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

November 26, 2025

MINNEAPOLIS, Nov. 26, 2025 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced that an abstract was accepted for an oral presentation at the 2025 San Antonio Breast Cancer Symposium (SABCS) and is now available on the SABCS website. The 2025 SABCS is being held virtually and in-person from December 9-12, 2025. The presentation will include additional sub-group efficacy analyses and safety data.

Abstract presentation details are provided below.

Abstract Title: Gedatolisib, a multi-target PI3K/AKT/mTOR (PAM) inhibitor, plus fulvestrant with or without palbociclib for second-line (2L) treatment of patients with HR+/HER2-/PIK3CA-wild type (WT) advanced breast cancer (ABC): updated results from the randomized, phase 3 VIKTORIA-1 trial
Author: Barbara Pistilli, MD
Presentation number: RF7-04
Session Title: Rapid Fire 7
Presentation Date: December 11, 2025

For more details about SABCS please visit: https://www.sabcs.org/.

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.

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