Celcuity's Phase 3 VIKTORIA-2 Trial of Gedatolisib as a First-Line Treatment for HR+/HER2- Advanced Breast Cancer Expanding to Include Endocrine-Sensitive Patients

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Development of a gedatolisib formulation for subcutaneous injection is underway; first patent application submitted to the U.S. Patent and Trademark Office

MINNEAPOLIS, May 14, 2026 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company focused on the development of targeted therapies for the treatment of multiple solid tumor indications, today announced updates to the Phase 3 VIKTORIA-2 clinical trial of gedatolisib as a first-line treatment for patients with hormone receptor positive ("HR+"), human epidermal growth factor receptor 2 negative ("HER2-") locally advanced or metastatic breast cancer ("ABC").

Following last year's announcement and subsequent data presentation demonstrating clinically meaningful improvement in progression-free survival ("PFS") for patients treated with gedatolisib combined with palbociclib and fulvestrant compared to those treated with fulvestrant in the *PIK3CA* wild-type ("WT") cohort of the VIKTORIA-1 Phase 3 study, several important elements of the VIKTORIA-2 clinical trial protocol have been amended. First, in addition to evaluating patients in the first-line setting with endocrine-resistant HR+/HER2- ABC, VIKTORIA-2 will now include a separate study to evaluate the safety and efficacy of patients in the first-line setting who have endocrine-sensitive HR+/HER2- ABC. Second, patients will be assigned manually according to their endocrine sensitivity status to either Study 1 (endocrine-resistant) or Study 2 (endocrine-sensitive) and subsequently be randomized to a treatment arm. Third, efficacy analyses for both Study 1 and Study 2 of VIKTORIA-2 will evaluate the entire intent-to-treat population (combined WT and mutant type ("MT")) enrolled in their respective study. Each study will have independent statistical analysis plans that will include separate primary endpoints. The primary endpoints for the VIKTORIA-2 clinical trial are PFS, per RECIST 1.1 criteria, as assessed by blinded independent central review ("BICR").

Prior to finalizing the amended Phase 3 trial design, Celcuity conducted a Type B meeting with the U.S. Food and Drug Administration (the "FDA") to obtain their feedback and to gain alignment on these planned amendments.

"We are excited to expand the VIKTORIA-2 study to include patients with endocrine-sensitive HR+/HER2- ABC. For patients with endocrine-sensitive HR+/HER2- advanced breast cancer who received gedatolisib in combination with palbociclib and letrozole in our Phase 1b clinical trial, median progression free survival was 48.6 months, median overall survival was 77.3 months, and the objective response rate was 79%," said Igor Gorbatchevsky, MD, Chief Medical Officer of Celcuity. "These results are very encouraging and compare favorably to published data for the current standard-of-care regimens for these patients."

"Results from the *PIK3CA* wild-type and mutation cohort of our VIKTORIA-1 study demonstrated the benefit of gedatolisib combination treatment in HR+/HER2- ABC in the second-line setting," said Brian Sullivan, CEO and co-founder of Celcuity. "Developing the gedatolisib triplet for nearly all patients in the first-line setting, irrespective of their endocrine sensitivity or *PIK3CA* status, offers the potential to advance the standard of care for the approximately 90,000 women each year who are diagnosed with late-stage HR+/HER2- ABC."

Gedatolisib Subcutaneous Formulation

To support its long-term lifecycle development plan, Celcuity also announced that it submitted to the United States Patent and Trademark Office ("USPTO") its first patent application for a subcutaneous formulation of gedatolisib that would enable a patient to receive gedatolisib as an injection as an alternative to an infusion. Development of the subcutaneous gedatolisib formulation is ongoing with the goal of demonstrating clinical equivalence to the current intravenous formulation of gedatolisib. The subcutaneous formulation is aimed to support potential future indications for gedatolisib regimens that may result in duration of treatment periods greater than several years.

"As we initiate pivotal studies for indications that may offer several years of progression-free survival benefit, development of a subcutaneous formulation of gedatolisib would particularly benefit patients who may potentially be receiving treatment with gedatolisib for extended time periods," said Brian Sullivan, CEO and co-founder of Celcuity.

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, only 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- ABC.[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 Phase 3 VIKTORIA-2 Study

VIKTORIA-2 is a Phase 3, global, open-label, randomized, clinical trial designed to evaluate the efficacy and safety of gedatolisib plus palbociclib and endocrine therapy as first-line treatment for patients with HR+/HER2- ABC. Patients will be assigned manually according to their endocrine sensitivity status to either Study 1 (endocrine-resistant) or Study 2 (endocrine-sensitive) and subsequently be randomized 1:1 to either investigational treatment or standard-of-care control.

Study 1 is expected to enroll approximately 440 patients with treatment-naïve endocrine-resistant ABC whose cancer progressed while receiving or within 12 months of completing adjuvant endocrine therapy. The trial will evaluate the efficacy and safety of gedatolisib combined with palbociclib and fulvestrant (Arm A) compared to ribociclib combined with fulvestrant (Arm B).

Study 2 is expected to enroll approximately 740 subjects with treatment-naïve endocrine-sensitive ABC whose cancer relapsed or progressed 12 months or more after completion of adjuvant endocrine therapy, or those with de novo metastatic disease without prior endocrine therapy exposure. The trial will evaluate the efficacy and safety of gedatolisib combined with palbociclib and letrozole (Arm C) compared to ribociclib combined with letrozole (Arm D).

The clinical trial primary endpoints for the VIKTORIA-2 clinical trial are PFS, per RECIST 1.1 criteria, as assessed by BICR.

This global trial is expected to enroll subjects at up to 200 clinical sites across North America, Europe, and Asia-Pacific.

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* MT and WT breast tumor cells in nonclinical studies and early clinical data.[11,12]

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

About Celcuity

Celcuity is a clinical-stage biotechnology company focused on the development of targeted therapies for the treatment of multiple solid tumor indications. Our lead therapeutic candidate is gedatolisib, a kinase inhibitor of the PAM pathway that binds to all class I PI3K isoforms and the mTOR complexes, mTORC1 and mTORC2. By targeting all class I PI3K isoforms and mTORC1/2, gedatolisib induces comprehensive inhibition of 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. Our 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 Study 1, which evaluated patients with *PIK3CA* WT tumors, and announced topline results for Study 2, which evaluated patients with *PIK3CA* MT tumors. Our Phase 3 clinical trial, VIKTORIA-2, is ongoing and incorporates two independent studies, Study 1 and Study 2, evaluating two separate cohorts of patients with ABC who are treatment-naive in the advanced setting. Study 1 is evaluating gedatolisib combined with palbociclib and fulvestrant as first-line treatment for patients with endocrine-resistant HR+/HER2- ABC. Study 2 is evaluating gedatolisib combined with palbociclib and letrozole as first-line treatment for patients with endocrine-sensitive HR+/HER2- ABC. A Phase 1b/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 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 future subcutaneous formulations of gedatolisib; 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 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.

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