



MEMORANDUM

Altimune 1Q26 – Global phase 3 PERFORMA trial of pemvidutide in MASH expected to initiate in 2H26, trial design submitted to FDA/EMA – May 13, 2026

Executive Highlights

- **Altimune presented its 1Q26 results today** in a call led by new CEO Mr. Jerry Durso, CMO Dr. Christophe Arbet-Engels, Chief Commercial Officer Ms. Linda Richardson, and CFO Mr. Gregory Weaver. See the [webcast](#) and [press release](#).
- **In MASH**, pemvidutide (GLP-1/glucagon RA) remains Altimune's primary strategic focus as the company seeks to establish a differentiated therapy for patients with metabolic liver disease. Management shared that the company is preparing to initiate its global phase 3 [PERFORMA](#) trial in 2H26. The finalized protocol has been submitted to regulatory agencies and aligns with FDA and EMA feedback. A 52-week readout expected in 2029.
 - MASH remains a major unmet need in liver disease, with limited approved therapies (Madriral's Rezdiffra and Novo Nordisk's Wegovy) and growing concern around progression to fibrosis, cirrhosis, liver failure, and transplant. Altimune is positioning pemvidutide as a potentially differentiated option within the increasingly competitive incretin landscape, emphasizing its direct glucagon-mediated liver effects, favorable tolerability profile, simple titration strategy, and potential to preserve lean muscle mass during chronic treatment.
- **Management highlighted a simple titration strategy** and established phase 2b data, which supported an FDA Breakthrough Therapy Designation and will be presented at [EASL 2026](#) on Thursday afternoon, May 28.
- **Altimune did not offer any new updates on its previously discontinued phase 3 [VELOCITY](#) program (n=5,000) of pemvidutide for obesity.** The company said it would not advance the program without a partner, which it continues to seek, and has instead decided to focus on serious liver disease, where obesity is a comorbidity.

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Pipeline Highlights

1. Global phase 3 PERFORMA trial design for pemvidutide in MASH finalized and submitted to FDA/EMA; trial to initiate in 2H26 and will include a higher dose

Management emphasized today that Altimune's primary focus remains advancing pemvidutide (GLP-1/glucagon RA) in MASH. Accordingly, the company is preparing to initiate its global phase 3 PERFORMA trial in 2H26. Notably, the trial protocol (randomized and placebo-controlled) has been finalized and submitted to the FDA. Its design aligns with FDA and EMA feedback, therefore positioning the study to support global regulatory filings. A 52-week data readout is expected in 2029. The company's current efforts are focused on contract research organization coordination, site activation, and building global support to allow rapid enrollment once screening begins.

- **The phase 3 trial will also investigate a higher 2.4 mg dose, compared to the 1.8 mg dose used in the phase 2 trial.** The 2.4 mg dose demonstrated additional weight loss in earlier phase studies, which may translate into improved liver outcomes. The PERFORMA study design also introduces a 1-2 step titration schedule, which begins at an active 1.2 mg dose and escalates patients to 1.8 mg or 2.4 mg over four-week intervals.

The phase 3 program was informed by positive phase 2b [IMPACT trial](#) (n=227) data, which was announced in [December 2025](#):

- **At 48 weeks, pemvidutide achieved [statistically significant reductions](#) (p<0.001) in enhanced liver fibrosis (ELF) and liver stiffness measurement (LSM) tests compared to placebo.** Specifically, pemvidutide achieved mean ELF score reductions from baseline of 0.49 and 0.58 for the 1.2 mg and 1.8 mg doses, respectively, versus an increase of 0.16 with placebo. In the LSM test, the 1.2 mg and 1.8 mg doses of pemvidutide achieved mean reductions from baseline of 3.04 and 3.97, respectively, compared with 0.03 in the placebo group. Overall, 28% of participants receiving pemvidutide 1.2 mg or 1.8 mg achieved both a ≥ 0.5 reduction in ELF and a $\geq 30\%$ reduction in LSM, versus 3% of patients treated with placebo. Pemvidutide also conferred statistically significant reductions in non-invasive measures of liver health and inflammation, including: (i) liver fat content, (ii) alanine aminotransferase, and (iii) corrected T1.
 - **Pemvidutide continued to demonstrate a favorable tolerability profile at Week 48.** No patients treated with pemvidutide 1.2 mg and 1.8 mg discontinued due to adverse events, compared to 4% in the placebo group. There were no reports of serious adverse events related to pemvidutide.

