Celcuity Announces Completion of Submission of Its New Drug Application to the U.S. FDA for Gedatolisib in HR+/HER2-/PIK3CA Wild-Type Advanced Breast Cancer

November 17, 2025

MINNEAPOLIS, Nov. 17, 2025 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced the completion of the submission of its New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for gedatolisib in hormone receptor positive ("HR+"), human epidermal growth factor receptor 2 negative ("HER2-"), advanced breast cancer ("ABC"). The NDA was submitted under the FDA's Real-Time Oncology Review ("RTOR") program, which is intended to facilitate shorter regulatory review periods. Gedatolisib previously received both Breakthrough Therapy and Fast Track designations based on promising preliminary clinical data. The submission is based on clinical data from the *PIK3CA* wild-type cohort of the Phase 3 VIKTORIA-1 clinical trial.

"This NDA submission is an important milestone, and it brings gedatolisib one step closer to becoming available for patients with HR+/HER2- advanced breast cancer," said Brian Sullivan, CEO and co-founder of Celcuity. "We look forward to working with the FDA during the NDA review process. We believe the unprecedented efficacy results and overall safety profile of the gedatolisib regimens are potentially practice changing for patients with HR+/HER2- advanced breast cancer."

The NDA submission is based on the positive clinical 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.

Gedatolisib

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.[1,2,3] As a multi-target PAM inhibitor, gedatolisib's mechanism of action is highly differentiated from currently approved single-target inhibitors of the PAM pathway.[2] Inhibition of only a single PAM component results in cross-activation of the uninhibited components, which limits the suppression of PAM pathway activity. Gedatolisib's comprehensive PAM pathway inhibition enables full suppression of the PAM pathway by minimizing the adaptive cross-activation that occurs with single-target inhibitors. Unlike single-target inhibitors of the PAM pathway, gedatolisib has demonstrated comparable potency and cytotoxicity in *PIK3CA*-mutant and wild-type breast tumor cells in nonclinical studies and early clinical data.[3,4]

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; and 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 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 an NDA with the 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.

References

1. Venkatesan, A. M., et al. Bis(morpholino-1,3,5-triazine) derivatives: potent adenosine 5'-triphosphate competitive phosphatidylinositol-3-kinase/mammalian target of rapamycin inhibitors: discovery of compound 26 (PKI-587), a highly efficacious dual inhibitor. J Med Chem, 2010;53(6), 2636-2645. https://doi.org/10.1021/jm901830p
2. Mallon, R., et al. Antitumor efficacy of PKI-587, a highly potent dual PI3K/mTOR kinase inhibitor. Clin Cancer Res, 2011;17(10), 3193-3203. https://doi.org/10.1158/1078-0432.CCR-10-1694
3. Rossetti, S., et al. Gedatolisib shows superior potency and efficacy versus single-node PI3K/AKT/mTOR inhibitors in breast cancer models. NPJ Breast Cancer, 2024;10(1), 40. https://doi.org/10.1038/s41523-024-00648-0
4. Layman, R., et al. Gedatolisib in combination with palbociclib and endocrine therapy in women with hormone receptor-positive, HER2-negative advanced breast cancer: results from the dose expansion groups of an open-label, phase 1b study. Lancet Oncol, 2024;25(4), 474-487. https://doi.org/10.1016/S1470-2045(24)00034-2

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

celcuity

Source: Celcuity Inc.