Celcuity Announces Issuance of New Patent for Gedatolisib that Extends Patent Exclusivity into 2042

July 14, 2025

MINNEAPOLIS, July 14, 2025 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced the issuance of U.S. Patent No. 12,350,276 covering the clinical dosing regimen for its lead drug candidate, gedatolisib, in ER+/HER2- breast cancer patients. The patent extends Celcuity's patent exclusivity in the U.S. into 2042.

"This dosing regimen patent reflects our commitment to enhancing our intellectual property portfolio," said Brian Sullivan, CEO and Co-Founder of Celcuity. "With patent exclusivity for gedatolisib now extended into 2042, we expect to have a long runway to optimize development of gedatolisib."

The United States Patent and Trademark Office previously issued five U.S. patents directed to gedatolisib's composition of matter, four U.S. patents directed to various formulations comprising gedatolisib, and three U.S. patents directed to methods of using gedatolisib. The worldwide gedatolisib-related patent portfolio now comprises 13 granted gedatolisib-related patents in the U.S. and 290 patents granted in foreign jurisdictions.

Celcuity expects to announce topline data for the *PIK3CA* wild-type cohort of the VIKTORIA-1 clinical trial in the third quarter of 2025 and to report topline data for the *PIK3CA* mutant cohort in the fourth quarter of 2025.

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- advanced breast cancer 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. 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 recruiting 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 "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to patent scope and length of protection and the anticipated timing of topline data from the VIKTORIA-1 clinical trial. 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 generics or others could challenge the validity of the gedatolisib patents, Celcuity may not be able to enforce the patents, there could be patent-related litigation or the progress of the VIKTORIA-1 clinical trial may be delayed. 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. 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 news release to reflect events or circumstances after the date hereof.

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