Celcuity's Phase 3 VIKTORIA-1 Trial Achieves Primary Endpoint With Clinically Meaningful Improvement in Progression-Free Survival in PIK3CA Mutant Cohort

May 1, 2026

Detailed data for the gedatolisib triplet and doublet regimens will be presented at a late-breaking abstract oral session at the 2026 ASCO Annual Meeting

MINNEAPOLIS, May 01, 2026 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced positive topline results from the *PIK3CA* mutant cohort of the Phase 3 VIKTORIA-1 clinical trial evaluating gedatolisib plus fulvestrant with or without palbociclib in patients with hormone receptor positive ("HR+"), human epidermal growth factor receptor 2 negative ("HER2-"), *PIK3CA* mutant locally advanced or metastatic breast cancer ("ABC"), following progression on or after treatment with a CDK4/6 inhibitor and an aromatase inhibitor. Detailed results will be presented in a late-breaking abstract ("LBA") oral session at the American Society of Clinical Oncology ("ASCO") Annual Meeting, taking place May 29 – June 2, 2026, in Chicago, Illinois.

The primary efficacy analysis of gedatolisib combined with fulvestrant and palbociclib (the "gedatolisib triplet") demonstrated a statistically significant and clinically meaningful improvement in progression-free survival ("PFS") compared to alpelisib, a PI3Kα inhibitor, and fulvestrant. The secondary endpoint comparing gedatolisib plus fulvestrant (the "gedatolisib doublet") versus alpelisib plus fulvestrant, which was not part of the primary efficacy analysis in the hierarchical order, also demonstrated a statistically significant and clinically meaningful improvement in PFS compared to alpelisib and fulvestrant. Both gedatolisib regimens were generally well tolerated, with manageable safety profiles, and no new safety signals.

Celcuity intends to submit these data to the U.S. Food and Drug Administration (the "FDA") as a supplemental New Drug Application ("sNDA") and to submit VIKTORIA-1 data to other regulatory authorities following the sNDA submission.

"Patients with *PIK3CA* mutant HR+/HER2- advanced breast cancer whose disease has progressed while on or after treatment with a CDK4/6 inhibitor typically derive modest benefit from subsequent therapies that target only PI3Kα or AKT," said Sara Hurvitz, MD, Senior Vice President, Clinical Research Division, Fred Hutch Cancer Center, Smith Family Endowed Chair in Women's Health and Professor and Head, Division of Hematology and Oncology, University of Washington, School of Medicine and co-principal investigator for the trial. "VIKTORIA-1 represents the first Phase 3 study to demonstrate that comprehensively blocking the PI3K/AKT/mTOR, or PAM, pathway can significantly improve outcomes for patients with *PIK3CA* mutations compared to therapies only targeting a single component of this pathway."

HR+/HER2- breast cancer is the most common subtype of breast cancer, accounting for approximately 70% of all breast cancers.[2] Among this breast cancer subtype, approximately 40% have *PIK3CA* mutations.

"These positive topline results demonstrate the potential for gedatolisib to become a transformative new medicine for the treatment of patients with *PIK3CA* mutant HR+/HER2-advanced breast cancer," said Igor Gorbatchevsky, MD, Chief Medical Officer of Celcuity. "When considered alongside previously presented data from the VIKTORIA-1 *PIK3CA* wild-type cohort, the gedatolisib regimens have now demonstrated the potential to improve the standard of care in the second-line setting regardless of the *PIK3CA* status of a patient's tumor."

The FDA has granted Priority Review of Celcuity's New Drug Application ("NDA") for gedatolisib in patients with HR+/HER2-/*PIK3CA* wild-type ("WT") ABC and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of July 17, 2026.

"We believe the results from the VIKTORIA-1 study validate our pioneering approach to targeting cancers involving the PI3K/AKT/mTOR pathway. Researchers have sought for nearly 20 years to develop a drug that blockades this pathway comprehensively without inducing unacceptable levels of toxicity," commented Brian Sullivan, Chairman, CEO and co-founder of Celcuity.

Mr. Sullivan added, "The implications of these results may extend beyond HR+/HER2- advanced breast cancer patients in the second-line setting, and we are working urgently to explore the development of gedatolisib for additional groups of patients whose cancers involve the PI3K/AKT/mTOR pathway."

