BlossomHill Therapeutics Presents Updated Data from Ongoing Phase 1/2 SOLARA Trial Demonstrating Encouraging Anti-Tumor Activity of OMNI-EGFR™ Inhibitor BH-30643 in EGFR C797S-Positive NSCLC at IASLC 2026 World Conference on Lung Cancer

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45% objective response rate and 88% disease control rate observed in patients with EGFR C797S-positive resistance to prior EGFR inhibitors, with or without concurrent T790M, a difficult-to-treat population with no approved targeted therapies

BH-30643 demonstrated a favorable safety profile with low rates of dose reduction or discontinuation due to treatment-related adverse events

Presentation follows receipt of FDA Fast Track designation for BH-30643 for the treatment of advanced or metastatic EGFR C797S-positive NSCLC

SAN DIEGO, Sept. 15, 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 updated data from the ongoing Phase 1/2 SOLARA trial of BH-30643 in non-small cell lung cancer (NSCLC) patients with secondary *epidermal growth factor receptor* (*EGFR*) resistance mutations such as EGFR C797S. The data were highlighted in a mini-oral presentation at the International Association for the Study of Lung Cancer (IASLC) 2026 World Conference on Lung Cancer in Seoul, South Korea.

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. In patients with EGFR C797S-positive resistance to prior EGFR inhibitor treatment, with or without concurrent T790M, BH-30643 demonstrated a 45% objective response rate (ORR; 18/40) and an 88% disease control rate (DCR; 35/40). At the time of efficacy follow-up, 63% (25/40) of patients remained on treatment with a median follow-up of 6.9 months. BH-30643 also demonstrated a favorable safety profile with low rates of dose reduction or discontinuation due to treatment-related adverse events.

“C797S-driven resistance to third-generation EGFR inhibitors was first described over 10 years ago, yet patients whose tumors develop this mutation currently have no approved targeted treatment options,” said Hidehito Horinouchi, M.D., Ph.D., National Cancer Center Hospital, Tokyo, and presenting author of the study. “The responses observed with BH-30643 in this heavily pretreated population, together with encouraging early evidence of durability, support the potential of BH-30643 to directly target this resistance mechanism. These results are particularly encouraging given the need for new precision treatment options that can extend the benefits of targeted therapy for patients with *EGFR*-mutant lung cancer.”

“These updated results provide important clinical validation of the approach we took in intentionally designing BH-30643 to address on-target EGFR resistance, including C797S,” said Geoff Oxnard, M.D., Chief Medical Officer of BlossomHill Therapeutics. “We are encouraged to see meaningful anti-tumor activity across a molecularly diverse group of patients with C797S-positive disease, including patients with concurrent T790M and those who have received multiple prior therapies, with a favorable safety profile. Together with the recent FDA Fast Track designation, these data strengthen our conviction in the potential of BH-30643 and support our plans to advance into a Phase 2 trial in patients with C797S-positive NSCLC in 2027.”

Presentation highlights:

As of the May 12, 2026 data cutoff, with efficacy follow-up through August 10, 2026:

- **Encouraging anti-tumor activity was observed in patients with C797S-positive resistance.** Among 40 patients with EGFR C797S-positive resistance to prior EGFR inhibitor treatment, with or without concurrent T790M, 18 patients achieved a confirmed (16) or ongoing unconfirmed (2) partial response, representing an ORR of 45% (95% CI: 29%-62%). The DCR was 88% (35/40), and 25 patients (63%) remained on treatment at the time of efficacy follow-up. Median follow-up was 6.9 months.
- **Activity was observed across a clinically heterogeneous, previously treated population.** Patients had received a median of two prior lines of therapy; 98% had received prior osimertinib, 53% had received prior chemotherapy and/or an antibody-drug conjugate, and 53% had a history of brain metastases. 35% of patients had concurrent T790M.
- **BH-30643 demonstrated a favorable safety profile at expansion doses.** Among 174 patients treated at doses of 40 mg, 50 mg and 60 mg twice daily, treatment-related dose reductions and discontinuations occurred in 9% and 3% of patients, respectively. EGFR wild-type-associated treatment-related adverse events were primarily Grade 1. The most common treatment-related adverse event was bilirubin elevation, which was generally asymptomatic and predominantly unconjugated, consistent with UGT1A1 inhibition by BH-30643.
- **Development of BH-30643 is continuing across multiple *EGFR*-mutant populations.** Expansion cohorts are evaluating

on-target resistance mutations, targeted therapy-naive patients and BH-30643 in combination with chemotherapy. BlossomHill plans to initiate a global Phase 2 study targeting *EGFR* C797S-positive NSCLC in Q1 2027.

The presentation is available on the company's Posters & Presentations page here: https://bhtherapeutics.com/pipeline/#posters-and-presentations.

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 1/2, 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-naive 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 the SOLARA Trial
The Phase 1/2 SOLARA clinical trial (NCT06706076) is a global, open label, multicenter study assessing the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary anti-tumor activity of BH-30643 in patients with epidermal growth factor receptor (EGFR) mutant non-small cell lung cancer (NSCLC). Phase 1 will determine the recommended Phase 2 dose (RP2D) of BH-30643 as a monotherapy and in combination with chemotherapy. Phase 2 is designed to evaluate the antitumor efficacy and safety in specified cohorts determined by mutation subtypes and/or treatment history at the RP2D, as well as the population pharmacokinetics.

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, non-covalent, macrocyclic, brain active, mutant-selective OMNI-EGFR™ inhibitor for the treatment of EGFR-mutant non-small cell lung cancer (NSCLC), which 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 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 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 preclinical studies; the company's planned regulatory interactions and submissions; anticipated program milestones, announcements and updates, including the initiation of the Phase 2 study for BH-30643 in Q1 2027; 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 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 regulatory designations, including Fast Track and orphan drug designation, may not result in a faster development, review or approval process, do 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 final prospectus 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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