the COVID-19 pandemic will interfere with collection of the remaining biopsies and data from other scheduled clinical visits, including the safety follow-up visit at week 20, is unclear,” Akero said in a statement. However, the company will delay a portion of the study that will test the drug, AKR-001, in NASH patients with compensated cirrhosis.

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Amgen had studied the drug through phase 1 in patients with diabetes. Akero pitted three dose levels—28mg, 50mg and 70mg—against placebo in an 80-patient study. After 12 weeks of treatment, patients in all three dose groups saw their absolute liver fat fall by at least 12%, meeting the primary endpoint of the study. All three groups also met the study’s secondary endpoint too, with the drug cutting their liver fat by more than half and, in the case of the two higher doses, more than 70%.

"The magnitude and rate of improvements in liver fat content and ALT observed over 12 weeks in the BALANCED study are among the most robust NASH clinical trial results reported to date," said Stephen Harrison, M.D., medical director of Pinnacle Clinical Research, in a statement. "AKR-001 is emerging as one of the most promising drug candidates in development for this serious disease."

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“[The] good news today that helps improve our confidence is all three doses were very active so there will be at least 50 pts across 3 drug arms who are undergoing biopsy and checking fibrosis rather than just relying on the high dose for best efficacy or 10-15 pts (out of 20) getting a biopsy,” wrote Jefferies analyst Michael Yee in a note. “Thus, we have more confidence the totality of evidence from 3 doses will show the drug works. It's maybe even now more about 'which dose' is best rather than hoping the high dose works for a decision for Phase IIB/III.”

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"Also - though some risk on COVID impacting biopsies coming, they've already done 25/50 biopsies and we're hopeful the other 25 pending can be spread out and are at centers not as much impacted such as NY, CA, etc.," Yee added.

People with nonalcoholic fatty liver disease store excess fat in the liver. Some of them go on to develop NASH, in which the fat buildup causes inflammation and damage, which can in turn cause liver scarring, or fibrosis. Akero’s AKR-001 is designed to tackle inflammation and scarring, as well as the metabolic causes underlying the disease.

The drug is a long-acting analog of fibroblast growth factor 21 (FGF21), a hormone involved in regulating metabolism and signaling in the body. But the native hormone has a short half-life of about half an hour and so, would require frequent dosing. AKR-001 is designed to confer the benefits of native FGF21, but with a half-life of three to four days, which supports once-weekly dosing, said Akero Chief Scientific Officer Tim Rolph, D.Phil., in a previous interview.

"We are encouraged by these results, which support continued development of AKR-001 for treatment of NASH," said Akero CEO Andrew Cheng, M.D., Ph.D., in the statement. "AKR-001 has the potential to provide NASH patients with an important treatment option when there are still no approved therapies. We look forward to the full data set with anticipation and are preparing for the next steps in AKR-001's development."

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