Presentation Details

Presenting Author: Sara Hurvitz, MD, Senior Vice President, Clinical Research Division, Fred Hutchinson Cancer Center, Professor and Head, Division of Hematology and Oncology, University of Washington, Department of Medicine

Title: A randomized, open-label, phase 3 study of gedatolisib + fulvestrant ± palbociclib vs standard of care in HR+/HER2−/*PIK3CA*-mutant advanced breast cancer (VIKTORIA-1 Study 2)

Abstract: LBA1008

Session Type/Title: Oral Abstract Session - Breast Cancer—Metastatic

Date and Time: June 2, 2026, 9:45 AM-12:45 PM CDT

Late-breaking abstracts accepted for an Oral Abstract Session at the ASCO Annual Meeting will be published online via the ASCO website on the day of presentation.

About HR+/HER2- Breast Cancer

Breast cancer is the second most common cancer and one of the leading causes of cancer-related deaths worldwide.[1] More than two million breast cancer cases were diagnosed globally in 2022.[1] While survival rates are high for those diagnosed with early breast cancer, approximately 30% of patients who are diagnosed with or who progress to metastatic disease are expected to live five years after their diagnosis.[2] HR+/HER2- breast cancer is the most common subtype of breast cancer, accounting for approximately 70% of all breast cancers.[2] Among this breast cancer subtype, approximately 40% have *PIK3CA* mutations.[13]

Three interconnected signaling pathways, estrogen, cyclin D1-CDK4/6 and PI3K/AKT/mTOR ("PAM"), are primary oncogenic drivers of HR+/HER2- breast cancer.[3] Therapies inhibiting these pathways are approved and used in various combinations for ABC. Currently approved inhibitors of the PAM pathway for breast cancer target a single PAM pathway component, such as PI3Kα, AKT or mTORC1.[4,5,6,7] However, resistance to CDK4/6 inhibitors and current endocrine therapies develops in many patients with advanced disease.[8] Optimizing the inhibition of the PAM pathway is an active area of focus for breast cancer research.

About the VIKTORIA-1 Phase 3 Trial

VIKTORIA-1 is a Phase 3 open-label, randomized clinical trial to evaluate the efficacy and safety of gedatolisib in combination with fulvestrant, with or without palbociclib, in adults with HR+/HER2- ABC whose disease progressed on or after prior CDK4/6 therapy in combination with an aromatase inhibitor. The clinical trial is fully enrolled. The trial enrolled subjects regardless of *PIK3CA* status while enabling separate evaluation of subjects according to their *PIK3CA* status. Detailed results from the *PIK3CA* WT cohort of VIKTORIA-1 have been previously reported. For the *PIK3CA* mutant cohort, subjects who met eligibility criteria and had confirmed *PIK3CA* mutations were randomly assigned (3:3:1) to receive a regimen of either the gedatolisib triplet, alpelisib and fulvestrant, or the gedatolisib doublet.

About Gedatolisib

Gedatolisib is an investigational, multi-target PAM inhibitor that potently targets all four class I PI3K isoforms, mTORC1 and mTORC2 to induce comprehensive blockade of the PAM pathway.[9,10,11] As a multi-target PAM inhibitor, gedatolisib's mechanism of action is highly differentiated from currently approved single-target inhibitors of the PAM pathway.[11] Inhibition of only a single PAM component gives tumors an escape mechanism through cross-activation of the uninhibited targets. Gedatolisib's comprehensive PAM pathway inhibition ensures full suppression of PAM activity by eliminating adaptive resistance cross-activation that occurs with single-target inhibitors. Unlike single-target inhibitors of the PAM pathway, gedatolisib has demonstrated equal potency and comparable cytotoxicity in *PIK3CA*-mutant and -wild-type breast tumor cells in nonclinical studies and early clinical data.[11,12]

About Celcuity

Celcuity is a clinical-stage biotechnology company pursuing the development of targeted therapies for the treatment of multiple solid tumor indications. The company's lead therapeutic candidate is gedatolisib, a potent, pan-PI3K and mTORC1/2 inhibitor that comprehensively blockades the PAM pathway. Its mechanism of action and pharmacokinetic properties are differentiated from other currently approved and investigational therapies that target PI3Kα, AKT, or mTORC1 alone or together. A Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant, with or without palbociclib, in patients with HR+/HER2- ABC, has reported detailed results for the *PIK3CA* WT cohort and topline results for the *PIK3CA* mutant cohort. A Phase 3 clinical trial, VIKTORIA-2, evaluating gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with endocrine treatment resistant HR+/HER2- ABC, is ongoing. A Phase 1/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with metastatic castration-resistant prostate cancer, is ongoing. More detailed information about Celcuity's active clinical trials can be found at ClinicalTrials.gov. Celcuity is headquartered in Minneapolis. Further information about Celcuity can be found at www.celcuity.com. Follow us on LinkedIn and X.

