BlossomHill Therapeutics Announces FDA Fast Track Designation for BH-30643, a Macrocyclic OMNI-EGFR™ Inhibitor for the Treatment of Advanced EGFR C797S-positive NSCLC

August 18, 2026

SAN DIEGO, Aug. 18, 2026 (GLOBE NEWSWIRE) -- BlossomHill Therapeutics, Inc. (Nasdaq: BLSM), a clinical-stage biopharmaceutical company applying an intentional, chemistry-based approach to design and develop innovative small molecule medicines for the treatment of cancer, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to BH-30643 for the treatment of adult patients with advanced or metastatic *epidermal growth factor receptor* (*EGFR*) C797S-positive non-small cell lung cancer (NSCLC) after prior treatment with a third-generation EGFR tyrosine kinase inhibitor (TKI). BH-30643 is being evaluated in SOLARA, a global Phase 1/2, first-in-human clinical trial enrolling patients at more than 40 sites in 10 countries. ™

“Fast Track designation is an important regulatory milestone and reflects FDA's recognition, based on its review of our preliminary data, of the potential for BH-30643 to address a significant unmet medical need in this molecularly defined population, for which no oral targeted therapies are approved,” said Geoff Oxnard, M.D., Chief Medical Officer of BlossomHill Therapeutics. “Receiving this designation reaffirms our confidence in the development strategy for BH-30643 as a novel EGFR inhibitor designed to overcome C797S-mediated resistance. It also provides opportunities for more frequent engagement with FDA and potential access to other expedited programs, including potential eligibility for rolling review and accelerated approval, if applicable criteria are met.”

The FDA’s Fast Track process was designed to bring new medicines to patients more quickly, facilitating the development and expediting the review of therapies intended to treat serious conditions and address unmet medical needs. Companies whose programs are granted Fast Track designation are eligible for more frequent interactions with FDA regarding all aspects of a designated drug’s clinical development program, as well as for rolling review of a New Drug Application (NDA), meaning that completed sections may be submitted and reviewed on an ongoing basis rather than upon completion of the entire application. Fast Track–designated programs may also be eligible for Accelerated Approval and Priority Review if the applicable criteria for those programs are met. For more information on the Fast Track process, please visit the FDA’s official website .

About BH-30643
BH-30643 is an investigational, novel, orally bioavailable, non-covalent, macrocyclic, brain-active, mutant-selective, OMNI-EGFR inhibitor for the treatment of *EGFR*-mutant NSCLC. BH-30643 was designed to overcome the limitations of currently approved EGFR inhibitors, which were discovered over a decade ago without the current, modern understanding of the structure and protein dynamics of mutant EGFRs. In preclinical studies, BH-30643 demonstrated potent inhibitory activity across diverse *EGFR* mutation categories – classical activating mutations, on-target resistance mutations such as C797S with or without T790M, atypical mutations and exon 20 insertions – while maintaining marked selectivity over wild-type EGFR. BH-30643 is being evaluated in SOLARA, a global Phase 1/2, first-in-human clinical trial spanning more than 40 sites in 10 countries. Ongoing dose expansion cohorts are enrolling in both TKI-pretreated and TKI-naïve settings, including a C797S resistance cohort. For additional information on SOLARA, including a list of study sites and how to enroll, please visit clinicaltrials.gov (NCT06706076).

About BlossomHill Therapeutics
BlossomHill Therapeutics, Inc. is a clinical-stage biopharmaceutical company applying an intentional, chemistry-based approach to design and develop innovative small molecule medicines that address significant unmet medical needs in cancer treatment. Founded and led by industry veteran J. Jean Cui, Ph.D., with her proven track record in oncology drug design and development – including three FDA-approved drugs – BlossomHill Therapeutics applies cutting-edge science to address key oncogenic drivers and improve patient outcomes in difficult-to-treat cancers. The company’s lead clinical programs include BH-30643, an investigational, non-covalent, macrocyclic, brain active, mutant-selective OMNI-EGFR inhibitor for the treatment of EGFR-mutant NSCLC with an initial development focus in the C797S resistance population after 3rd generation EGFR TKI treatment, and BH-30236, an investigational macrocyclic CDC-like kinase (CLK) inhibitor initially being developed for the treatment of relapsed or refractory acute myeloid leukemia (R/R AML) or higher-risk myelodysplastic syndrome (HR-MDS) and BH-501284, a preclinical, non-covalent, selective, pan-KRAS Switch II inhibitor for potential future development in diverse KRAS-mutant tumors. BlossomHill Therapeutics is headquartered in San Diego, California. For more information, visit bhtherapeutics.com and follow us on LinkedIn and X.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other federal securities laws, including, without limitation, statements regarding: the therapeutic potential, clinical benefits, safety and differentiated profile of BH-30643; the anticipated benefits of Fast Track designation and whether the company will be able to meet the criteria to access other expedited programs; the design, enrollment, timing and results of the SOLARA trial; and other statements regarding management’s plans and expectations. The words “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “upcoming,” “will,” “would” and similar expressions

are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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, including, without limitation: the risk that receipt of Fast Track designation may not result in a faster development, review or approval process compared to conventional FDA procedures, and does not increase the likelihood that BH-30643 will receive regulatory approval; the risk that the FDA may later determine that BH-30643 no longer meets the conditions for Fast Track designation, or may withdraw the designation; the risk that preliminary and interim clinical data, including data from the SOLARA trial, are subject to further analysis and may not be predictive of, may be inconsistent with, or may be more favorable than, data generated as the trial continues or data from future clinical trials; uncertainties inherent in the initiation, timing, design and enrollment of clinical trials, and the availability and timing of data from ongoing and future trials; the company's ability to successfully demonstrate the safety and efficacy of BH-30643 and its other product candidates; the timing and outcome of planned interactions with, and submissions to, the FDA and other regulatory authorities, including whether an accelerated approval pathway will be available to the company; competition, including from other agents in development for EGFR-mutant NSCLC; the company's reliance on third parties; and the company's need for additional financing and its estimates regarding operating expenses and capital requirements. These and other risks are described in greater detail under the heading "Risk Factors" in the company's final prospectus dated August 6, 2026 and filed with the Securities and Exchange Commission (the "SEC") on August 7, 2026 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, as well as in the company's subsequent filings with the SEC. Any forward-looking statements represent the company's views only as of the date of this press release, and the company expressly disclaims any obligation to update any forward-looking statements, except as required by law.

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