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Monopar Therapeutics

Monopar Presents Phase 2 ALXN1840 Data Demonstrating Liver Disease Stabilization and Neurologic Improvement in Treatment-Experienced Wilson Disease Patients at EASL 2026

WILMETTE, Ill., June 01, 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 the presentation (link) of Phase 2 ALXN1840-WD-205 data at the European Association for the Study of the Liver (EASL) Congress 2026. In a presentation titled “ALXN1840 (tiomolibdate choline) Stabilizes Liver Disease and Improves Neurological Symptoms as well as Quality of Life in Treatment-Experienced Wilson Disease Patients,” lead author Valentina Medici, MD, Professor of Medicine at the University of California Davis, presented results from the open-label, multicenter Phase 2 trial evaluating the effects of ALXN1840 on liver pathology and clinical outcomes in heavily pre-treated patients with Wilson disease.

Wilson disease is a rare and progressive genetic condition caused by mutations in the ATP7B gene, 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. Today’s standard of care therapies carry significant safety risks, including paradoxical neurologic worsening, and require cumbersome multi-dose daily regimens.

The open-label, multicenter, pathologist-blinded Phase 2 trial evaluated ALXN1840 monotherapy over 48 weeks in 29 treatment-experienced (at least one year on standard of care) Wilson disease patients, with an optional 48-week extension period. The study population had extensive prior treatment, with a median duration of 13.8 years. Liver biopsy was performed at baseline and Week 48 to assess hepatic copper concentration, stage of fibrosis, and grade of steatosis. Neurologic, clinical, and quality-of-life outcomes were also assessed at baseline and Week 48, with patients continuing in the extension period assessed again at Week 96.

Key findings presented at EASL 2026:

- **Liver pathology stabilization and improvement:** By Week 48, among the 24 patients with paired biopsies, the preponderance demonstrated stabilization or improvement across histologic measures assessed, including hepatocyte necrosis (96%), steatosis grade (88%), lobular inflammation (79%), portal inflammation (71%), NAFLD Activity Score total (71%), hepatocellular ballooning (75%), and fibrosis stage (67%).
- **Hepatic copper concentration:** No statistically significant change in hepatic copper concentration after 48 weeks, consistent with published Wilson disease studies of

standard of care therapies showing hepatic copper remains stable or increases even after years on treatment.

- **Neurologic improvement:** Significant improvements in the Unified Wilson Disease Rating Scale (UWDRS) Part III score were observed at Week 48 ($p < 0.05$ vs. baseline).
- **Global clinical status:** Significant improvements in the Clinical Global Impressions (CGI) scale were observed at Week 48 ($p < 0.05$ vs. baseline).
- **Quality of life:** Significant improvements in patient-reported quality of life, as measured by the EuroQoL 5-Dimensions (EQ-5D) UK Health Index, were observed at Week 48 ($p < 0.05$ vs. baseline).
- **Safety:** ALXN1840 was generally well tolerated; most treatment-emergent adverse events were nonserious and Grade 1 or 2 in severity. A safety analysis of the extension period showed a consistent treatment-emergent adverse event profile.

These results, in a heavily pre-treated Wilson disease population, demonstrate that ALXN1840 can stabilize liver disease and provide clinically meaningful improvements in neurologic symptoms and quality of life. The neurologic and quality of life findings from this study complement the increased copper mobilization and clinical improvement shown in the completed Phase 3 pivotal trial (Study WTX101-301).

“These results are encouraging,” said Dr. Medici. “Despite heavy prior treatment, ALXN1840 was able to stabilize or improve liver pathology while simultaneously delivering meaningful and durable improvements in neurologic symptoms and quality of life. This underscores the potential of ALXN1840 to address important unmet medical needs in Wilson disease patients.”

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) 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. With a copper-binding affinity orders of magnitude greater than currently approved chelators, ALXN1840 is also uniquely capable of removing copper from metallothionein, directly protecting the liver. 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. An example of a forward-looking statement includes the statement concerning: that this (the Phase 2 study results) underscores the potential of ALXN1840 to address important unmet medical needs in Wilson disease patients. 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.

CONTACT:

Monopar Therapeutics Inc.
Investor Relations
Quan Vu
Chief Financial Officer
vu@monopartx.com

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