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Monopar Therapeutics

Monopar Announces Publication of Phase 2 Study Demonstrating ALXN1840 Significantly Improves Copper Balance in Patients with Wilson Disease

WILMETTE, Ill., May 19, 2026 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. ("Monopar" or the "Company") (Nasdaq: MNPR), a clinical-stage biopharmaceutical company developing innovative treatments for patients with unmet medical needs, today announced that *Hepatology Communications* has published a peer-reviewed manuscript entitled "Effect of Tiomolibdate Choline on Copper Balance in Patients with Wilson Disease: an Open-label Phase 2 Trial."

The publication, which can be found at (link), reports results from the Phase 2 ALXN1840-WD-204 study (NCT04573309) and demonstrates that ALXN1840 (tiomolibdate choline) produces a rapid, statistically significant, and sustained improvement in daily copper balance in patients with Wilson disease, driven by increased fecal copper excretion.

Wilson disease is a rare and progressive genetic condition in which the body's pathway for removing excess copper is compromised, leading to damage from toxic copper build-up in organs such as the liver and brain.

The open-label, single-arm Phase 2 trial evaluated daily dosing of ALXN1840 in nine patients with Wilson disease across two centers in the United Kingdom and New Zealand. Patients were admitted to a clinical research unit and initiated on a copper-controlled diet, with all copper intake and output collected during a pre-treatment baseline period and after initiation of daily ALXN1840 over multiple weeks.

The publication builds on a recently published peer-reviewed *Journal of Hepatology* Letter to the Editor (link), which highlighted the importance of comparing outcomes to a pre-treatment baseline to accurately assess the effect of a potential Wilson disease treatment on copper balance.

Key findings reported in the publication:

- Statistically significant reduction in daily copper balance from baseline, due to increased fecal copper excretion
- Cumulative mean decrease from baseline in copper balance of -6.08 mg over 21 days (95% CI: -10.18 mg to -1.98 mg)
- Mean daily copper balance change from baseline of -0.37 mg (p=0.005) during the 15 mg/day treatment period and -0.29 mg (p=0.023) through the overall study period
- Approximately 50% increase in the daily fecal copper output-to-intake ratio compared to baseline (p=0.041)
- Immediate increases in plasma total copper and directly measured non-ceruloplasmin-

bound copper (dNCC), consistent with copper mobilization and formation of stable albumin tripartite complexes (ATCs) consisting of copper, ALXN1840, and albumin
- ALXN1840 was generally well tolerated; no serious adverse events were reported

Notably, the observed improvements in copper balance and copper mobilization occurred in a Wilson disease patient population with a mean prior current standard of care treatment duration of 16 years, suggesting that despite years of treatment with currently available therapies, patients present with a considerable amount of residual copper in the body that ALXN1840 is able to mobilize and eliminate. This finding is consistent with data from the completed 48-week Phase 3 trial, in which ALXN1840 demonstrated superior copper mobilization compared to standard of care even in patients with a mean prior standard of care treatment duration of 11 years.

“These findings highlight ALXN1840’s ability to rapidly improve copper balance in Wilson disease, reinforcing its promise as a meaningful new treatment option,” said Professor Aftab Ala, MBBS, MD, FRCP, PhD, Consultant Hepatologist at The Roger Williams Institute of Liver Studies, King’s College London, and King’s College Hospital, London, and lead author of the publication.

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company with late-stage ALXN1840 for Wilson disease, and radiopharmaceutical programs including MNPR-101-Zr (Phase 1) for imaging advanced cancers along with MNPR-101-Lu (Phase 1a) and MNPR-101-Ac (late preclinical) for the treatment of advanced cancers. For more information, visit: www.monopartx.com.

About ALXN1840

ALXN1840 (tiomolibdate choline, TMC) is a novel first-in-class Albumin Tripartite Complex (ATC) activator under investigation for the treatment of Wilson disease. ALXN1840 rapidly mobilizes and tightly sequesters excess copper in ATCs, suppressing its redox reactivity, limiting oxidative damage, and blocking transport across the blood–brain barrier. In the Phase 3 pivotal trial, ALXN1840 demonstrated rapid and sustained copper mobilization (primary endpoint) that was significantly greater than standard of care over 48 weeks in both previously treated and untreated patients. Durable clinical improvement and a favorable safety and tolerability profile were observed across 645 patient-years of follow-up in 266 patients.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “target” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Examples of these forward-looking statements include statements concerning: that these findings highlight ALXN1840’s ability to rapidly improve copper balance in Wilson disease, reinforcing its promise as a meaningful new treatment option. The forward-looking statements involve risks and uncertainties including, but not limited to: uncertainties related to the regulatory process that Monopar

intends to initiate related to ALXN1840 and the outcome thereof; the rate of market acceptance and competitiveness in terms of pricing, efficacy and safety, of any products for which Monopar receives marketing approval, and Monopar's ability to competitively market any such products as compared to larger pharmaceutical firms; Monopar's ability to raise sufficient funds in order for the Company to support continued preclinical, clinical, regulatory, precommercial and commercial development of its programs and to make contractual milestone payments, as well as its ability to further raise additional funds in the future to support any existing or future product candidate programs through completion of clinical trials, the approval processes and, if applicable, commercialization; and the significant general risks and uncertainties surrounding the research, development, regulatory approval, and commercialization of imaging agents and therapeutics. Actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in Monopar's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Monopar undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made. Any forward-looking statements contained in this press release represent Monopar's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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