



Terns Pharmaceuticals Announces FDA Breakthrough Therapy Designation Granted to TERN-701 for Certain Patients with Chronic Myeloid Leukemia

April 27, 2026

Designation for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in the chronic phase (CP) without the T315I mutation previously treated with two or more tyrosine kinase inhibitors (TKIs)

FOSTER CITY, Calif., April 27, 2026 (GLOBE NEWSWIRE) -- Terns Pharmaceuticals, Inc. ("Terns" or the "Company") (Nasdaq: TERN), a clinical-stage oncology company, today announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation to TERN-701, a novel, oral allosteric BCR::ABL1 inhibitor, for the treatment of adult patients with Ph+ CML in the chronic phase without the T315I mutation previously treated with two or more TKIs.

"There remains an urgent need for CML treatments that offer improved efficacy, safety, and tolerability over current therapies," said Scott Harris, chief development and operations officer at Terns. "This designation from the FDA supports the significant potential of TERN-701 to be a best-in-disease therapy for CML patients and offer substantial improvement based on the faster, deeper responses compared to prior TKIs and encouraging safety and tolerability profile observed to date."

"This Breakthrough Therapy Designation, along with the recent agreement for Merck to acquire Terns, has the potential to accelerate efforts to advance TERN-701 to a pivotal trial and to patients," said Amy Burroughs, chief executive officer of Terns. "This is an exciting time for everyone involved in the TERN-701 program. We are grateful to the investigators, patients and community advocates whose dedication and support have made these advancements possible."

Breakthrough Therapy Designation (BTD) is intended to expedite the development and review of potential new medicines designed to treat serious conditions or address significant unmet medical needs. Based on FDA guidelines, the medicine needs to have shown encouraging preliminary clinical evidence that demonstrates potential for substantial improvement over available medicines.

TERN-701 BTD is based on data from the ongoing Phase 1/2 CARDINAL clinical trial of TERN-701 in patients with CML previously treated with at least one prior TKI and who experienced treatment failure, suboptimal response or treatment intolerance. TERN-701 has shown promising activity, with encouraging rates of major molecular response and deep molecular response observed at week 24. Importantly, this includes responses in patients with high baseline disease burden who previously received multiple lines of therapy, including many who were treated with an allosteric TKI. The majority of treatment-emergent adverse events were reported as low grade with a low incidence of severe adverse events and discontinuations.

About Terns Pharmaceuticals

Terns Pharmaceuticals is a clinical-stage oncology company reimagining known biology to deliver high impact medicines. Our lead program, TERN-701, is a highly selective, oral, allosteric BCR::ABL1 inhibitor with a potentially best-in-disease profile that could meaningfully improve upon the efficacy, safety and convenience of existing treatments for chronic myeloid leukemia. For more information, please visit: www.ternspharma.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements about the Company within the meaning of the federal securities laws that involve substantial risks and uncertainties. Forward-looking statements include statements related to or in connection with, expectations, timing and potential results of clinical trials and other development activities, including with respect to the CARDINAL trial; the potential indications to be targeted by the Company with its product candidates; the therapeutic potential of the Company's product candidates; the potential for the mechanisms of action of the Company's product candidates to be therapeutic targets for their targeted indications; the potential utility and progress of the Company's product candidates in their targeted indications, including the clinical utility of the data from and the endpoints used in the Company's clinical trials; the applicability of expected parameters and benchmarks on which to assess clinical trial results; the Company's clinical development plans and activities, including potential future dosing regimens and trial designs, milestones and results of any interactions with regulatory authorities on its programs; the Company's expectations regarding the profile and potential benefit characteristics and therapeutic effects of its product candidates, including with respect to efficacy, tolerability, safety, convenience and pharmacokinetic profile; the potential differentiation of the Company's product candidates compared to similar, competitive or other products or product candidates; the best in disease potential for TERN-701; the Company's plans for and ability to continue to execute on its current development strategy, the process, timing or potential to establish a strategic partnership or similar arrangement for future development and/or potential commercialization of any of its product candidates, the potential approval and commercialization of the Company's product candidates and the Company's expectations with regard to its cash runway and sufficiency of its cash

resources. All statements other than statements of historical facts contained in this press release, including statements regarding the Company's strategy, future financial condition, future operations, future trial results, future approvals, future commercial launches, projected costs, prospects, plans, objectives of management and expected industry and market trends, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "develop," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. The Company has based these forward-looking statements largely on its current expectations, estimates, forecasts and projections about future events and financial trends that it believes may affect its financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. These statements are subject to risks and uncertainties that could cause the actual results and the implementation of the Company's plans to vary materially, including the risks associated with the initiation, cost, timing, progress, results and utility of the Company's current and future research and development activities and preclinical studies and clinical trials. These risks are not exhaustive. For a detailed discussion of the risk factors that could affect the Company's actual results, please refer to the risk factors identified in the Company's reports filed with the Securities and Exchange Commission, including but not limited to its Annual Report on Form 10-K for the year ended December 31, 2025. New risk factors emerge from time to time and it is not possible for Company management to predict all risk factors, nor can the Company assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

Contacts for Terns

Investors

Justin Ng

investors@ternspharma.com

Media

Jenna Urban

CG Life

media@ternspharma.com