Celcuity Announces First Patient Dosed in Phase 3 VIKTORIA-2 Clinical Trial of Gedatolisib as a First-Line Treatment for HR+/HER2- Advanced Breast Cancer

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MINNEAPOLIS, July 24, 2025 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced that the first patient has been dosed in VIKTORIA-2, its Phase 3 clinical trial evaluating gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with HR+/HER2- advanced breast cancer (“ABC”) who are endocrine therapy resistant. Gedatolisib is an investigational, multi-target PI3K/AKT/mTOR (“PAM”) inhibitor that potently targets all four class I PI3K isoforms, mTORC1, and mTORC2 to induce comprehensive blockade of the PAM pathway.

“We are excited to begin enrolling patients in the Phase 3 VIKTORIA-2 trial and advancing gedatolisib into the front-line setting for HR-positive, HER2-negative advanced breast cancer,” said Igor Gorbatchevsky, M.D., Chief Medical Officer of Celcuity. “Treatment naïve patients with advanced breast cancer who are endocrine treatment resistant receive limited benefit from a CDK4/6 inhibitor and fulvestrant, the current standard of care regimen for most of these patients. In patients with endocrine sensitive HR+/HER2- advanced breast cancer who received gedatolisib in combination with palbociclib and letrozole in a 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%. These results provide preliminary evidence that comprehensive inhibition of the PAM pathway may induce a clinical benefit to treatment naïve patients with endocrine resistant advanced breast cancer.”

“There is an urgent need for better first-line therapeutic options for HR+/HER2- advanced breast cancer patients whose disease progressed while on or within 12 months of completing adjuvant endocrine treatment for early breast cancer,” said Giuseppe Curigliano, M.D., Ph.D., Director of the Early Drug Development Division and co-chair for the Experimental Therapeutics Program at the European Institute of Oncology and co-principal investigator for the VIKTORIA-2 clinical trial. “The Phase 3 VIKTORIA-2 study aims to evaluate whether the gedatolisib triplet can induce a clinically meaningful benefit in patients regardless of the PIK3CA status of their tumor or their metabolic profile. We intend to generate a robust data package with the goal of bringing gedatolisib to the clinic as a potential first-line treatment.”

About VIKTORIA-2

VIKTORIA-2 is a Phase 3 open-label, randomized clinical trial to evaluate the efficacy and safety of gedatolisib combined with fulvestrant plus a CDK4/6 inhibitor in comparison to fulvestrant plus a CDK4/6 inhibitor as first-line treatment for patients with HR+/HER2- ABC who are endocrine therapy resistant. For the CDK4/6 inhibitor, investigators may choose either ribociclib or palbociclib. Prior to enrolling patients in the Phase 3 portion of the study and confirming the Phase 3 dose with ribociclib, a safety run-in of approximately 12-36 subjects will evaluate the safety profile of gedatolisib combined with ribociclib and fulvestrant. The safety profile of gedatolisib combined with fulvestrant and palbociclib is well described, but the investigational combination of gedatolisib with ribociclib has not yet been clinically tested.

For the Phase 3 study, approximately 638 subjects who meet the eligibility criteria will be assigned to a cohort based on their *PIK3CA* mutation status. After the investigator selects the CDK4/6 inhibitor for a subject, the subject will then be randomly assigned on a 1:1 basis to either Arm A (gedatolisib, fulvestrant, and Investigator’s choice of ribociclib or palbociclib) or Arm B (fulvestrant and Investigator’s choice of ribociclib or palbociclib). This global trial is expected to enroll subjects at up to 200 clinical sites across North America, Europe, Latin America, and Asia. The clinical trial primary endpoints are progression free survival ("PFS"), per RECIST 1.1 criteria, as assessed by blinded independent central review. The primary PFS endpoints will be evaluated separately in subjects who are *PI3KCA* wild type and *PI3KCA* mutant.

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 is currently enrolling patients. More detailed information about the VIKTORIA-1 study can be found at ClinicalTrials.gov. 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. 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- advanced breast cancer is currently enrolling patients. Celcuity is headquartered in Minneapolis. Further information about Celcuity can be found at www.celcuity.com. Follow us on LinkedIn and Twitter.

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; 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 planned 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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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