Critically, management emphasized pemvidutide's potential in chronic use. The company believes its therapeutic profile could address an emerging unmet need among patients who cannot tolerate existing GLP-1 RAs. Management highlighted today that pemvidutide can confer "quality weight loss," referencing its ability to preserve lean muscle mass. This feature is especially relevant for the MASH population, which is typically older and at elevated risk for sarcopenia. Phase 2 data have previously suggested that pemvidutide has a lower impact on lean mass than traditional GLP-1 RAs, and management is positioning this as a clinically meaningful advantage, as loss of lean mass is associated with worse metabolic function, reduced mobility, and a higher risk of adverse outcomes in this population.

In 1Q26, pemvidutide was granted Breakthrough Therapy Designation by the FDA based on 24-week data from the phase 2b [IMPACT trial](#) (n=227). The company plans to host multiple sessions at [EASL 2026](#) in Barcelona, including a late-breaking oral presentation on the 48-week phase 2 results for pemvidutide in MASH on Thursday afternoon, May 28. Additionally, pemvidutide will be featured in several posters on fibrosis regression, non-invasive test responses, and cardiovascular risk factors.

2. Topline data for phase 2 trial of pemvidutide in alcohol-associated liver disease expected 3Q26

Pemvidutide continues to be investigated for alcohol use disorder (AUD) and alcohol-associated liver disease (ALD) in multiple phase 2 trials. The phase 2 [RESTORE](#) trial (n=100) continues to evaluate pemvidutide for ALD with a 48-week randomized, placebo-controlled design. The study is assessing the safety and efficacy of pemvidutide

versus placebo on liver-related non-invasive tests, markers of alcohol consumption, and body weight. Management noted that RESTORE is actively recruiting and now expects enrollment completion in 3Q26. The study intends to further characterize pemvidutide's potential role across alcohol-related liver disease.

Financial and Leadership Highlights

1. Cash and cash equivalents increase to \$331 million (+21% Q/Q); R&D for pemvidutide development decreases 12% Q/Q due to IMPACT trial completion

Cash, cash equivalents, and short-term investments totaled \$332 million at the end of 1Q26. This balance reflects proceeds from a \$75 million registered direct offering completed in [January 2026](#) and \$8.9 million raised via the At-the-Market (ATM) facility during [1Q26](#).

In [April 2026](#), Altimune also completed an oversubscribed public offering of common stock, pre-funded warrants, and stock warrants, which raised \$225 million in gross proceeds. After this transaction, Altimune reports \$535 million in cash, cash equivalents, and short-term investments as of April 30, 2026. Management said that its operating cash runway will now extend through the 52-week data readout of the phase 3 PERFORMA trial of pemvidutide in MASH, which is expected in 2029. Net loss for 1Q26 totaled \$22.6 million, up 15% from 1Q25.

- **R&D expenses totaled \$16.2 million in 1Q26, up 3% from 1Q25 and down 12% sequentially.** The increase from 1Q25 was attributed to ongoing phase 2 trials in AUD and ALD, as well as startup costs associated with the PERFORMA phase 3 MASH trial. These were partially offset by lower expenses following completion of the phase 2b IMPACT trial of pemvidutide for MASH in 4Q25. Of the 1Q26 R&D spend, \$9.5 million represented direct costs related to pemvidutide development, up 3% from 1Q25. By indication, \$3.7 million was allocated for MASH and \$4.2 million was spent to support the phase 2 AUD and ALD programs.

Analyst Q&A

On Altimune's EASL presentations

Q (Ms. Ellie Merle, Barclays Capital, Inc.): You announced this morning some presentations at EASL. Can you go into some more details on what new information we'll learn from these?

A (Dr. Christophe Arbet-Engels, Chief Medical Officer): The different presentations we're bringing to EASL will cover our qFibrosis data and additional evidence of early fibrosis. The anti-fibrotic effects that we had at 24 weeks on our biopsy are a different type of reading from the AI-generated read. We're going to take a look at our weight loss and potential lipid data and associated cardiovascular risk in this population. Very importantly, we'll share our 48-week data in our oral presentation.

On pipeline

Q (Dr. Roger Song, Jefferies): Since you're finalizing the Phase 3 MASH trial starting in the second half, I'm curious if any interim analysis has been updated to the design for security or the sample size adjustment. And then on AUD, can you elaborate on what will be the “go” versus “no-go” decision criteria before you can commit to more investment to the pivotal stage?

