BlossomHill Therapeutics to Present Preliminary Results From Phase 1 Dose Escalation/Backfill Cohorts in Phase 1/2 SOLARA Trial of OMNI-EGFR Inhibitor, BH-30643, in Advanced EGFR-mutant NSCLC at the 2026 ASCO Annual Meeting

May 21, 2026

BH-30643 has demonstrated encouraging clinical activity against diverse EGFR genotypes and on-target resistance in heavily pretreated Phase 1 dose escalation/backfill population with advanced EGFR-mutant NSCLC

Responses observed in patients with difficult-to-treat C797S/T790M mutations and in patients with brain metastases

Phase 1 dose expansion ongoing to determine recommended Phase 2 dose and support further clinical development in EGFR-mutant NSCLC

SAN DIEGO, May 21, 2026 – BlossomHill Therapeutics, Inc., a privately-held, 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 an upcoming presentation of the preliminary, Phase 1 dose escalation/backfill data from the company's ongoing Phase 1/2 SOLARA clinical trial of BH-30643 in epidermal growth factor receptor (EGFR)-mutant non-small cell lung cancer (NSCLC). The data will be presented in an oral session at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting on Tuesday, June 2, 2026.

BH-30643 is a non-covalent, macrocyclic, brain active, mutant-selective OMNI-EGFR inhibitor designed to address a broad spectrum of EGFR mutations, including classical mutations, on-target resistance mutations such as C797S (with or without T790M), atypical mutations and exon 20 insertion mutations.

"BH-30643 represents a potentially important advancement in the evolution of targeted therapies for treating EGFR mutant NSCLC," said Xiuning Le, M.D., Ph.D., Associate Professor in Medical Oncology at the MD Anderson Cancer Center. "Using a novel macrocyclic approach, BH-30643 has the potential to impact multiple clinically relevant EGFR mutation classes while minimizing inhibition of wild-type EGFR. The response data we are presenting at ASCO are encouraging – in a heavily pretreated Phase 1 dose escalation/backfill population, in patients with brain metastases, and even in the difficult-to-treat C797S/T790M population. These findings suggest BH-30643's potential to address a significant unmet need for patients, especially those whose disease has progressed on prior EGFR TKIs."

"These Phase 1 dose escalation/backfill data demonstrated encouraging clinical activity for BH-30643, with a favorable tolerability profile in the setting of high PK exposures, and with responses observed across a broad range of EGFR genotypes," said Geoff Oxnard, M.D., Chief Medical Officer of BlossomHill Therapeutics. "Importantly, we are seeing confirmed responses in patients harboring C797S resistance mutations, a population where current treatment options remain limited and outcomes are poor. We believe these findings support the potential for BH-30643 to address significant unmet need. Phase 1 dose expansion is ongoing to determine the recommended Phase 2 dose and support further clinical development, with an initial focus on patients with C797S-positive resistance."

Key presentation highlights to include:

- Preliminary results (March 2, 2026, data cut, with efficacy follow-up through April 29, 2026) from the Phase 1 dose escalation/backfill in Phase 1/2 SOLARA trial in patients with heavily pretreated and heterogeneous EGFR-mutant NSCLC. The Phase 1 dose escalation/backfill portion enrolled 82 patients (median of 3 prior lines of therapy, 66% with history of brain metastases, and 71% ECOG=1) across dose cohorts ranging from 20 mg to 160 mg total daily dose of BH-30643.
- High plasma exposures were observed that exceeded target EC_{90} at candidate doses.
- BH-30643 demonstrated a favorable tolerability profile with primarily low-grade EGFR wildtype toxicity as well as asymptomatic Gilbert's-like bilirubin elevation; Grade ≥2 EGFR-wildtype treatment related adverse events (TRAEs) were reported in 27% of patients. No clinically significant cardiac effects were seen.
- Responses and prolonged stable disease were observed across diverse EGFR genotypes in a heavily pretreated Phase 1 cohort, suggesting effective targeting of on-target resistance.
- 32 patients with C797S mutations were response evaluable across escalation and expansion cohorts; favorable overall response rate (ORR, confirmed or unconfirmed and ongoing) were seen both without prior chemo (50%) and with prior chemo (39%).
    - Responses were observed with or without concurrent T790M and with or without prior history of brain metastases
    - Robust C797S and T790M ctDNA clearance was observed in the context of diverse EGFR driver mutations including exon 19 del or indel, L858R, G719X, and exon20ins

Presentation Details

Abstract Title: First-in-human trial of BH-30643, a novel macrocyclic, non-covalent, mutant-selective OMNI-EGFR inhibitor, in EGFR-mutant (EGFRm) NSCLC
Abstract Number: 3014
Session Type/Title: Rapid Oral Abstract Session – Developmental Therapeutics – Molecularly Targeted Agents and Tumor Biology
Date and Time: June 2, 2026, at 9:45 AM – 11:15 AM CDT / 10:45 AM-12:15 PM EDT
About BH-30643

BH-30643 is an investigational, novel, orally bioavailable, non-covalent, macrocyclic, mutant-selective, OMNI-EGFR inhibitor. 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 currently being evaluated in the Phase 1/2 SOLARA clinical trial in adults with locally advanced or metastatic NSCLC harboring EGFR or HER2 mutations. 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 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 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, macrocyclic, non-covalent, mutant-selective OMNI-EGFR inhibitor for the treatment of EGFR-mutant non-small cell lung cancer (NSCLC), and BH-30236, an investigational macrocyclic CDC-like kinase (CLK) inhibitor for the treatment of relapsed or refractory acute myeloid leukemia (R/R AML) or higher-risk myelodysplastic syndrome (HR-MDS). BlossomHill Therapeutics is headquartered in San Diego, California and has raised over $257 million since its inception from experienced healthcare-focused investors. For more information, visit bhtherapeutics.com and follow us on LinkedIn and X.

Company Contacts:

Investors:
Michael Moore, BlossomHill Therapeutics
michael.moore@bhtherapeutics.com

Media:
Ashlea Kosikowski, 1AB
ashlea@1abmedia.com