

## Genfit's latest delay could see a last-minute endpoint change



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Another delay to Genfit's Resolve-It trial of elafibranor looks suspicious, but you can hardly blame the French company for wanting to give the study the best possible spin. After all, the Nash trial's odds of success are low, given elafibranor's phase II flop, the failure of most other Nash projects and the discontinuation of Cymabay's similarly acting seladelpar. Resolve-It's readout had already quietly been delayed from the end of last year ([Genfit's liver disease Hail Mary approaches, September 19, 2019](#)). Yesterday the group [revealed a plan to sit on the blinded dataset](#) until the second quarter "to incorporate the latest FDA insights". Presumably this is to allow Reduce-It's endpoints to be tweaked at the last moment – permissible before unblinding – should evidence emerge that this would increase the trial's chances of showing an effect on Nash. More clarity is possible when Genfit reports 2019 financials on April 8, but a likely timeline will see Resolve-It results only after Intercept's Ocaliva faces a US adcom on April 22, or after the FDA's verdict on that drug. Lots more should then be known about the agency's thinking, and not all of it will be favourable to Genfit.

### A Nash timeline

Mar 2015	Elafibranor's <a href="#">phase 2 Golden study</a> fails
Feb 2016	Gastroenterology paper published post-hoc analysis of Golden study, suggesting a path forward
Mar 2016	Genfit's <a href="#">phase 3 Resolve-It study</a> begins
Apr 2018	Resolve-It recruits 1,000 Nash subjects necessary for interim analysis, data expected by end 2019
Feb 2019	Gilead's Ask1 inhibitor selonsertib fails
Jun 2019	Conatus collapses after failure of emricasan
Sep 2019	Genfit delays Resolve-it readout to Q1 2020
Nov 2019	Cymabay discontinues PPAR delta agonist seladelpar
Dec 2019	Gilead's multi-project Atlas study fails
Dec 2019	Boehringer discontinues AOC3 inhibitor BI 1467335
Feb 2020	Genfit delays Resolve-it readout to Q2 2020
8 Apr 2020e	Genfit to report 2019 financials
22 Apr 2020e	US adcom for Intercept's Ocaliva
26 Jun 2020	US FDA action on Intercept's Ocaliva
Q2 2020e	Resolve-It to read out

Source: company announcements.