Celcuity to Present Results from the Pivotal Phase 3 VIKTORIA-1 Trial at the 2025 European Society for Medical Oncology (ESMO) Congress

September 22, 2025

MINNEAPOLIS, Sept. 22, 2025 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced that a late breaking abstract reporting clinical data from the Phase 3 VIKTORIA-1 trial has been selected for an oral presentation at the upcoming European Society of Medical Oncology (ESMO) Congress, being held October 17-21, 2025. The presentation will provide detailed efficacy and safety data from the *PIK3CA* wild-type cohort of the VIKTORIA-1 trial.

Late Breaking Oral Presentation Details:

Title : Gedatolisib + fulvestrant ± palbociclib vs fulvestrant in patients with HR+/HER2-/ *PIK3CA* wild-type advanced breast cancer: First results from VIKTORIA-1

Abstract Number : 3535

Session Title : Proffered paper session 1: Breast Cancer, metastatic

Date : October 18, 2025

Time : 10:15 am – 11:45 am CEST

Late-breaking abstracts (LBA) accepted for a Proffered Paper Session at the ESMO Congress 2025 will be published online via the ESMO website on the day of presentation.

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 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 of and reported topline data for the *PIK3CA* wild-type cohort, and is currently enrolling patients for the *PIK3CA* mutant cohort. 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. 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. 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 .

View source version of release on GlobeNewswire.com

Contacts:

Celcuity Inc.
Brian Sullivan, bsullivan@celcuity.com
Vicky Hahne, vhahne@celcuity.com
(763) 392-0123

ICR Healthcare
Patti Bank, patti.bank@icrhealthcare.com
(415) 513-1284

EXPANDING TREATMENT OPTIONS

News Provided by GlobeNewswire via QuoteMedia