A (Dr. Arbet-Engels): Regarding MASH, the study is designed as an event-driven study to reach the final clinical outcome for final registration. **We have an interim analysis planned at 52 weeks based on biopsy data to support accelerated approval; we expect that readout in 2029.** There is no other interim analysis planned beyond these two, as we are, again, very well-powered.

A (Mr. Jerome B. Durso, Chairman, President, and CEO): We're definitely encouraged by all the interest emerging in the AUD indication overall and look forward to the readout, which we expect next quarter at this point. Obviously, we'll assess the data fully once we get it, and we'll disclose that to the market. We will also then undertake conversations

with regulators. All these factors will inform how we evaluate potential value.

If we believe there's value in moving ahead with that indication, then we will definitely prefer to explore non-dilutive funding options for moving that program ahead. The next important step for us is to get the Phase 2 data readout. That'll give us some additional insight on an indication where we think pemvidutide can play a unique role — potentially not only on drinking, but also the direct liver benefit, which is such an important part of that disease as it progresses.

Q (Ms. Annabel Samimy, Stifel, Nicolaus & Co.): Given that semaglutide recently showed some pretty meaningful data in AUD with the addition of glucagon, are there any measurements that you're looking at for AUD that could show the benefit of the direct liver targeting that you'll have with pemvidutide over Wegovy? Is there anything else you are incorporating into the trial to further differentiate pemvidutide from Wegovy, given that Wegovy might be generic by the time you reach market? And, in terms of the clinically meaningful endpoints, you have heavy drinking days and abstinence. Is it clear what the final endpoints should be for Phase 3, from a regulatory perspective?

A (Dr. Arbet-Engels): We're excited to see the semaglutide data, because this is clearly validating the hypothesis that pemvidutide has a real potential in this population. The glucagon addition is a really important differentiator. There have been presentations at past scientific conferences that these patients have early markers of liver disease, including steatosis, inflammation, and even early fibrosis. This is why targeting the liver is really critical, but the GLP-1 RA alone cannot achieve this since there is no GLP-1 receptor in the liver. In our study, we have specific markers of liver health. We will evaluate all the resulting data to determine how to best incorporate those differentiation factors into our phase 3 and the registration program. We believe here that we have a product that is really well-suited for this population.

The last piece that I would remind you about is the treatment adherence and tolerability in a population that is fairly healthy otherwise. If we continue to show what we've seen in our IMPACT Phase 2 MASH data, pemvidutide should, again, have a clear advantage.

Regarding the endpoints for Phase 3, the FDA has proposed two endpoints: the zero drinking days and heavy drinking days. What we will explore is a change in those two steps — two levels in the WHO drinking.

Q (Dr. Michael DiFiore, Evercore Group): At your December IMPACT call, you said that there was no obvious path to re-evaluate the 24-week biopsy data in an AIM-MASH-like way because Liver Explore is a different quantitative tool. That said, the EASL poster now says quantitative digital pathology showed fibrosis regression at 24 weeks, so can you clarify what exactly is new in that analysis? Secondly, given Roche's proposed acquisition of PathAI, does that change anything in how you plan to incorporate AI and MASH Assist into the Phase 3 biopsy read process?

A (Mr. Durso): There are a lot of different AI tools, so it is a little important to track exactly which one is being used where. On the acquisition of PathAI by Roche Diagnostics, the teams are working extremely closely between Altimmune and Path on the Phase 3 incorporation of the AIM-MASH Assist tool. That conversation has continued fully since the announcement, and we don't anticipate any change to the process.

A (Dr. Arbet-Engels): We are going to be the first registration study using AIM-MASH Assist, so we are collaborating with the best AI team really closely. There's no change there; we're just continuing to move forward directly. It's a little bit of a different approach with qFibrosis. Essentially, it subtracts the steatosis through an AI process to allow for a more accurate reading of the fibrosis itself.

We believe that pemvidutide is decreasing MASH or leading to MASH resolution very rapidly and very early, which can sometimes make it harder for the pathologist to identify the changes in the fibrosis. We're really excited about showing these data, which demonstrate very clear anti-fibrotic effects early, even at 24 weeks at EASL.

Q (Ms. Arabella Ng, Wainwright & Co.): Will PERFORMA use a prefilled syringe or auto-injector? If it is in an auto-injector, have you secured a partner for that? Generally, are there any gating items you need to complete before you initiate the trial?

