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Monopar Initiates Rolling NDA Submission for ALXN1840 in Wilson Disease

WILMETTE, Ill., July 22, 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 it has initiated the rolling submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for ALXN1840 (tiomolibdate choline, TMC), its first-in-class albumin tripartite complex ("ATC") activator for the treatment of Wilson disease. The FDA has authorized Monopar to submit the NDA on a rolling basis, allowing completed sections of the application to be submitted and reviewed while the Company finalizes the remaining sections. Monopar has submitted the first completed sections of the NDA.

If the completed NDA is accepted for filing and subsequently approved, ALXN1840 would be the first therapy with a novel mechanism of action approved in the United States for Wilson disease in decades.

"Wilson disease is a serious, lifelong condition, and patients and their families have waited a long time for a new treatment option," said Chandler Robinson, M.D., Chief Executive Officer of Monopar. "Initiating the rolling NDA submission marks an important milestone in our efforts to bring this novel copper-sequestering therapy to patients."

In addition to Fast Track and Orphan Drug designations, ALXN1840 received Rare Pediatric Disease ("RPD") designation by the FDA in June 2026. The RPD designation provides the Company with the potential, at the time of NDA approval, to receive a pediatric Priority Review Voucher ("PRV").

About Wilson Disease

Wilson disease is a rare genetic disorder that affects approximately 1 in 30,000 people worldwide. It is caused by mutations in the ATP7B gene, which impairs the body's ability to excrete copper. It is characterized by toxic accumulation of copper in the liver, brain, and other organs, leading to progressive 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 stable ATCs, suppressing copper's redox reactivity, limiting oxidative damage, and blocking its transport across the blood–brain barrier. Clinical data have also demonstrated that ALXN1840 improves copper balance by increasing fecal copper excretion.

In the pivotal Phase 3 trial, ALXN1840 met its primary endpoint, demonstrating rapid and sustained copper mobilization that was significantly greater than standard of care over 48

weeks in both previously treated and treatment-naïve patients. Across the ALXN1840 clinical development program, durable clinical improvement and favorable tolerability were observed across 645 patient-years of follow-up in 266 patients, with a well-characterized safety profile.

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company developing ALXN1840, a late-stage program for Wilson disease, and a portfolio of 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. Examples of these forward-looking statements include statements concerning: that if the completed NDA is accepted for filing and subsequently approved, ALXN1840 would be the first therapy with a novel mechanism of action approved in the United States for Wilson disease in decades; and that the RPD designation provides the Company with the potential, at the time of NDA approval, to receive a pediatric Priority Review Voucher (“PRV”). The forward-looking statements involve risks and uncertainties including, but not limited to: uncertainties related to the regulatory process that Monopar has initiated related to ALXN1840, including whether the FDA will accept the NDA for filing and the outcome of any review thereof; uncertainties related to whether the ALXN1840 marketing application will receive marketing approval and, if approved, whether Monopar will be awarded a Priority Review Voucher; whether, if awarded, the Priority Review Voucher can be used to obtain priority review of a subsequent marketing application or sold or transferred to another sponsor; the continued authorization and availability of the Rare Pediatric Disease Priority Review Voucher program; 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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