BlossomHill Therapeutics to Present Updated Data from Ongoing Phase 1/2 SOLARA Trial of its Macrocyclic OMNI-EGFR™ Inhibitor, BH-30643, in EGFR-mutant NSCLC at the 2026 World Conference on Lung Cancer

September 1, 2026

Data to be presented in a mini-oral session will describe anti-tumor activity of BH-30643 in patients with secondary EGFR resistance mutations such as EGFR C797S

BH-30643 was recently granted Fast Track designation by the FDA for the treatment of C797S-positive resistance in EGFR-mutant NSCLC, a setting where no oral targeted therapies are approved

SAN DIEGO, Sept. 01, 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 updated data from the ongoing Phase 1/2 SOLARA trial describing anti-tumor activity of BH-30643 in patients with secondary *epidermal growth factor receptor* (*EGFR*) resistance mutations such as EGFR C797S will be shared as a mini-oral presentation on September 15, 2026 at the 2026 World Conference on Lung Cancer in Seoul, South Korea.

"C797S is a widely recognized mechanism of resistance in *EGFR*-mutant lung cancer after progression on a third-generation EGFR inhibitor, such as osimertinib, yet there are currently no approved oral targeted therapies for these patients," said Geoff Oxnard, M.D., Chief Medical Officer of BlossomHill Therapeutics. "The anti-tumor activity observed with BH-30643 to date, including across a range of C797S co-mutations and prior treatment histories, is encouraging and supports its potential to address this significant unmet need. We look forward to presenting updated data at WCLC, including longer follow-up that will further inform the emerging clinical profile of BH-30643."

Presentation details:
Title: Anti-Tumor Activity of BH-30643, a Novel Macrocyclic EGFR TKI, in Patients With Secondary EGFR Resistance Mutations
Presenter: Dr. Hidehito Horinouchi, National Cancer Center Hospital, Tokyo, Japan
Date and time: Tuesday, September 15, 11:00 AM KST / Monday, September 14, 10:00 PM EDT
Session: MO12. Closing The Gaps In Driver Altered NSCLC: Moving Beyond Current Boundaries
Location: Room 202, ASEM Ballroom, 2F

The presentation will be available on the company's Posters & Presentations page following the session: 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 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 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 syndrome (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 differentiated profile of BH-30643; the potential for BH-30643, including its potential to address the unmet need in C797S-positive EGFR-mutant NSCLC; the design, enrollment, timing and results of the SOLARA trial; and the company's other development plans and objectives, including with respect to BH-30236 and BH-501284. 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 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. 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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