2026年7月16日

H.C. Wainwright & Co.による当社レポートの発表に関するお知らせ

現地時間の7月15日、当社が公表したALS対象の拡大アクセスプロトコール臨床試験の患者登録完了に関するプレスリリースに対し、米国ニューヨークに本拠を置く投資銀行 H.C. Wainwright & Co.のアナリストであるLander Egaña Gorroño氏らによる、当社レポートが発表されましたので、参考情報としてお知らせいたします。

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First Take

MediciNova, Inc. (MNOV)

July 15, 2026

Price: $1.37; Market Cap (M): $67; *7/14/2026 Close*

Rating: Buy; Price Target: $10.00

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Enrollment Completion in SEANOBI EAP Reinforces Ibudilast Momentum Ahead of COMBAT-ALS Readout by YE26

Our takeaways from SEANOBI-ALS EAP enrollment updates:

- Target enrollment of 200 patients completed in the NIH-funded EAP of ibudilast in ALS
- We expect SEANOBI to complement the randomized efficacy findings from COMBAT-ALS by providing supportive real-world biomarker and functional observations across a broader ALS population
- We remain focused on: 1) tipelukast topline Phase 2 NATG-202 data in 3Q26; and 2) ibudilast Phase 2b/3 COMBAT-ALS data by YE26 (potential to advance into registrational ALS studies and become the first genotype-agnostic, multi-target therapy for ALS)

SEANOBI EAP fully enrolled and on track to complement COMBAT-ALS. This morning, MediciNova announced that the target enrollment of 200 patients has been achieved in the SEANOBI Expanded Access Program (EAP) evaluating ibudilast in ALS patients. With funding from the National Institute of Neurological Disorders and Stroke (NINDS/NIH), the multicenter, open-label EAP offers access to ibudilast treatment to ALS patients who are not eligible to participate in the COMBAT-ALS randomized clinical trial, while also generating important biomarker (NfL) and clinical outcome (ALSFRS-R) data from a real-world ALS population (NCT06743776). Active participants in SEANOBI remain on track with treatment and protocol-specified follow-ups. Final patient follow-ups are projected to conclude in early 2027, triggering the data analysis phase. We believe this enrollment milestone underscores strong interest from the ALS community in ibudilast and its potential as a novel therapeutic option for ALS. Together with Orphan Drug Designations from the FDA and EMA, and Fast Track Designation from the FDA, ibudilast continues to advance toward potential approval for the treatment of ALS.

NATG-202 completion sets up key 3Q26 readout for tipelukast. Recently, MediciNova announced the completion of last patient last visit (LPLV) in the ongoing Phase 2 NATG-202 clinical trial evaluating tipelukast for the treatment of HTG and NAFLD associated with T2D. As a reminder, HTG and NAFLD are common metabolic conditions in T2D, and the prior, open-label, PoC, Phase 2 NATG-201 study showed greater TG reductions after tipelukast treatment in T2D patients. NATG-202 is a multi-center (U.S.), randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of tipelukast in ~40 T2D patients with HTG and NAFLD (NCT05464784). Participants (FibroScan score ≥ 248 dB/m, HbA1c >6.5 and ≤10% at screening, oral anti-diabetic therapy for ≥3 months, fasting TG levels >150 mg/dL at screening) were randomized (1:1) to receive either 500 mg/day of tipelukast or placebo for 24 weeks. The co-primary endpoints are change from baseline in liver fat content (FibroScan; controlled attenuation parameter (CAP) score) and change from baseline in fasting serum TG levels at week 24. Secondary endpoints include safety and tolerability, and changes in lipid profile. Topline data are expected in 3Q26. We believe that NATG-202 represents a key inflection point in assessing whether the drug demonstrates sufficient clinical signal (TG and fibrosis improvements) and tolerability to justify a larger Phase 3 trial and eventual regulatory filing. In addition, the trial should define the optimal endpoints for the later-stage study design. While several agents are in clinical development for the treatment of NAFLD, tipelukast is the only investigational asset targeting HTG and NAFLD due to T2D, representing a more holistic therapeutic approach, in our belief. Details on tipelukast's MoA, preclinical data demonstrating significant anti-fibrotic effects, and clinically meaningful triglyceride reductions in NAFLD patients with HTG can be found below and in: *A Novo Approach to Multi-Target Medicine; Initiating at Buy and $10 PT*.

