Damora Therapeutics Initiates Phase 1/1b CLARITY-101 Clinical Trial of DMR-001 in Patients with Mutant Calreticulin-Driven Essential Thrombocythemia and Myelofibrosis

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-- DMR-001 is a highly potent, long-acting antibody therapy targeting Type 1 and non-Type 1 mutant calreticulin (mutCALR), designed for convenient once-monthly subcutaneous dosing --

-- In preclinical studies, DMR-001 demonstrated up to 30-fold greater potency and an approximately five-fold longer half-life than a reference anti-mutCALR antibody, supporting its best-in-class potential --

WALTHAM, Mass., Aug. 05, 2026 (GLOBE NEWSWIRE) -- Damora Therapeutics, Inc. (NASDAQ: DMRA), a biotechnology company working to fundamentally redefine care for patients with blood disorders, today announced the initiation of the global Phase 1/1b CLARITY-101 clinical trial of DMR-001, an investigational monoclonal antibody therapy designed to selectively target mutant calreticulin (mutCALR), in patients with mutCALR-driven essential thrombocythemia (ET) and myelofibrosis (MF), based on receipt of health authority approval.

“We’re excited to announce the initiation of our first clinical trial of DMR-001, a potentially best-in-class mutCALR-targeted therapy,” said Becker Hewes, M.D., Chief Medical Officer of Damora Therapeutics. “In preclinical studies, DMR-001 showed a differentiated profile that we believe can translate into deeper, more durable disease control with the simplicity and convenience of a once-monthly subcutaneous injection. The achievement of this important clinical milestone furthers Damora’s commitment to solving important medical needs in hematology, beginning with DMR-001’s potential to redefine treatment for the tens of thousands of patients living with mutCALR-driven myeloproliferative neoplasms.”

David Ross, M.D., Ph.D., Associate Professor of Haematology at Flinders Medical Centre in Adelaide, South Australia, and an investigator on the Phase 1/1b CLARITY-101 study, added: “Targeting the root cause of mutCALR-driven disease is one of the most exciting frontiers in myeloproliferative neoplasms today and has the potential to be the first disease modifying treatment for patients with this disease. DMR-001’s broad activity and convenient administration makes it a potentially compelling new therapy for patients with ET and MF.”

Overview of the CLARITY-101 study in mutCALR-driven ET and MF

The Phase 1/1b CLARITY-101 trial is a global, open-label, multi-center, dose escalation and dose expansion study designed to evaluate the safety, tolerability and preliminary efficacy of DMR-001.

The Phase 1 dose escalation portion of the trial is designed to rapidly identify a recommended dose for further development, with a starting dose of 100 mg monthly (as a subcutaneous injection), which is predicted to be in the range of therapeutic exposure. Additionally, the trial utilizes an adaptive Bayesian design enabling cohort enrichment during dose escalation. Eligible patients include adults with a documented CALR mutation and ET resistant, refractory or intolerant to at least one prior cytoreductive therapy or MF resistant, refractory or intolerant to at least one JAK inhibitor.

The planned Phase 1b expansion portion of the trial will further evaluate the safety and efficacy of DMR-001 in additional populations and settings, including in early-line disease and in combination with other therapies.

Damora continues to expect to report initial data from the trial beginning mid-2027.

DMR-001: a highly potent, long-acting mutCALR targeted therapy with best-in-class potential

DMR-001 is a highly potent, long-acting monoclonal antibody therapy designed to selectively target CALR mutations, a known disease driver in ET and MF. In these diseases, CALR mutations create an abnormal protein that binds to and continuously activates the thrombopoietin receptor (TpoR), driving the uncontrolled blood cell production, clotting and bleeding risk, and bone marrow scarring that characterize these diseases. DMR-001 is designed to block this interaction while leaving normal, wild-type calreticulin untouched, an important distinction intended to minimize off-target effects.

DMR-001 was specifically engineered for highly potent inhibition of both Type 1 and non-Type 1 CALR mutations, including Type 2 mutations. It also incorporates a YTE modification that extends half-life to support optimized target coverage and convenient, infrequent subcutaneous dosing. In addition, DMR-001 features an Fc-null design that eliminates Fc-mediated immune effector function, an approach intended to support a favorable safety profile.

Preclinical DMR-001 data presented at the European Hematology Association (EHA) 2026 Congress highlights DMR-001’s best-in-class potential. In head-to-head preclinical studies, DMR-001 demonstrated up to 30-fold higher binding affinity for mutCALR compared to a reference anti-mutCALR antibody, with the largest gains observed against Type 2 mutations — historically the more difficult mutCALR subtype to target — where DMR-001 was up to 26-fold more potent at inhibiting disease-driving cell growth. In addition, DMR-001 demonstrated an approximately five-fold longer half-life in non-human primates (15 days vs. 3.1 days), supporting a target dosing schedule of once every four weeks or longer by subcutaneous injection.

DMR-001 is an investigational therapy and has not been approved by any regulatory authority for any indication.

About mutCALR-driven Myeloproliferative Neoplasms

CALR mutations are the primary disease driver in 25 percent of ET cases and 35 percent of MF cases, representing approximately 42,000 patients in the U.S. alone. These mutations — most commonly a Type 1 deletion or Type 2 insertion in the CALR gene — produce an abnormal protein that continuously switches on blood cell growth signals, driving complications such as blood clots, bleeding, and life-threatening bone marrow fibrosis, as well as debilitating symptoms including fatigue, headaches, problems concentrating, and extremity pain. There are no approved mutCALR-targeted therapies, and the current standard of care in ET and MF primarily relies on symptom-directed treatments that do not address the underlying cause of

disease.

About Damora Therapeutics

Damora Therapeutics is an innovative biotechnology company that aims to fundamentally redefine care for people with hematologic disorders. We are advancing a new generation of biologics to treat mutCALR-driven myeloproliferative neoplasms, including ET and MF, where there is significant medical need for disease-modifying treatments. With multiple programs with best-in-class potential on track to enter clinical development in 2026, our goal is to rapidly bring forward optimized therapies with broad mutation coverage and exceptional convenience to dramatically improve patient outcomes. For more information, visit www.damoratx.com or follow us on LinkedIn.

Forward-Looking Statements

Certain statements in this press release, other than purely historical information, may constitute “forward-looking statements” within the meaning of the federal securities laws, including for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements relating to the Company’s expectations, hopes, beliefs, intentions or strategies regarding the future of its assets, pipeline and business including, without limitation, the Company’s plans for enrollment in the CLARITY-101 Phase 1/1b trial and that results from preclinical studies of DMR-001 may translate into deeper, more durable disease control with the simplicity and convenience of a once-monthly subcutaneous injection. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting the Company will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond the Company’s control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those uncertainties and factors described under the headings “Risk Factors,” “Cautionary Information Regarding Forward-Looking Statements” or “Cautionary Statement Regarding Forward-Looking Statements” in the Company’s most recent filings with the SEC. Should one or more of these risks or uncertainties materialize, or should any of the Company’s assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth therein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this press release, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. The Company does not undertake or accept any duty to make any updates or revisions to any forward-looking statements.

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