Prime Medicine Announces New Zealand Clearance of Clinical Trial Application for PM577a in H1069Q-mutated Wilson Disease

June 18, 2026

-- First clinical authorization for an in vivo Prime Editing therapy from Prime Medicine --

-- PM577a targets the H1069Q mutation in the ATP7B gene, the most prevalent WD-causing allele in North America and Europe --

-- Initiation of Phase 1/2 clinical trial expected in second half of 2026; initial clinical data expected in 2027 --

-- Shared LNP delivery platform may enable rapid expansion into additional WD pathogenic variant populations; most advanced follow-on candidate targets the R778L mutation frequently found in East Asian populations --

CAMBRIDGE, Mass., June 18, 2026 (GLOBE NEWSWIRE) -- Prime Medicine, Inc. (Nasdaq: PRME), a biotechnology company committed to delivering a new class of differentiated one-time curative genetic therapies, today announced that the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) has cleared the Company's Clinical Trial Application (CTA) for PM577a, an investigational Prime Editor for Wilson Disease (WD). The clearance represents the first clinical authorization for an in vivo Prime Editing therapy from Prime Medicine and enables the initiation of the Company's global Phase 1/2 study.

"This is a defining moment for Prime Medicine and, we hope, for the global Wilson Disease community," said Allan Reine, M.D., Chief Executive Officer of Prime Medicine. "Wilson Disease is a well-characterized, serious genetic disorder with no approved curative option, and a standard of care burdened by low adherence, significant side effects, and lifelong dependency. With PM577a, we have the potential to offer patients a one-time therapy that precisely corrects the root cause of disease at the genomic level. The modular design of our platform also enables a systematic approach to addressing additional Wilson Disease mutations and underpins each of our liver-directed programs."

Phase 1/2 Clinical Trial

The Phase 1/2 clinical trial is an open-label, global, first-in-human study designed to evaluate the safety, tolerability, biological activity, and efficacy of ascending doses of PM577a in adults and adolescents with WD. The study will initially enroll adults who are clinically stable on standard-of-care therapy. Biological activity and efficacy assessments may include copper efflux by ^{64}Cu PET, serum ceruloplasmin, non-ceruloplasmin bound copper, 24-hour urinary copper excretion, and hepatic copper by biopsy.

"The design of our Wilson Disease clinical trial is grounded in the translational insights from our preclinical work," said Mohammed Asmal, M.D., Ph.D., Chief Medical Officer of Prime Medicine. "The incorporation of ^{64}Cu PET as a non-invasive functional readout of ATP7B activity is a particular strength of the program and we look forward to sharing proof-of-concept data in 2027."

About PM577

PM577 is a family of LNP-formulated Prime Editing products designed to correct pathogenic ATP7B mutations in hepatocytes via a single intravenous infusion. Prime Medicine's initial candidate, PM577a, targets the ATP7B H1069Q allele, which accounts for approximately 30–50% of WD-associated variants in the United States and Europe. The Company intends to develop additional products to address the majority of pathogenic variants on a global basis. Currently, a follow-on candidate is in pre-clinical development targeting R778L, the most common mutant allele in East Asian populations.

About Wilson Disease

Wilson Disease is a rare, autosomal recessive disorder of hepatic copper transport caused by loss-of-function mutations in the ATP7B gene, affecting an estimated 1 in 30,000 individuals globally. Impaired biliary excretion drives progressive copper accumulation in the liver, followed by multi-organ involvement including the brain, kidneys, and cornea. Clinical manifestations range from asymptomatic hepatomegaly to decompensated cirrhosis and acute liver failure; neuropsychiatric complications affect approximately two-thirds of patients. Current pharmacologic therapies, copper chelators and zinc salts, are non-curative, require lifelong daily dosing under strict dietary conditions, carry tolerability challenges, and are associated with high non-adherence rates. Liver transplantation remains the sole curative option but is constrained by organ availability and carries substantial procedural risk.

About Prime Medicine

Prime Medicine is a leading biotechnology company dedicated to creating and delivering the next generation of gene editing therapies to patients. The Company is deploying its proprietary Prime Editing platform, a versatile, precise and efficient gene editing technology, to develop a new class of differentiated one-time curative genetic therapies. Designed to make only the right edit at the right position within a gene while minimizing unwanted DNA modifications, Prime Editors have the potential to repair almost all types of genetic mutations and work in many different tissues, organs and cell types. Taken together, Prime Editing's versatile gene editing capabilities could unlock opportunities across thousands of potential indications.

Prime Medicine is currently progressing a diversified portfolio of investigational therapeutic programs organized around its core areas of focus: liver, lung, and immunology and oncology. Across each core area, Prime Medicine is focused initially on a set of high value programs, each targeting a disease with well-understood biology and a clearly defined clinical development and regulatory path, and each expected to provide the foundation for expansion into additional opportunities. Over time, the Company intends to maximize Prime Editing's broad and versatile therapeutic potential, as well as the modularity of the Prime Editing platform, to rapidly and efficiently expand beyond the diseases in its current pipeline, potentially including additional genetic diseases, immunological diseases, cancers, infectious diseases, and targeting genetic risk factors in common diseases, which

collectively impact millions of people. For more information, please visit www.primemedicine.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements about Prime Medicine's beliefs and expectations regarding: the potential of PM577a to correct the causative mutations of, and to cure, WD; the Phase 1/2 clinical trial of PM577a, including the anticipated timing of trial initiation in the second half of 2026 and initial clinical data in 2027; the continued development and advancement of its WD program, including the development of follow-on candidates; the modularity of the Prime Editing platform and the benefits thereof; its expectations regarding the breadth of Prime Editing technology and the implementation of its strategic plans for its business, programs, and technology; and the potential of Prime Editing as a transformative gene editing technology and its ability to unlock opportunities across thousands of potential indications.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: uncertainties related to Prime Medicine's product candidates entering clinical trials; the authorization, initiation, and conduct of preclinical and IND-enabling studies and other development requirements for potential product candidates, including uncertainties related to opening INDs and obtaining regulatory approvals; risks related to the development and optimization of new technologies, the results of preclinical studies, or clinical studies not being predictive of future results in connection with future studies; the scope of protection Prime Medicine is able to establish and maintain for intellectual property rights covering its Prime Editing technology; Prime Medicine's ability to identify and enter into future license agreements and collaborations; Prime Medicine's expectations regarding the anticipated timeline of its cash runway and future financial performance; and general economic, industry and market conditions. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Prime Medicine's most recent Annual Report on Form 10-K, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Prime Medicine's views only as of today and should not be relied upon as representing its views as of any subsequent date. Prime Medicine explicitly disclaims any obligation to update any forward-looking statements subject to any obligations under applicable law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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