Important clinical inflection points for ibudilast and tipelukast in the year ahead. MediciNova entered 2026 fully focused on its core pipeline assets, including ibudilast (MN-166), currently in Phase 2b/3 studies for amyotrophic lateral sclerosis (ALS), and tipelukast (MN-001), under Phase 2 evaluation for the treatment of hypertriglyceridemia (HTG) and nonalcoholic fatty liver disease (NAFLD) in patients with type 2 diabetes (T2D). As a reminder, Ibudilast demonstrated stabilization or improvement in several functional ALS scores and prolonged survival in Phase 2 studies. The ongoing Phase 2b/3 COMBAT-ALS trial aims to validate ibudilast's longer-term efficacy in a larger ALS population, and inform next regulatory/clinical steps (topline data by YE26). For tipelukast, following preclinical data demonstrating significant anti-fibrotic effects, and clinically meaningful triglyceride reductions in NAFLD patients with HTG, which were greater in those with concomitant T2D, results from the ongoing Phase 2 NATG-202 trial (topline data in 3Q26) aim to support a registrational trial in T2D patients with HTG and NAFLD. Current cash position of $27.3 million should provide runway through ibudilast (Phase 2b/3) and tipelukast (Phase 2) readouts and, if results are positive, the initiation of later-stage trials. See additional details from both programs below, and in our initiation report: *A Novo Approach to Multi-Target Medicine; Initiating at Buy and $10 PT*. We believe that ibudilast and tipelukast are well-positioned to achieve favorable data-driven clinical milestones and progress in their respective indications, and look forward to upcoming updates.

Early functional and survival signals meet ibudilast's late-stage validation; Phase 2b/3 COMBAT-ALS data by YE26. MediciNova in-licensed ibudilast from Kyorin Pharmaceutical (TSE:4569; OTC:KYRNF; not rated) in 2004, following approval in Japan and South Korea for the treatment of asthma and post-stroke complications (i.e. dizziness) in the late 1980s. Ibudilast is a multi-target, oral small molecule inhibitor of phosphodiesterase (PDE), macrophage migration inhibitory factor (MIF), and toll-like receptor (TLR)-mediated pathways, that presents a multi-modal anti-inflammatory and neuroprotective MoA. The responder analysis from the Phase 2 ALS-1201 clinical trial evaluating ibudilast, in combination with riluzole SoC, in 49 ALS patients showed higher rates of stable or improved ALS Functional Rating Scale-Revised (ALSFRS-R), manual muscle testing (MMT), and five-item ALS Assessment Questionnaire (ALSAQ-5) scores at month six compared to the placebo + riluzole group. In addition, subjects who completed six or 12 months of treatment exhibited improved survival (p=0.0025) of up to 30 months following treatment. Ibudilast was generally safe and tolerable when administered with riluzole. While we acknowledge ALS-1201's single-site risk and the potential confounding effect of riluzole combination, our positive view is primarily driven by the favorable ALSFRS-R outcomes. Notably, prior late-stage ALS trials have shown that investigational therapies often struggle to sustain long-term functional ALSFRS-R improvements and meet clinical endpoints. We expect the ongoing Phase 2b/3 COMBAT-ALS trial to validate prior efficacy (functional and survival) and safety signals in a larger population in the longer-term (12 months), and inform next steps for ibudilast, including potential progression to regulatory filing or a confirmatory pivotal trial. Enrollment in COMBAT-ALS has been completed with a total of 234 randomized patients, and topline data are anticipated by YE26. While COMBAT-ALS does not incorporate prespecified biomarker endpoints, the ongoing NIH-supported SEANOBI Expanded Access Program (EAP) aims to generate meaningful neurofilament light chain (NfL) and clinical outcome (ALSFRS-R) data from the real-world ALS population. We believe that its broad, genotype-agnostic, and multi-modal approach, together with Phase 2 evidence of favorable safety and efficacy, support the clinical and regulatory advancement of ibudilast as a novel treatment to delay ALS disease progression.

Tipelukast set to reshape the HTG-NAFLD-T2D axis; Phase 2 NATG-202 data in 3Q26. Tipelukast was in-licensed from Kyorin in 2002 as an orally bioavailable small molecule with multiple MoA targeting inflammation (5-lipoxygenase (5-LO)/ leukotriene (LTs), PDE, and CD36 pathways), fibrosis, and lipid metabolism. Preclinical studies demonstrated anti-fibrotic effects in livers from NAFLD animal models, and inhibition of triglyceride (TG) biosynthesis and lipid-modifying activity in hepatotoxic and monocytic human cell lines, respectively. Of note, HTG, NAFLD, and T2D are pathophysiologically interconnected through systemic insulin resistance, dysregulated lipid metabolism, and chronic inflammation, forming a self-reinforcing metabolic axis. An open-label Phase 2 trial in patients with NAFLD and HTG (n=14) showed that tipelukast treatment led to early serum TG reductions (28.8%; p=0.00006) at week eight. Interestingly, subgroup analyses demonstrated that compared to participants without T2D (n=9), T2D patients (n=10) showed greater TG reductions at week eight (50.8% vs. 17.8% reduction in non-T2D), and a greater high-density lipoprotein cholesterol (HDL-C) increases (15.8% vs. 1.0% in non-T2D; p<0.0002), strengthening the case for prioritizing T2D patients in further clinical evaluation. There were no clinically significant safety and tolerability issues related to tipelukast. The Phase 2 NATG-202 trial is evaluating tipelukast in T2D patients with HTG and NAFLD over 24 weeks. Enrollment has been completed, and topline data are anticipated in 3Q26.

