BlossomHill Therapeutics Announces Outcome from the End-of-Phase 1 Meeting with the FDA and Pivotal Phase 2 Trial Design for OMNI-EGFR™ Inhibitor, BH-30643, in EGFR C797S-Positive NSCLC

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Alignment with the US Food and Drug Administration on 50 mg twice daily as the recommended Phase 2 dose for BH-30643

SOLARA-2, the Phase 2 portion of the SOLARA trial, designed with registrational intent to evaluate BH-30643 in patients with EGFR C797S-positive NSCLC; expect to dose first patient in Q1 2027

SAN DIEGO, Nov. 09, 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 the outcome of its End-of-Phase 1 meeting with the U.S. Food and Drug Administration (FDA) regarding BH-30643 for the treatment of patients with advanced or metastatic *epidermal growth factor receptor* (*EGFR*) C797S-positive non-small cell lung cancer (NSCLC). BH-30643 is an investigational, novel, orally bioavailable, non-covalent, macrocyclic, brain active, mutant-selective, OMNI-EGFR™ inhibitor designed to overcome the limitations of currently approved EGFR inhibitors for the treatment of *EGFR*-mutant NSCLC.

BlossomHill plans to advance BH-30643 into SOLARA-2, the Phase 2 portion of the SOLARA trial, following alignment with FDA on a recommended Phase 2 dose of 50 mg twice daily. SOLARA-2 is the global, open-label, single-arm Phase 2 portion of the SOLARA trial, intended to generate data that could potentially support an accelerated approval application in patients with *EGFR* C797S-positive NSCLC, a population for which there are currently no approved oral targeted therapies. SOLARA-2 is designed to evaluate both chemotherapy-naive and chemotherapy-pretreated patients following treatment with a third-generation EGFR tyrosine kinase inhibitor (TKI). The trial will leverage the current global footprint of the SOLARA trial, with the first patient anticipated to be dosed in the first quarter of 2027. BH-30643 previously received FDA Fast Track designation for *EGFR* C797S-positive NSCLC.

“We are pleased with the outcome of our End-of-Phase 1 meeting with FDA and are confident in our development strategy for BH-30643 in *EGFR* C797S-positive NSCLC. Our planned Phase 2 trial, designed with registrational intent, builds on the encouraging clinical activity observed in SOLARA, where BH-30643 has demonstrated promising anti-tumor activity in NSCLC patients with *EGFR* C797S-positive resistance, including those with and without concurrent T790M mutation and brain metastasis, and those who have received multiple prior therapies,” said J. Jean Cui, Ph.D., Founder and Chief Executive Officer of BlossomHill Therapeutics. “The selection of 50 mg twice daily as our recommended Phase 2 dose, together with the clinical experience we have observed to date, provides strong support for advancing the program. By evaluating BH-30643 in both chemotherapy-naive and chemotherapy-pretreated patients, we aim to further characterize its potential to address this important resistance mechanism and generate the evidence needed to support a potential accelerated approval.”

Preliminary data from SOLARA were presented in 2026 at both the American Society of Clinical Oncology (ASCO) and World Conference on Lung Cancer (WCLC). The company expects to share additional updates from SOLARA at medical meetings in 2027, including updates on C797S durability and TKI-naive durability, as well as initial data from the chemotherapy-combination cohort.

SOLARA-2 Trial
SOLARA-2 is the pivotal single-arm Phase 2 portion of the SOLARA trial, designed with registrational intent to evaluate BH-30643 in approximately 150 patients with locally advanced or metastatic *EGFR* C797S-positive NSCLC who have previously received a third-generation EGFR TKI. The open-label study will include two sub-cohorts of approximately 75 patients each: chemotherapy-naive patients and chemotherapy-pretreated patients. All patients will receive BH-30643 at the recommended Phase 2 dose of 50 mg twice daily. The primary endpoint will be objective response rate (ORR), as assessed by blinded independent central review (BICR), with additional endpoints including duration of response (DOR), progression-free survival (PFS), overall survival (OS), intracranial ORR and safety. For additional information on SOLARA, including a list of study sites and how to enroll, please visit clinicaltrials.gov (NCT06706076).

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 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 has received Fast Track designation and is being evaluated in SOLARA, a global Phase 1, first-in-human clinical trial with ongoing dose expansion cohorts enrolling in both TKI-pretreated and TKI-naive settings, including a C797S resistance cohort. SOLARA-2, a global Phase 2 pivotal study in

C797S-Positive NSCLC is scheduled to dose the first patient in the first quarter of 2027. 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 with a goal to address key oncogenic drivers and improve patient outcomes in difficult-to-treat cancers. The company's lead clinical program is BH-30643, an investigational, novel, orally bioavailable, non-covalent, macrocyclic, brain active, mutant-selective OMNI-EGFR™ inhibitor for the treatment of EGFR-mutant non-small cell lung cancer (NSCLC), has received Fast Track designation for the C797S resistance population after 3rd generation EGFR TKI treatment. The company is also conducting clinical development of BH-30236, an investigational macrocyclic CDC-like kinase (CLK) inhibitor initially being studied in a clinical trial for the treatment of relapsed or refractory acute myeloid leukemia (R/R AML) and higher-risk myelodysplastic syndromes (HR-MDS). The company's pipeline also includes 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 www.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 design, size, endpoints, registrational intent and anticipated timing of SOLARA-2, including the expected dosing of the first patient in the first quarter of 2027; the potential for data from SOLARA-2 to support an accelerated approval application; the therapeutic potential, clinical benefits, safety and potential competitive differentiation of the company's product candidates, including BH-30643, BH-30236 and BH-501284; the anticipated benefits of regulatory designations received, or that may be received, by the company's product candidates; the design, enrollment, timing, progress and results of the company's clinical trials and nonclinical studies; the company's planned regulatory interactions and submissions; anticipated program milestones, including the timing of program and data updates; statements by the company's management; and the company's development plans and continued advancement of its pipeline.

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 company's limited operating history, history of significant losses and the early stage of development of its product candidates; the risk that preclinical data may not be predictive of results in clinical trials; the risk that preliminary and interim clinical data are subject to further analysis and may not be predictive of, may be inconsistent with, or may be more favorable than, data generated as clinical trials continue 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 its product candidates and to obtain and maintain regulatory approvals; 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; the risk that the FDA's feedback, including feedback from the End-of-Phase 1 meeting, is not binding and may change; the risk that the FDA may disagree with the company's interpretation of that feedback, with the design or endpoints of SOLARA-2, or with whether single-arm data are sufficient to support accelerated approval; the risk that the FDA may require additional trials, including randomized confirmatory trials; the risk that regulatory designations, including Fast Track and orphan drug designation, may not result in a faster development, review or approval process, may not increase the likelihood of regulatory approval, and may be withdrawn; competition from third parties that are developing products for similar indications; the prior success of the company's management team not being indicative of future success; the company's reliance on third parties, including contract research organizations and contract manufacturing organizations; the company's ability to obtain, maintain and protect its intellectual property; 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 filings with the Securities and Exchange Commission (the "SEC"), including the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, 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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