

NEWS | TECHNOLOGY

Inventiva Completes Phase 3 NATiV3 Trial of Lanifibranor in MASH

The 1,009-patient study has reached its final 72-week visit, with topline results expected in Q4 2026 and potential U.S. regulatory submission planned for the first half of 2027.

By **Ankit Kankar** | September 13, 2026



Picture Courtesy | Public Domain

Inventiva("Inventiva" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of an oral small molecule therapy for the treatment of metabolic dysfunction-associated steatohepatitis ("MASH"), announced the last patient has completed their final 72-week visit in the NATiV3 Phase 3 clinical trial evaluating lanifibranor for the treatment of patients with MASH with moderate and advanced fibrosis.

NATiV3 enrolled 1,009 adults with biopsy-proven non-cirrhotic MASH and F2/F3 fibrosis, with an additional 410 patients enrolled in an exploratory cohort. With the last patient having completed their final visit, all patients have completed the 72-week treatment period.

Inventiva expects to report topline results from NATiV3 in the fourth quarter of 2026, as previously communicated. If the results are favorable, the Company anticipates regulatory submission in the first half of 2027 and is preparing for a potential U.S. launch of lanifibranor in 2028, subject to FDA approval.

Andrew Obenshain, Chief Executive Officer, Inventiva: "Our ambition is to develop a treatment that can make a meaningful difference for patients, and reaching last patient, last visit in NATiV3 is an important milestone for Inventiva and for the development of lanifibranor in noncirrhotic MASH. We are deeply grateful to the patients who participated in the study and to the investigators and clinical teams who led its execution alongside our dedicated Inventiva team. We now look forward to topline results later this year."

Prof. Arun Sanyal, M.D., Director of the Stravitz-Sanyal Institute for Liver Disease and Metabolic Health, Virginia Commonwealth University and co-principal investigator of NATiV3, stated:"Having been involved in the clinical program of lanifibranor over the years, it is particularly meaningful to see the last patient complete their final visit in this important Phase 3 trial. Given the significant unmet need in MASH, where many patients continue to face limited treatment options and the burden of a progressive disease, and the positive results observed in the NATiV3 Phase 2b trial, I am looking forward to the topline read-out of the NATiV3 trial and the potential for lanifibranor to become a leading treatment for MASH."

Prof. Sven Francque, M.D., Ph.D., Professor of Gastroenterology and Hepatology at the University of Antwerp and co-principal investigator of NATiV3, stated: "The completion of NATiV3 marks an important milestone for the MASH field and for the development of next-generation PPAR therapies. Lanifibranor's pan-PPAR mechanism has the potential to address the complexity of MASH disease, by working on the interconnected pathways through both intrahepatic and

extrahepatic effects. The NATIVE Phase 2b results provided compelling clinical evidence of the potential of this broad mechanism, with improvements in both MASH and fibrosis. I very much look forward to the NATiV3 topline results.”

Read online: <https://worldbusinesswatch.com/news/13/49/inventiva-completes-phase-3-nativ3-trial-of-lanifibranor-in-mash.html>

© 2026 World Business Watch. All rights reserved.