Forward Looking Statements

This press release contains statements that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including statements relating to the potential therapeutic benefits of gedatolisib; the size, design and timing of our clinical trials; our interpretation of clinical trial data; the status and timing of the FDA's review of our NDA for

gedatolisib, including the PDUFA goal date assigned by the FDA; the ability of our data to support the filing of an sNDA with the FDA and comparable filings with other regulatory authorities; our intent to present data at the 2026 ASCO Annual Meeting; the market opportunity for gedatolisib; our expectations regarding the timing of and our ability to obtain FDA approval to commercialize gedatolisib; our strategy, marketing and commercialization plans, including the benefits of strategic decisions regarding studies and trials; other expectations with respect to gedatolisib, including expectations regarding potential benefits to additional groups of patients whose cancers involve the PAM pathway; our anticipated use of cash; and the strength of our balance sheet. Words such as, but not limited to, “look forward to,” “believe,” “expect,” “anticipate,” “estimate,” “intend,” "confidence," "encouraged," “potential,” “plan,” “targets,” “likely,” “may,” “will,” “would,” “should” and “could,” and similar expressions or words identify forward-looking statements. The forward-looking statements included in this press release are based on management's current expectations and beliefs which are subject to a number of risks, uncertainties and factors, including that our topline clinical results are based on an ongoing analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial; unforeseen delays in our clinical trials or the FDA's review of our NDA for gedatolisib; our ability to obtain and maintain regulatory approvals to commercialize gedatolisib, and the market acceptance of gedatolisib; the development of therapies and tools competitive with gedatolisib; and our ability to access capital upon favorable terms. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2025, as such risks may be updated in our subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by these cautionary statements, and we undertake no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

References:

1. Sung H, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA Cancer J Clin. 2021;10.3322/caac.21660.
2. National Cancer Institute. Surveillance, Epidemiology and End Results Program (Accessed July 2025). https://seer.cancer.gov/statfacts/html/breast-subtypes.html
3. Alves, C. L., & Ditzel, H. J. Drugging the PI3K/AKT/mTOR Pathway in ER+ Breast Cancer. Int J Mol Sci, 2023;24(5),4522. https://doi.org/10.3390/ijms24054522
4. United States Package Insert, US FDA, ITOVEBI
5. United States Package Insert, US FDA, PIQRAY
6. United States Package Insert, US FDA, TRUCAP
7. United States Package Insert, US FDA, AFINITOR
8. Lloyd M R, et al. Mechanisms of Resistance to CDK4/6 Blockade in Advanced Hormone Receptor-positive, HER2-negative Breast Cancer and Emerging Therapeutic Opportunities. Clin Cancer Res. 2022;28(5):821-30
9. Venkatesan, A. M., et al. Bis(morpholino-1,3,5-triazine) derivatives: potent adenosine 5'-triphosphate competitive phosphatidylinositol-3-kinase/mammalian target of rapamycin inhibitors: discovery of compound 26 (PKI-587), a highly efficacious dual inhibitor. J Med Chem, 2010;53(6), 2636-2645. https://doi.org/10.1021/jm901830p
10. Mallon, R., et al. Antitumor efficacy of PKI-587, a highly potent dual PI3K/mTOR kinase inhibitor. Clin Cancer Res, 2011;17(10), 3193-3203. https://doi.org/10.1158/1078-0432.CCR-10-1694
11. Rossetti, S., et al. Gedatolisib shows superior potency and efficacy versus single-node PI3K/AKT/mTOR inhibitors in breast cancer models. NPJ Breast Cancer, 2024;10(1), 40. https://doi.org/10.1038/s41523-024-00648-0
12. Layman, R., et al. Gedatolisib in combination with palbociclib and endocrine therapy in women with hormone receptor-positive, HER2-negative advanced breast cancer: results from the dose expansion groups of an open-label, phase 1b study. Lancet Oncol, 2024;25(4), 474-487. https://doi.org/10.1016/S1470-2045(24)00034-2
13. Anderson, E. et al. A Systematic Review of the Prevalence and Diagnostic Workup of PIK3CA Mutations in HR+/HER2– Metastatic Breast Cancer, Int J Breast Cancer. 2020 Jun 20;2020:3759179

Contacts:

For Investors:
Brian Sullivan, bsullivan@celcuity.com
Vicky Hahne, vhahne@celcuity.com
(763) 392-0123
Jodi Sievers, jsievers@celcuity.com
(415) 494-9924

For Media:
Sam Brown LLC
Laura Morgan, lauramorgan@sambrown.com
(951) 333-9110