Celcuity to Initiate NDA Submission of Gedatolisib in PIK3CA Wild-Type Cohort in HR+/HER2- Advanced Breast Cancer Under FDA's Real-Time Oncology Review Program

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MINNEAPOLIS, Aug. 27, 2025 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced the U.S. Food and Drug Administration (“FDA”) agreed to accept its New Drug Application (“NDA”) for gedatolisib in HR+/HER2- advanced breast cancer (“ABC”) for review under the Real-Time Oncology Review (“RTOR”) program, which facilitates earlier submission of topline efficacy and safety results, prior to the submission of the complete application, to support an earlier start to the FDA’s evaluation of the application. Celcuity is expected to initiate in September a rolling submission to the FDA of its NDA for gedatolisib, based on topline data from the *PIK3CA* wild-type cohort of the Phase 3 VIKTORIA-1 clinical trial. Completion of the NDA submission is targeted for the fourth quarter of 2025.

“On the heels of announcing positive pivotal data last month, we are pleased that the FDA agreed to review our NDA application for gedatolisib under the RTOR program,” said Brian Sullivan, CEO and co-founder of Celcuity. “Gedatolisib previously received both Breakthrough Therapy and Fast Track designations based on our promising preliminary clinical data. The FDA’s decision further highlights the urgent need for more efficacious therapies than those currently available for patients with HR+, HER2- advanced breast cancer who have received prior treatment with a CDK4/6 inhibitor. We look forward to working with the FDA to complete the review of our NDA for gedatolisib.”

The NDA submission is based on the positive topline results for the *PIK3CA* wild-type cohort of the Phase 3 VIKTORIA-1 trial. The efficacy results established several new milestones in the history of drug development for HR+/HER2- ABC. The gedatolisib-triplet (gedatolisib, fulvestrant and palbociclib) reduced the risk of disease progression or death by 76% compared to fulvestrant based on a hazard ratio of 0.24. The median progression-free survival (“PFS”) was 9.3 months with the gedatolisib-triplet versus 2.0 months with fulvestrant, an incremental improvement of 7.3 months. The gedatolisib-doublet (gedatolisib and fulvestrant) reduced the risk of disease progression or death by 67% compared to fulvestrant based on a hazard ratio of 0.33. The median PFS was 7.4 months with the gedatolisib-doublet versus 2.0 months with fulvestrant, an incremental improvement of 5.4 months. These hazard ratios and improvements in median PFS are unprecedented in HR+/HER2- ABC.

About RTOR

The FDA established the RTOR program to facilitate a more efficient review process for drugs to ensure that safe and effective treatments are available to patients as early as possible, while improving review quality and engaging in early iterative communication with the applicant. To be considered for RTOR, submissions should demonstrate the following: 1) clinical evidence from adequate and well-controlled investigation that indicates the drug may demonstrate substantial improvement on a clinically relevant endpoint over available therapies; 2) easily interpreted clinical trial endpoints; 3) no aspect of the submission is likely to require a longer review time. Additional information about RTOR can be found at: https://www.fda.gov/about-fda/oncology-center-excellence/real-time-oncology-review-pilot-program .

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- 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 .

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 topline clinical trial data; the ability of our data to support the filing of an NDA with

the FDA; our expectations regarding the timing of and our ability to obtain FDA approval to commercialize gedatolisib under the RTOR pilot program; 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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