Celcuity Announces Publication of Results from PIK3CA Wild-Type Cohort of Phase 3 VIKTORIA-1 Study of Gedatolisib Regimens in HR+/HER2- Advanced Breast Cancer in Journal of Clinical Oncology

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- *As previously presented, gedatolisib + palbociclib + fulvestrant ("gedatolisib triplet") and gedatolisib + fulvestrant ("gedatolisib doublet") reduced the risk of disease progression or death versus fulvestrant by 76% and 67%, respectively*

MINNEAPOLIS, March 09, 2026 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced publication of efficacy and safety results from the *PIK3CA* wild-type ("WT") cohort of the Phase 3 VIKTORIA-1 clinical trial of gedatolisib, an investigational pan-PI3K/mTORC1/2 inhibitor, in the *Journal of Clinical Oncology*. The cohort consists of patients with hormone receptor positive ("HR+"), human epidermal growth factor receptor 2 negative ("HER2-") *PIK3CA* WT advanced breast cancer ("ABC"), following progression on or after treatment with a CDK4/6 inhibitor and an aromatase inhibitor.

The publication is titled "VIKTORIA-1 Trial of Gedatolisib Plus Fulvestrant With or Without Palbociclib in Hormone Receptor-Positive/HER2-/PIK3CA Wild-Type Advanced Breast Cancer."

"VIKTORIA-1 is the first Phase 3 study to show a significant improvement in median progression-free survival with inhibition of the PI3K/AKT/mTOR pathway in patients with *PIK3CA* wild-type HR+/HER2- advanced breast cancer who previously received a CDK4/6 inhibitor," said Sara Hurvitz, MD, lead study author and Senior Vice President, Clinical Research Division, Fred Hutchinson Cancer Center, Smith Family Endowed Chair in Women's Health, Professor and Head, Division of Hematology and Oncology, University of Washington, Department of Medicine.

In the *PIK3CA* WT cohort of the Phase 3 VIKTORIA-1 trial, median progression-free survival ("PFS") with the gedatolisib triplet was 9.3 months versus 2.0 months with fulvestrant, an incremental improvement of 7.3 months (HR=0.24; 95% CI: 0.17-0.35; p<0.0001). The objective response rate ("ORR") of the gedatolisib triplet was 31.5% compared to 1% with fulvestrant and the median duration of response ("DOR") was 17.5 months. For the gedatolisib doublet, the median PFS was 7.4 months versus 2.0 months with fulvestrant, an incremental improvement of 5.4 months (HR=0.33; 95% CI: 0.24-0.48; p<0.0001). The ORR of the gedatolisib doublet was 28.3% and the median DOR was 12.0 months. The median DOR was not determinable for fulvestrant because there was only one objective response.

The gedatolisib triplet and doublet were generally well tolerated in the trial with mostly low-grade treatment-related adverse events ("TRAEs"). The most common grade 3 TRAEs for the gedatolisib triplet, gedatolisib doublet, and fulvestrant groups included neutropenia (52.3%, 0%, and 0.8% of patients, respectively); stomatitis (19.2%, 12.3%, and 0%) rash (4.6%, 5.4%, and 0%); and hyperglycemia (2.3%, 2.3%, and 0%). The primary grade 4 TRAEs for the gedatolisib triplet and gedatolisib doublet groups were neutropenia (10.0% and 0.8%, respectively), leukopenia (0.8% in the gedatolisib triplet group), and pneumonitis (0.8% in gedatolisib doublet group). TRAEs led to the discontinuation of study treatment in 2.3% of patients in the gedatolisib triplet group, 3.1% in the gedatolisib doublet group, and 0% in the fulvestrant group.

"The efficacy data from the VIKTORIA-1 PIK3CA wild-type cohort represent an important addition to the clinical evidence in HR-positive, HER2-negative, PIK3CA wild-type advanced breast cancer," said Igor Gorbatchevsky, MD, Chief Medical Officer of Celcuity. "Importantly, these findings are potentially practice changing for patients with limited options."

The U.S. Food and Drug Administration has granted Priority Review of Celcuity's New Drug Application for gedatolisib and assigned a Prescription Drug User Fee Act goal date of July 17, 2026.

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]

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 advanced breast cancer. 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. Subjects who met eligibility criteria and did not have confirmed *PI3KCA* mutations (WT) were randomly assigned (1:1:1) to receive a regimen of either gedatolisib, palbociclib, and fulvestrant, gedatolisib and fulvestrant, or fulvestrant. Subjects who met eligibility criteria and had confirmed *PI3KCA* mutations (MT) 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 PI3K/AKT/mTOR ("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- advanced breast cancer ("ABC"), has completed enrollment, and the company has reported detailed results for the PIK3CA wild-type cohort. A Phase 3 clinical trial, VIKTORIA-2, evaluating gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with 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 topline clinical trial data; the status and timing of the FDA's review of our New Drug Application for gedatolisib; and other expectations with respect to gedatolisib. 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 results are based on a preliminary 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; and unanticipated developments that may impact the design of our clinical trials. 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, 2024, 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.

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