



MetaVia Presents Positive New Phase 2a Data on Vanoglipel (DA-1241) in Patients with Presumed MASH at the AASLD The Liver Meeting® 2025

November 7, 2025

Oral GPR119 Agonist Demonstrated Clinically Meaningful Reductions in HbA1c, Improvements in Liver Inflammation and Fibrosis, and Favorable Changes in Plasma Lipidomic Profiles

CAMBRIDGE, Mass., Nov. 7, 2025 /PRNewswire/ -- **MetaVia Inc.** (Nasdaq: MTVA), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced the presentation of positive new data from its Phase 2a clinical trial evaluating vanoglipel (DA-1241), a potent and selective G protein-coupled receptor 119 (GPR119) agonist, as a potential treatment for metabolic dysfunction-associated steatohepatitis (MASH). The data highlight vanoglipel's differentiated dual activity across both hepatic and metabolic pathways, demonstrating clinically meaningful improvements in glucose control, liver health, and plasma lipidomic profiles following 16 weeks of treatment. The data will be presented in a poster presentation at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® 2025, taking place November 7-11, in Washington D.C.



The Phase 2a randomized, placebo-controlled trial evaluated vanoglipel as a potential treatment for MASH, both as monotherapy and in combination with a dipeptidyl peptidase-4 inhibitor (DPP4i) to augment endogenous GLP-1 action. GPR119 agonists directly stimulate GLP-1 secretion, thereby increasing total GLP-1 levels; when combined with a DPP4 inhibitor, the treatment can extend the action, not only of basal endogenous GLP-1, but also of the secreted GLP-1 induced by GPR119 activation. A total of 109 subjects with presumed MASH and qualifying baseline alanine transaminase (ALT) and imaging analyses were randomized to receive placebo, vanoglipel 50 mg, vanoglipel 100 mg alone, or vanoglipel 100 mg with a DPP4 inhibitor once daily for 16 weeks in a 2:1:2:2 ratio.

"The encouraging additional Phase 2a results, presented at AASLD, highlight vanoglipel's differentiated mechanism and its potential to target both hepatic and metabolic drivers of MASH in a single oral therapy," stated Hyung Heon Kim, President and Chief Executive Officer of MetaVia. "In addition to improvements in liver inflammation, fibrosis, and steatosis, vanoglipel demonstrated meaningful reductions in HbA1c among patients with type 2 diabetes and prediabetes, as well as favorable shifts in plasma lipidomic profiles, reducing disease-associated glycerolipids and glycerophospholipids linked to hepatic injury. These data reinforce vanoglipel's potential to address the complex interplay between metabolic dysfunction and liver disease. Following 16 weeks of treatment, vanoglipel showed consistent biochemical, imaging, and metabolic improvements, supporting its continued development as both a monotherapy and combination therapy for MASH and related metabolic disorders."

Following 16 weeks of treatment, vanoglipel demonstrated rapid and sustained improvements in glycemic control, with reductions in glycated hemoglobin (HbA1c) observed from the fourth week of treatment. At Week 16, mean HbA1c decreased by -0.54% with vanoglipel monotherapy and -0.66% with combination therapy, reflecting enhanced incretin action. In the study, patients treated with vanoglipel showed clinically meaningful HbA1c reductions of 0.37% , 0.41% , and 0.54% at weeks 4, 8, and 16, from a baseline of 6.99% , despite nearly half of participants being non-diabetic ($p < 0.05$ vs. PBO). These findings highlight vanoglipel's ability to improve glucose control independently of weight loss, suggesting its mechanism is differentiated from other metabolic liver disease therapies.

In addition to its glycemic effects, vanoglipel significantly decreased plasma ALT levels in subjects with baseline ALT between 40 and 200 U/L. The reduction in ALT was not further enhanced by co-administration with a DPP4 inhibitor, suggesting that vanoglipel monotherapy drives the majority of the observed hepatoprotective effects. Vanoglipel improved liver steatosis as measured by controlled attenuation parameter (CAP) and reduced liver stiffness by vibration-controlled transient elastography (VCTE). Non-invasive assessments, including FAST and NIS-4 scores, also improved from baseline, reinforcing vanoglipel's potential to address both hepatic and metabolic components of MASH.

