

Monopar to Present New Long-Term Neurological Efficacy and Safety Data for ALXN1840 in Wilson Disease at the 150th American Neurological Association Annual Meeting

WILMETTE, Ill., Sept. 14, 2025 (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 new data on the long-term neurological efficacy and safety of its investigational therapy ALXN1840 (tiomolybdate choline) for Wilson disease will be presented at the 150th American Neurological Association (ANA) Annual Meeting on September 14-15, 2025. The poster and oral presentations will be delivered by Matthew Lorincz, M.D., Ph.D., Professor of Neurology and Co-Director of the Wilson Disease Center of Excellence at the University of Michigan. Monopar's poster presentation is available at the following link: <https://www.monopartx.com/ALXN1840-ANA-2025-Poster-14-Sep-2025>. The oral presentation will be made available online at www.monopartx.com concurrently with Dr. Lorincz's presentation on September 15, 2025.

The analysis pooled efficacy outcomes from three independent clinical trials (n=255), while safety data included a fourth independent clinical trial (n=266). Median treatment duration with ALXN1840 was approximately 2.6 years for both the efficacy and safety analyses.

The new data presented at ANA highlight the long-term neurological benefit of ALXN1840, and follow the recent presentation of long-term hepatic and systemic efficacy and safety data at the European Association for the Study of the Liver (EASL) International Liver Congress 2025. Together, these findings underscore the potential of ALXN1840 for both the neurological and hepatic manifestations of Wilson disease.

Key findings to be presented at ANA include:

- **Sustained Neurological Improvement:** Statistically significant neurologic improvement from baseline on the Unified Wilson Disease Rating Scale ("UWDRS") Part II (patient-reported symptoms) and Part III (clinician-reported symptoms) was sustained over 6 years.
- **Crossover Benefit:** Patients who crossed over from standard of care ("SoC") to ALXN1840 showed additional neurological improvement, including a majority of patients who had worsened on SoC demonstrating a reversal on ALXN1840.
- **Psychiatric Outcomes:** Statistically significant psychiatric improvement from baseline was sustained over multiple years, as measured by the Brief Psychiatric Rating Scale ("BPRS").

- **Consistency Across Trials:** Neurological benefit was observed consistently across multiple independent studies.
- **Favorable Safety Profile:** Across more than 645 patient-years on ALXN1840, less than 1% of patients experienced a drug-related neurological serious adverse event ("SAE").

"These results are very encouraging for Wilson disease patients, including for those already on standard of care treatment," said Dr. Matthew Lorincz.

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company with late-stage ALXN1840 for Wilson disease, and radiopharmaceutical programs including Phase 1-stage MNPR-101-Zr for imaging advanced cancers, and Phase 1a-stage MNPR-101-Lu and late preclinical-stage MNPR-101-Ac225 for the treatment of advanced cancers. For more information, visit: www.monopartrx.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. Examples of these forward-looking statements include statements concerning: that these findings underscore the potential of ALXN1840 for both the neurological and hepatic manifestations of Wilson disease; and that these results are very encouraging for Wilson disease patients, including for those already on standard of care treatment. 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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