Broad indication optionality strengthens strategic collaboration prospects for ibudilast. MediciNova structures its pipeline around internally-funded core programs (strategic priority; ALS and HTG/NAFLD/T2D) and a capital-efficient, non-core portfolio characterized by a differentiated "platform-in-a-molecule" approach focused on ibudilast. The likelihood of ibudilast's multi-indication potential is reinforced by its multi-modal MoA and extensive human safety data pre- and post-approval in Japan and South Korea. This model enables focused investment in priority indications (ALS) while expanding the clinical reach of ibudilast through external collaborations. We view the non-core pipeline as a meaningful value driver for the company, offering: 1) capital-efficient development with

minimal internal R&D spend; 2) diversified clinical risk for ibudilast beyond ALS; and 3) a strategic pathway to potential partnerships for late-stage development and commercialization. Collectively, this framework enhances both downside protection and long-term optionality across indications, in our belief. Non-core programs include clinical development in progressive multiple sclerosis (MS; Phase 2b completed), substance dependence (Phase 2 ongoing in methamphetamine dependence), chemotherapy-induced peripheral neuropathy (CPIN; Phase 2b ongoing), degenerative cervical myelopathy (DCM; Phase 3 ongoing), glioblastoma (Phase 1/2 completed), acute respiratory distress syndrome (ARDS; Phase 2 completed), and Long COVID (Phase 2/3 ongoing). On top of ALS, the FDA granted Fast Track designations to ibudilast for the treatment of progressive MS and methamphetamine dependence. With respect to the lead, non-core MS program, ibudilast showed ability to significantly reduce the rate of whole-brain atrophy (48% reduction) vs. placebo (p=0.04) in these patients. Ibudilast also demonstrated a 26% reduction (HR=0.74) in the risk of confirmed disability progression, with the greatest benefits observed in secondary progressive MS patients without relapse (46% risk reduction; HR=0.538). MediciNova finalized the design of a future registrational trial, and the progressive MS program is Phase 3-ready pending potential collaborators and/or partnerships.

Valuation and Risks. We maintain our Buy rating and $10 price target. Our valuation is based on our clinical net present value (NPV) model, which allows us to flex multiple assumptions affecting a drug's profile. We currently value MediciNova based on the contribution of its core clinical-stage assets, ibudilast (MN-166) in ALS (15% PoS; 33% contribution) and tipelukast (MN-001) for the treatment of HTG and NAFLD due to T2D (20% PoS; 67% contribution) in the U.S. Moving forward, we believe significant upside potential exists based on: (1) attaining higher market penetration than currently projected in the above-mentioned indications; (2) augmenting projected chances of success based on the progress of the clinical candidates; (3) adding additional commercial geographies; and (4) progress of non-core programs through licensing deals and/or collaboration agreements. Risk factors that could impede reaching our PT include failed or inconclusive clinical trials, the inability of the company to secure adequate funding to progress its drugs through the development pathway or the occurrence of dilutive capital raises.

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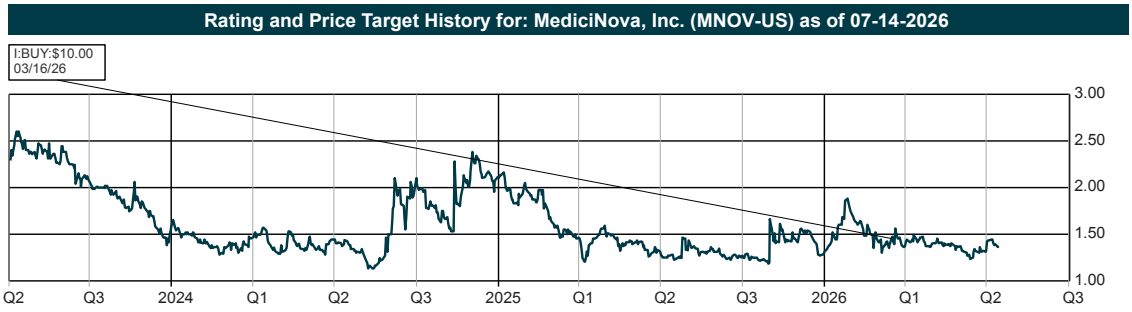

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			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
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Neutral	47	7.41%	12	25.53%
Sell	2	0.32%	0	0.00%
Under Review	53	8.36%	22	41.51%

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