Vanoglipel treatment reduced circulating biomarkers associated with cell death (CK18F/M30), inflammation (hs-CRP, CCL2), and fibrosis (TIMP1), consistent with its proposed hepatoprotective mechanism. Additionally, Vanoglipel 100 mg reduced pathogenic lipids in plasma lipidomic profiles, including glycerolipids (DG36:4, TG52:4) and glycerophospholipids (PE38:4, PE38:5), suggesting favorable remodeling of lipid metabolism.

Vanoglipel was well tolerated across all treatment groups, with no treatment-emergent adverse events leading to discontinuation,

except for one in the placebo group.

Presentation Details:

- **Title:** *Vanoglipel (DA-1241), a GPR119 Agonist, Demonstrates Hepatoprotective Effects Through Improving Inflammation and Metabolism in the Liver: A 16-week Randomized Placebo-Controlled Trial in Presumed MASH Patients*
- **Presenting Author:** Rohit Loomba, M.D., MHSc, Professor of Medicine, Chief, Division of Gastroenterology and Hepatology at the University of California at San Diego.
- **Poster Number:** 4012
- **Session:** Monday Poster Presenters Hall Hour
- **Poster Date:** Monday, November 10, 2025
- **Poster Time:** 1:00-2:00 pm ET
- **Poster Location:** Convention Center: Hall DE (Posters & Exhibits), Level 2

A copy of the poster is available on the [Posters](#) section of the MetaVia website.

About Vanoglipel (DA-1241)

Vanoglipel (DA-1241) is a novel G-Protein-Coupled Receptor 119 (GPR119) agonist with development optionality as a standalone and/or combination therapy for both MASH and type 2 diabetes (T2D). Agonism of GPR119 in the gut promotes the release of key gut peptides GLP-1, GIP, and PYY. These peptides play a further role in glucose metabolism, lipid metabolism and weight loss. Vanoglipel has beneficial effects on glucose, lipid profile and liver inflammation, supported by potential efficacy demonstrated during in vivo preclinical studies. The therapeutic potential of vanoglipel has been demonstrated in multiple pre-clinical animal models of MASH and T2D where vanoglipel reduced hepatic steatosis, inflammation, fibrosis, and improved glucose control. Furthermore, in Phase 1a, 1b and 2a trials, vanoglipel was well tolerated in both healthy volunteers and those with T2DM. In a Phase 2a clinical study, vanoglipel demonstrated direct hepatic action in addition to its glucose lowering effects.

About MetaVia

MetaVia Inc. is a clinical-stage biotechnology company focused on transforming cardiometabolic diseases. The company is currently developing DA-1726 for the treatment of obesity, and is developing Vanoglipel (DA-1241) for the treatment of Metabolic Dysfunction-Associated Steatohepatitis (MASH). DA-1726 is a novel oxyntomodulin (OXM) analogue that functions as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR) dual agonist. OXM is a naturally-occurring gut hormone that activates GLP1R and GCGR, thereby decreasing food intake while increasing energy expenditure, thus potentially resulting in superior body weight loss compared to selective GLP1R agonists. In a Phase 1 multiple ascending dose (MAD) trial in obesity, DA-1726 demonstrated best-in-class potential for weight loss, glucose control, and waist reduction. Vanoglipel is a novel G-protein-coupled receptor 119 (GPR119) agonist that promotes the release of key gut peptides GLP-1, GIP, and PYY. In pre-clinical studies, vanoglipel demonstrated a positive effect on liver inflammation, lipid metabolism, weight loss, and glucose metabolism, reducing hepatic steatosis, hepatic inflammation, and liver fibrosis, while also improving glucose control. In a Phase 2a clinical study, vanoglipel demonstrated direct hepatic action in addition to its glucose lowering effects.

For more information, please visit www.metaviatx.com.

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