MetaVia Presents Data on DA-1241, a GPR119 Agonist, Demonstrating Both Hepatoprotective and Glucose-Regulating Effects in Patients with Presumed MASH, at the EASL Congress 2025

May 7, 2025

DA-1241 Significantly Decreased Plasma ALT levels, with a Mean Reduction of 22.8 U/L After 16 Week-Treatment

Controlled Attenuation Parameter (CAP) Score Improved by 23.0 dB/m, Indicating Reduced Liver Fat Content

Improvement in Systemic Inflammatory and Fibrosis Biomarkers Supports Beneficial Effects on Liver Health

CAMBRIDGE, Mass., May 7, 2025 /PRNewswire/ -- **MetaVia Inc.** (Nasdaq: MTVA), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced that data from its Phase 2a clinical trial of DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist, in patients with presumed metabolic dysfunction-associated steatohepatitis (MASH), demonstrates both hepatoprotective and glucose-regulating effects. The data will be presented in late-breaking poster presentation at the European Association for the Study of the Liver (EASL) Congress 2025, taking place May 7-10, 2025, in Amsterdam, the Netherlands.

A total of 109 subjects with presumed MASH and qualifying baseline alanine transaminase (ALT) and imaging analysis were randomized to receive DA-1241 50 mg, DA-1241 100 mg alone, DA-1241 100 mg with a dipeptidyl peptidase 4 inhibitor (DPP4i), or placebo (PBO) in a 1:2:2:2 ratio, once daily for 16 weeks. The primary efficacy endpoint was the change from baseline in ALT after 16 weeks of treatment.

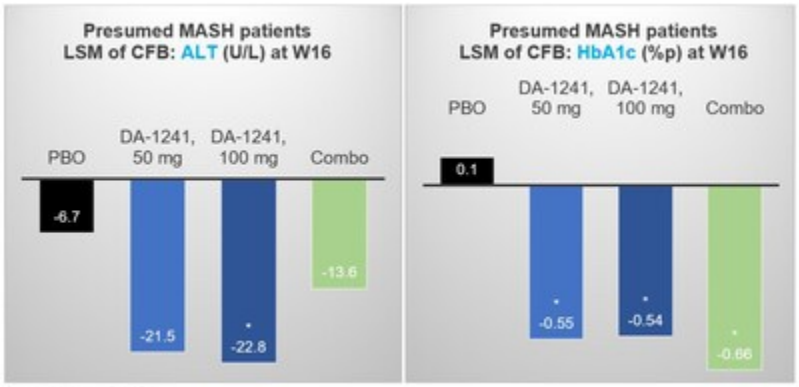
"The full data from our Phase 2 clinical study, as presented at the prestigious EASL Congress, confirm that DA-1241 is the first oral GPR119 agonist to demonstrate both hepatoprotective and glucose-regulating effects in presumed MASH patients," stated Hyung Heon Kim, President and Chief Executive Officer of MetaVia. "Importantly, treatment with DA-1241 significantly reduced key markers of liver injury, inflammation, and fibrosis, while also improving non-invasive liver assessments such as CAP and FibroScan-AST (FAST) scores. In addition, DA-1241 efficiently improved glycemic control in patients with comorbid prediabetes and type 2 diabetes. DA-1241 was well tolerated across patient groups, with a favorable safety profile. These results suggest that DA-1241's hepatoprotective effects are likely driven by its anti-inflammatory and anti-fibrotic actions rather than just glucose lowering, offering a promising multi-faceted therapeutic approach for patients at risk of progressive liver disease. Based on this data, we continue to believe that the novel mechanism of action of DA-1241 supports further development as either a monotherapy or combination therapy for MASH and metabolic diseases. We continue to conduct pre-clinical studies to explore other combination therapies for DA-1241, which may provide additional benefits to treat patients along the full spectrum on MASH. We look forward reviewing these findings at an end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in the first half of 2025."

In subjects with baseline ALT levels between 40 and 200 U/L, DA-1241 treatment led to dose-dependent reductions in ALT, with the 100 mg dose producing a significant 22.8 U/L decrease after 16 weeks ($p < 0.05$ vs. placebo). These effects were observed regardless of diabetes status and were accompanied by improvements in non-invasive tests (NITs) used to monitor MASH progression such as FAST, CAP, MRI-PDFF and NIS-4 score. Specifically, the average FAST score declined from 0.559 to 0.371, indicating improvements in liver fibrosis and fat accumulation. Liver fat, measured by CAP, was reduced by 23.0 dB/m with DA-1241 100 mg compared to just 1.4 dB/m with placebo.