A (Mr. Durso): I'll stress that we're currently in the full startup phase on the trial, so it's about establishing the global infrastructure, ensuring the vendors are online and ready, initiating the trial sites, and ensuring that the clinical supply chain is ready to support the initiation. All of that activity is ongoing. The start of the trial with initiation in the second half is what we're moving towards.

A (Dr. Arbet-Engels): For the PERFORMA Phase 3 study, we're not using the auto-injectors. We're going to do a separate comparison study on the auto injectors at launch. We've got some good adherence with our approach right now in Phase 2, and we'll continue using that approach to have the auto-injector ready for launch.

Q (Ms. Corinne Johnson, Goldman Sachs): In terms of digital pathology fibrosis, how should we think about translating the outcomes based on these measures of fibrosis improvement as they will be evaluated in the Phase 3 trial?

A (Mr. Durso): First, the regulatory path requires biopsies, and the digital pathology has different aspects to aid these evaluations. There's the AIM-MASH Assist, which is a tool that assists the pathologists in reading features on the biopsy slides. This should be able to decrease the variability and increase consensus between pathologists as they're all prompted to look for the same features.

One approach relates to some things we've done in our Phase 2 study on Liver Explore, which yielded highly significant results at 24 weeks, demonstrating the impact on fibrosis directly in a continuous manner.

Another approach, which we're presenting at EASL, is qFibrosis. Because pemvidutide reduces fat in the liver very rapidly, it becomes a little more challenging for the pathologist to read fibrosis changes around the 24-week mark. Being able to "subtract" the fat from the image allows for more consistent staging of the fibrosis. So these will be added during assessment to confirm biopsy reads from the pathology through to AIM-MASH Assist. In Phase 3, the primary endpoint will be done on the biopsy, using the AIM-MASH Assist tool for further reading. We'll have a large amount of evidence to cross-reference at the end of the 52-week study for accelerated approval.

On the titration strategy

Q (Dr. Kripa Devarakonda, Truist Securities): On the Phase 3 trial design, beyond the 52-week biopsy endpoint, I was wondering if you could provide a few more details on moving from the no-titration Phase 2 to starting with 1.2 mg and titrating. What is the rationale for this strategy? And then with the inclusion of both the 1.8 mg and the 2.4 mg arms for the primary endpoint, what is the statistical design there?

A (Dr. Arbet-Engels): First, our 48-week data show that basically the 1.2 and the 1.8 mg doses are efficacious. Our 1.2 mg dose had survivability similar to placebo, and the 1.8 mg had a little more GI effect when administered without titration. We believe there is an upside in offering patients a step-titration to help them improve tolerability, particularly for GI adverse effects occurring within the first four weeks. Starting at the 1.2 mg "placebo-like" dose should help with tolerability.

Regarding the statistical design, we've established two primary arms. Our first key 1.8 mg dose is based on our Phase 2 data. The data demonstrates its efficacy, and on top of this, the tolerability at 48 weeks confirms this choice. That's our "anchor" dose. We have also seen added weight loss in the obesity program with the 2.4 mg.

Based on this, we believe that there is a potential for added efficacy, which is why we included it. On the powering and the statistical approach, we've taken the more conservative approach, using both the 1.8 and the 2.4 milligram arms, to monitor added benefits for these patients.

On the long-term use of pemvidutide

Q (Dr. William Wood, B. Riley Securities): I'm curious how you're seeing the long-term treatment of patients with MASH on pemvidutide. Have you evaluated dose reductions or what happens when patients reduce dose potency or frequency? Is this expected to be investigated in upcoming trials or the Phase 3 readout? On the expected EASL data, will we be getting data on visceral adipose tissue, given what we've seen on CV benefits?

A (Dr. Arbet-Engels): On the dose reduction, this is something that we've explored in our Phase 2. We have seen very few patients discontinue, but we will be looking into this further. In our Phase 3, we have put in place increases all the way through to 2 mg, although patients can decide to reduce the dose. However, we are incentivizing the patients to stay at the most efficacious dose, which is 1.8 mg dose, or even all the way to 2.4 mg.

There is a whole system put in place to really have those efficacious doses tested, including on GI tolerability. We believe even with the current titration schemes that we proposed, that we're going to be able to eliminate most of those

and limit those effects to just a few patients.

On the lipids and the cardiovascular risk, we'll be looking at the lipid profile. We have shown some lipid benefits through our previous studies, but we don't have fat assessments in the poster itself.

