Evaluate Vantage

July 01, 2020

Akero continues to pull ahead of Nash rivals

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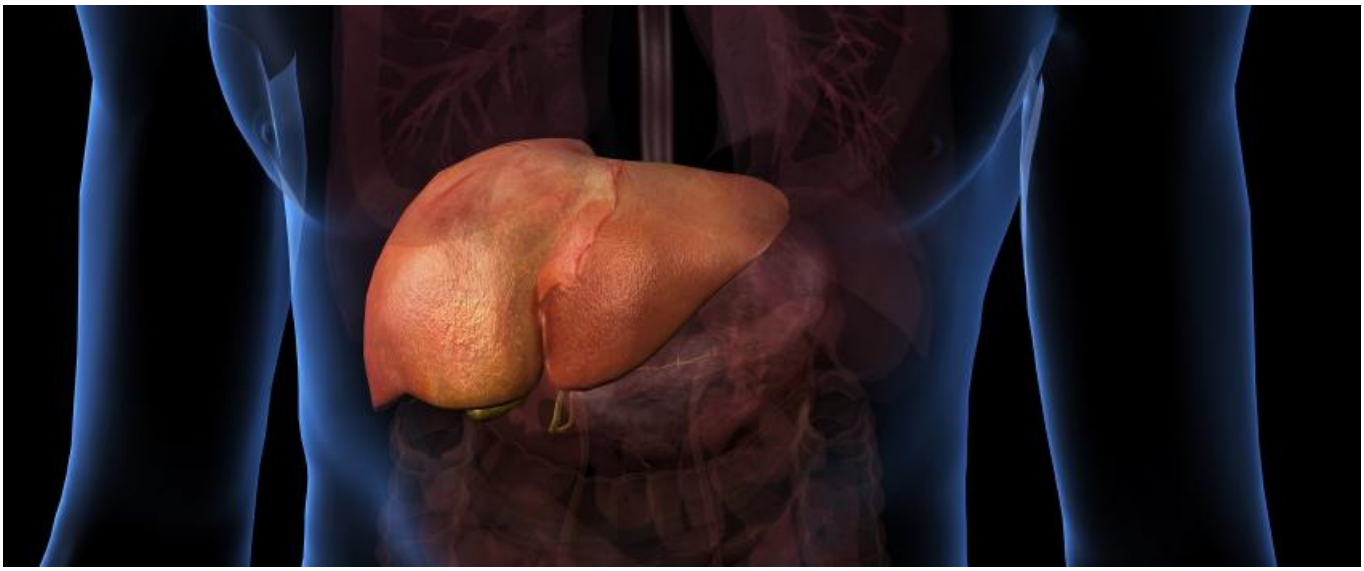

Biopsy data set up efruxifermin as a strong contender in the race to find an effective Nash treatment.

In a field beset by failure Akero Therapeutics continued on its Nash winning streak with another set of impressive data for efruxifermin, formerly known as AKR-001. Following its earlier triumph with MRI results, the group yesterday delivered stellar biopsy data for the FGF21 stimulant.

Most notable was efruxifermin's performance in fibrosis, the liver scarring associated with Nash, prompting some analysts to describe the results as "game-changing". In this secondary analysis of the phase IIb Balanced study, 48% of the 40 responders to treatment, who qualified for end-of treatment biopsies, showed improvement of at least one stage in fibrosis, without worsening of their Nash symptoms; 28% achieved a two-stage improvement in fibrosis.

Additionally, 48% of responders achieved NASH resolution with no worsening of fibrosis. These results are important because the study compared biopsies from treated and control subjects, which is considered a more robust measure than MRI scans.

The results saw Akero shares open up 37%, hitting a record high since the company floated in June 2019.

Better than the rest?

There had been fears that the Covid-19 pandemic would hit the study, and there was some disruption, with only 40 of the suitable 48 responders in the treatment arm receiving biopsies. Perversely, because the mean time to biopsy was pushed out to 20 weeks, meaning they were taken four weeks after the study's end, the treatment effect might have been even greater had biopsies been conducted at 16 weeks.

Akero also showed satisfying dose-related responses, with the 50mg arm of the study reporting 62% improvement in fibrosis, and 54% of patients showing Nash resolution.

Efruxifermin produced weight loss across all treatment groups, and importantly there were no increases in LDL, something that has beset other Nash treatments and could prove a drawback, given the cardiovascular profile of many patients with Nash.

Efruxifermin's win in fibrosis resolution also sets Akero apart from Novo Nordisk, which is attempting to extend the use of the diabetes drug semaglutide into Nash; in a recent trial the GLP-1 agonist failed to show a significant benefit on this measure.

Pulling ahead

Akero's success is even more salient because it comes hot on the heels of several stumbles in the field. Cymabay abandoned its Nash asset seladelpar after adverse liver events, Genfit's Resolve-It trial of elafibranor flopped back in May and earlier this week Intercept received a US complete response letter for its lead asset, obeticholic acid.

The Balanced trial also lends strength to the FG21 stimulant mechanism, which is also being studied by Ambrix, 89bio and Novo Nordisk. In morning trading 89bio shares were 18% higher; the company is due to release topline data from its phase Ib/IIa trial for BIO89-100 before the end of the year.

Given the strength of the efruxifermin data Akero said it would meet the FDA later this year with the aim of starting a phase IIb/III study in the first half of 2021, using both the 28mg and 50mg doses of efruxifermin.

On the surface it does look as if efruxifermin is addressing many of the metabolic imbalances of Nash. And, while the field is littered with projects that have failed to translate early signals into firmer evidence, Akero now looks like one of the stronger contenders.