Importantly, the 100 mg dose significantly lowered biomarkers of systemic inflammation (hs-CRP, CCL2) and fibrosis (TIMP1) ($p < 0.05$ vs. placebo), consistent with results from MASH mouse studies. Cytokeratin 18, a marker of liver cell death, also decreased significantly by 30.5% ($p < 0.05$ vs. placebo).

Beyond liver-related outcomes, DA-1241 100 mg produced rapid and significant reductions in hemoglobin A1c (HbA1c) of 0.37%p, 0.41%p, and 0.54%p at weeks 4, 8, and 16, respectively, from a baseline of 6.99%—despite nearly half of the participants being non-diabetic ($p < 0.05$ vs. placebo). In the subgroup of presumed MASH patients with type 2 diabetes, HbA1c decreased by 1.08%p. When 100 mg DA-1241 was co-administered with a DPP4 inhibitor pill preventing degradation of endogenous GLP-1, metabolic benefits were further enhanced without causing weight loss.

DA-1241 was well tolerated among presumed MASH patients, with no treatment-emergent adverse events (TEAEs) leading to discontinuation, except for one case in the placebo group.



* p<0.05 vs. placebo

Presentation Details:

- **Title:** *DA-1241, a GPR119 Agonist, Demonstrates Hepatoprotective and Glucose-Regulating Effects in a 16-week Randomized Placebo-Controlled Trial in Presumed Metabolic Dysfunction-Associated Steatohepatitis (MASH) Patients*
- **Presenting Author:** Rohit Loomba, MD, MHSc, Professor of Medicine in the Division of Gastroenterology, and Adjunct Professor in the Division of Epidemiology at University of California, San Diego.
- **Final Abstract ID:** LBP-005
- **Session:** Late Breaker Posters
- **Presentation Start:** May 7, 2025, 8:30 am CET

A copy of the poster is available on the Posters section of the MetaVia website.

About DA-1241
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. DA-1241 has beneficial effects on glucose, lipid profile and liver inflammation, supported by potential efficacy demonstrated during in vivo preclinical studies. The therapeutic potential of DA-1241 has been demonstrated in multiple pre-clinical animal models of MASH and T2D where DA-1241 reduced hepatic steatosis, inflammation, fibrosis, and improved glucose control. Furthermore, in Phase 1a, 1b and 2a trials, DA-1241 was well tolerated in both healthy volunteers and those with T2DM. In a Phase 2a clinical study, DA-1241 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 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. DA-1241 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, DA-1241 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, DA-1241 demonstrated direct hepatic action in addition to its glucose lowering effects.

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

Forward Looking Statements
Certain statements in this press release may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believes", "expects", "anticipates", "may", "will", "should", "seeks", "approximately", "potential", "intends", "projects", "plans", "estimates" or the negative of these words or other comparable terminology (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this press release, including, without limitation, those risks associated with MetaVia's ability to execute on its commercial strategy; our expectations regarding the sufficiency of our existing cash on hand to fund our operations; the timeline for regulatory submissions; the ability to obtain regulatory approval through the development steps of MetaVia's current and future product candidates; the ability to realize the benefits of the license agreement with Dong-A ST Co. Ltd., including the impact on future financial and operating results of

MetaVia; the cooperation of MetaVia's contract manufacturers, clinical study partners and others involved in the development of MetaVia's current and future product candidates; potential negative interactions between MetaVia's product candidates and any other products with which they are combined for treatment; MetaVia's ability to initiate and complete clinical trials on a timely basis; MetaVia's ability to recruit subjects for its clinical trials; whether MetaVia receives results from MetaVia's clinical trials that are consistent with the results of pre-clinical and previous clinical trials; impact of costs related to the license agreement, known and unknown, including costs of any litigation or regulatory actions relating to the license agreement; the effects of changes in applicable laws or regulations; the effects of changes to MetaVia's stock price on the terms of the license agreement and any future fundraising; and other risks and uncertainties described in MetaVia's filings with the Securities and Exchange Commission, including MetaVia's most recent Annual Report on Form 10-K. Forward-looking statements speak only as of the date when made. MetaVia does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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