On comparison to other incretins

Q (Mr. Jonathan Wolleben, Citizens JMP Securities): MASH trials are large and take a long time to run, but incretin trials go pretty fast. Do you think the pace of enrollment will be faster than expected in the MASH trial because of the potential obesity benefit? Additionally, big picture wise, you guys talked a little bit about differentiation. We're seeing more and more triple agonists get announced. Do you think that down the road, dual agonists will be leapfrogged by the triples that are becoming more popular?

A (Mr. Durso): We are expecting that the weight loss benefit, to your first question, and the overall profile of pemvidutide will help. We've seen in the other trials that the speed of the incretin trials typically goes quickly. We're building a robust study here, but we're targeting for good, efficient, effective enrollment, and the weight loss profile is one of the components that we think will help with that.

A (Dr. Arbet-Engels): Design of the study is also attractive because we have a couple of cohorts, increasing the chances for all patients and PIs to be included. The rate of enrollment is much higher for obesity when there are weight loss features, which are included in our developed study design.

A (Ms. Linda M. Richardson, CCO): We have an opportunity with pemvidutide to stand out by focusing on its direct-acting liver benefits via glucagon and our specific 1:1 GLP-1/glucagon ratio. The package of benefits that we're seeing is very competitive, even against "metabolic forward" triple agonists. Those agents have not defined their direct-acting components as clearly as we have with our 1:1 ratio. We offer, with our safety profile, the ability to be used in combination with other agents if needed. We're delivering the full package and our titration, unlike some of these others, is very simple.

We're seeing ourselves as a well-rounded package that can hold our own due to observed early, sustained effects with weight loss, with the 2.4 mg dose potentially offering even greater anti-fibrotic and weight benefits.

We'll keep an eye on the market, but I think looking at even our quality of weight loss could be a differentiator. You're not dumping a ton of weight right away, preventing excessive loss of muscle mass. We're confident in our ability to differentiate the benefits of pemvidutide in our Phase 3 and associated trials to make sure we have a very solid place in the MASH landscape.

Q (Dr. Andy T. Hsieh, William Blair & Co.): On the GLP-1/glucagon competitive asset, survodutide, that is going to be presented at ADA, how would you interpret both the obesity dataset and also the NAFLD dataset without biopsy? Second, you mentioned tolerability a lot during the call. Looking back at the Phase 2 trials that you've conducted, including MOMENTUM and IMPACT, do you have any persistence or adherence data?

A (Mr. Durso): On adherence, we do see in the 48-week data, when we talk about the strong tolerability profile, that a large percentage of the patients on pemvidutide at both doses stayed on therapy even more than placebo. And when we talk about tolerability, we're not just talking about it as an avoidance of some side effects, but also being able to get to the effective dose and stay on therapy, which we know are important real-world treatment concerns for physicians.

A (Dr. Arbet-Engels): In IMPACT and MOMENTUM, we see a clear dose response in favor of the higher doses of pemvidutide, where patients stay on treatment. Especially on my end as a physician, in a chronic therapy setting, keeping the patients on an efficacious dose long-term is key to what we're trying to achieve here.

We also have anecdotal evidence from some of our PIs running different studies. They're telling us that other GLP-1 RAs or even triple agonists are very different from pemvidutide. The treatment satisfaction is much different, so we feel that we have some advantage here which is really important in chronic settings like MASH, AUD, ALD, et cetera.

On survodutide, they've seen weight loss similar to ours. The big challenge in my mind is back to that tolerability. They needed a very long titration to get up to their efficacious dose and have even set up some aspects where down-titrating requires a new scheme to restart the patients, which is absolutely not our case. You've seen how in Phase 2 we can jump patients straight into their 1.8 mg dose without any titration, and the discontinuation rate is almost one in four patients.

Survodutide looks more like GLP-1 with a little bit of glucagon. That's the 8:1 ratio. We believe our 1:1 ratio is really important. Again, I cannot reemphasize in a chronic setting the importance of having adherence to treatment and to an efficacious dose. This is key: patients will stay. I'm sure that payers will be very happy with this, but we've also seen it already in our study. We'll continue to look into it in the Phase 3 PERFORMA trial.

Close Concerns' Questions

1. Would Altimune consider pursuing a cardiovascular indication for pemvidutide in the future, pending phase 3 results for MASH?
2. Given the planned phase 3 data readout in 2029, when does Altimune anticipate pemvidutide becoming available to patients with MASH?
3. Does Altimune intend to pursue a pemvidutide indication for obesity at any point?

-- by *Elizabeth Rose, Milenka Min, Esther Min, and Kelly Close*