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Monopar Presents Data Highlighting Residual Disease Burden in Treatment-Experienced Wilson Disease Patients and Long-Term Molybdenum Safety Data for ALXN1840 at AASLD – The Liver Meeting® 2026

WILMETTE, Ill., Nov. 09, 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 of baseline data from the Phase 3 FoCus trial characterizing residual disease burden in treatment-experienced patients with Wilson disease, along with molybdenum balance and long-term uric acid data for ALXN1840 (tiomolibdate choline, TMC), the Company's investigational therapy for Wilson disease, at the American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2026, held Nov. 5–9, 2026, in Denver, Colorado.

Frederick K. Askari, M.D., Ph.D., Associate Professor of Internal Medicine and Director of the Wilson Disease Program at the University of Michigan Health System, delivered an oral presentation of baseline findings from the Phase 3 FoCus study, the largest randomized controlled trial ever conducted in Wilson disease. Key findings included:

- Hepatic, neurologic, and psychiatric disease burden was common in both treatment-experienced and treatment-naïve patients at baseline: cirrhosis in 39% and 30%, neurologic symptoms in 79% and 83%, and psychiatric symptoms in 75% and 70%, respectively.
- Nearly three-quarters (73%) of evaluable patients had at least two of the following at baseline: cirrhosis, neurologic symptoms, or psychiatric symptoms.
- Fewer than half (47%) of treatment-experienced patients were within the guideline-recommended copper target range at baseline.
- Nearly a third (31%) of patients receiving standard-of-care therapy for more than 12 months had 24-hour urinary copper excretion above the guideline-recommended copper target range.

"The substantial disease burden at baseline was striking in both treatment-naïve and treatment-experienced patients. Notably, approximately 80% of patients in both groups had neurologic symptoms, despite treatment-experienced patients having received standard-of-care therapy for a median of more than nine years," said Dr. Askari. "The findings also highlighted the frequent overlapping hepatic, neurologic, and psychiatric manifestations in both groups. Having this level of detail from the largest randomized controlled trial conducted

in Wilson disease gives clinicians a clearer picture of the disease burden patients continue to carry."

Additionally, Professor Aftab Ala, MBBS, M.D., FRCP, Ph.D., presented a poster reporting neutral molybdenum balance and lack of molybdenum toxicity in subjects treated with ALXN1840, with serum uric acid remaining within normal limits over six years of treatment. These findings are consistent with ALXN1840's known albumin tripartite complex (ATC) mechanism and provide further evidence supporting its long-term safety profile.

The abstracts are available on the AASLD conference website. Copies of the presentations are available in the Investors section of Monopar's website at www.monopartx.com.

About Wilson Disease

Wilson disease is a rare genetic disorder that affects approximately 1 in 30,000 people worldwide. Caused by mutations in the ATP7B gene, the disease impairs the body's ability to excrete copper, resulting in toxic copper accumulation in the liver, brain, and other organs and potentially fatal outcomes if untreated.

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. Clinical data demonstrate that ALXN1840 improves copper balance by increasing fecal copper excretion. In the Phase 3 pivotal trial, ALXN1840 met the primary endpoint by demonstrating rapid and sustained copper mobilization 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.

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company with late-stage candidate 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.

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. The forward-looking statements involve risks and uncertainties including, but not limited to, uncertainties related to the regulatory and approval process for ALXN1840, 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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