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Monopar Presents ALXN1840 Late-Breaker Data at EASL 2025

WILMETTE, Ill., May 07, 2025 (GLOBE NEWSWIRE) -- Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biopharmaceutical company focused on developing innovative treatments for patients with unmet medical needs, is presenting today data on the long term efficacy and safety of its ALXN1840 (tiomolybdate choline) drug candidate for Wilson disease at the European Association for the Study of the Liver ("EASL") International Liver Congress 2025, one of the most prominent global conferences in liver disease. Monopar's late-breaker poster presentation is available at the following link: https://www.monopartx.com/pipeline/ALXN1840/EASL-poster-may-2025.

The poster supports the potential use of ALXN1840 as a therapeutic option for Wilson disease, 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 tissues and organs such as the liver and brain. Efficacy data were pooled and analyzed from three clinical trials: Phase 2 WTX101-201, Phase 2 ALXN1840-WD-205, and Phase 3 WTX101-301 (n=255). For safety analysis, data from the Phase 2 ALXN1840-WD-204 trial were also included (n=266). The median treatment duration with ALXN1840 was 961 days (2.63 years) and 943.5 days (2.58 years) for the efficacy and safety datasets, respectively. The data presented highlight the following:

- Sustained improvements from baseline in the Unified Wilson Disease Rating Scale ("UWDRS") Part II (patient-reported symptoms) and Part III (clinician-assessed symptoms);
- Increased copper mobilization as evidenced by a sustained increase in dNCC (directly measured non-ceruloplasmin-bound copper);
- Improvements on the Clinical Global Impression – Improvement ("CGI-I") scale for ALXN1840 compared to standard of care;
- Improvement in the New Wilson Index (based on bilirubin, AST, INR, leukocytes, and albumin) for patients treated with ALXN1840;
- Higher patient-reported convenience and effectiveness of ALXN1840 compared to standard of care, including those who transitioned from standard of care to ALXN1840 in the extension portion of the Phase 3 clinical trial; and
- Fewer than 5% of patients experienced a drug-related serious adverse event ("SAE"), with no cases of a drug-related renal or urinary system SAE.

"These data show that the long-term efficacy, safety, and convenience profile of ALXN1840 are very encouraging and that ALXN1840 has the potential to provide a meaningful benefit to Wilson disease patients' daily lives," said Dr. Karl Weiss, Medical Director of Salem Medical Center Heidelberg, and lead author of the presentation at EASL.

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.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. Examples of these forward-looking statements include statements concerning: that Monopar’s poster supports the potential use of ALXN1840 as a therapy for Wilson disease; and that ALXN1840 has the potential to provide a meaningful benefit to Wilson disease patients’ daily lives. 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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