Celcuity Presents Updated Results from the PIK3CA Wild-Type Cohort of the Phase 3 VIKTORIA-1 Trial at the 2025 San Antonio Breast Cancer Symposium

December 11, 2025

- *For patients whose time to progression on immediate prior therapy was >18 months, median progression-free survival ("PFS") was 12.4 months with gedatolisib + palbociclib + fulvestrant ("gedatolisib triplet") and 10.0 months with gedatolisib + fulvestrant ("gedatolisib doublet") versus 1.9 months for fulvestrant*

- *For patients enrolled in the U.S., Canada, Western Europe, and Asia Pacific, median PFS was 16.6 months with the gedatolisib triplet and 7.1 months with the gedatolisib doublet versus 1.9 months for fulvestrant*

- *Measures to mitigate stomatitis were generally effective; most patients experienced resolution to a lower grade of stomatitis within 2 weeks*

MINNEAPOLIS, Dec. 11, 2025 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced updated results from the randomized, Phase 3 VIKTORIA-1 trial for gedatolisib, a multi-target PI3K/AKT/mTOR ("PAM") inhibitor, in adults with hormone receptor positive ("HR+"), human epidermal growth factor receptor 2 negative ("HER2-"), *PIK3CA* wild-type ("WT"), advanced breast cancer ("ABC"), following progression on, or after, treatment with a CDK4/6 inhibitor and an aromatase inhibitor. The additional study results were presented in an oral presentation session at the 2025 San Antonio Breast Cancer Symposium ("SABCS") today, Thursday, December 11.

Efficacy was further evaluated in several additional patient sub-groups. For patients whose time to progression on immediate prior therapy was >18 months, representing nearly half of those enrolled, median PFS was 12.4 months (HR=0.17; 95% CI: 0.11-0.28) with the gedatolisib triplet and 10.0 months (HR=0.19; 95% CI: 0.12-0.31) with the gedatolisib doublet versus 1.9 months for fulvestrant. For patients enrolled in the U.S., Canada, Western Europe, and Asia Pacific, representing nearly 60% of those enrolled, median PFS was 16.6 months (HR=0.14; 95% CI: 0.09-0.26) with the gedatolisib triplet and 7.1 months (HR=0.36; 95% CI: 0.24-0.57) with the gedatolisib doublet versus 1.9 months for fulvestrant.

Additional safety analyses were also performed. For patients who experienced stomatitis, measures to mitigate it were generally effective. The median time to improvement to a lower grade of stomatitis for patients with Grade 2 or 3 stomatitis who received the gedatolisib triplet was 12 and 14 days, respectively, and for patients with Grade 2 or 3 stomatitis who received the gedatolisib doublet, the median time to improvement was 8 and 9 days, respectively. As reported previously, gedatolisib did not produce clinically relevant hyperglycemia and induced no dose reductions or withdrawals due to hyperglycemia. Consistent with these results, median glucose levels, both fasting and non-fasting, were stable over time.

Both the gedatolisib regimens delayed time to definitive deterioration versus fulvestrant according to patient reported outcomes for well-being measures that included mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (the EQ-5D-5L score). The median time to definitive deterioration was 23.7 months (HR=0.39; 95% CI: 0.25-0.67; p = 0.0003) for patients treated with the gedatolisib triplet and not reached for the gedatolisib doublet (HR=0.37; 95% CI: 0.24-0.66; p = 0.0003) versus 4.0 months for fulvestrant.

"The updated results provide further evidence of the potential for gedatolisib combined with fulvestrant with or without palbociclib to offer paradigm shifting results for patients with HR-positive, HER2-negative, *PIK3CA* wild-type advanced breast cancer," said Igor Gorbatchevsky, MD, Chief Medical Officer of Celcuity. "We are very excited that patients reported nearly two years of delay in definitive deterioration of their well-being. This provides meaningful evidence of how well patients tolerated the gedatolisib regimens. This safety-profile, combined with the 16.6 months of median PFS reported for patients from the U.S., Canada, Western Europe, and Asia Pacific who received the gedatolisib triplet, further highlights the differentiated profile of the gedatolisib regimens."

The gedatolisib clinical data being presented at the SABCS is available on the publications page of the Celcuity website.

About Celcuity

Celcuity is a clinical-stage biotechnology company pursuing development of targeted therapies for 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- ABC has completed enrollment and the company has reported detailed results for the *PIK3CA* wild-type cohort, and has completed enrollment of patients 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 HR+/HER2- ABC is currently enrolling patients. 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 ability of our data to support the filing of a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA"); our expectations regarding the timing of and our ability to obtain FDA approval under the RTOR program and to commercialize 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 clinical results are based on an ongoing analysis of key efficacy and safety data and our interpretation of such data may change; unforeseen delays in the review of our NDA for gedatolisib; and our ability to obtain and maintain regulatory approvals to commercialize gedatolisib. 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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