Celcuity Announces FDA Acceptance of sNDA for REVTORPYK™ (gedatolisib) for HR+/HER2-, PIK3CA Mutant Locally Advanced or Metastatic Breast Cancer

November 9, 2026

FDA assigned a PDUFA goal date of June 25, 2027

MINNEAPOLIS, Nov. 09, 2026 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a commercial-stage biotechnology company focused on developing and commercializing targeted therapies for the treatment of multiple solid tumor indications, today announced that the U.S. Food and Drug Administration ("FDA") has accepted for review its supplemental New Drug Application ("sNDA") for REVTORPYK™ (gedatolisib) for the treatment of patients with hormone receptor positive ("HR+"), human epidermal growth factor receptor 2 negative ("HER2-"), locally advanced or metastatic breast cancer ("ABC") with a *PIK3CA* mutation, following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting. The FDA assigned a Prescription Drug User Fee Act ("PDUFA") goal date of June 25, 2027.

The submission is based on clinical data from the *PIK3CA* mutant-type cohort of the Phase 3 VIKTORIA-1 clinical trial. Gedatolisib previously received both Breakthrough Therapy and Fast Track designations based on promising preliminary clinical data.

"The FDA's acceptance of this sNDA takes us one step closer to bringing REVTORPYK to more patients living with HR+/HER2- locally advanced or metastatic breast cancer," said Brian Sullivan, CEO and co-founder of Celcuity. "If approved, REVTORPYK would become available to patients as second-line therapy regardless of the *PIK3CA* status of a tumor, reflecting both the strength of our clinical development program and the potential to address a meaningful unmet need for a broader population of patients."

On July 14, 2026, REVTORPYK in combination with fulvestrant, with or without palbociclib, received FDA approval for the treatment of patients with HR+/HER2- ABC without a *PIK3CA* mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting.

About HR+/HER2- Breast Cancer
Breast cancer is the second most common cancer and one of the leading causes of cancer-related deaths worldwide.[1] More than two million breast cancer cases were diagnosed globally in 2022.[1] While survival rates are high for those diagnosed with early breast cancer, only approximately 30% of patients who are diagnosed with or who progress to metastatic disease are expected to live five years after their diagnosis.[2] HR+/HER2- breast cancer is the most common subtype of breast cancer, accounting for approximately 70% of all breast cancers.[2] Among this breast cancer subtype, approximately 40% have *PIK3CA* mutations.[3]

About REVTORPYK (gedatolisib)
REVTORPYK is a kinase inhibitor of class I PI3K isoforms (α, β, δ, γ) and mTOR complexes mTORC1 and mTORC2, resulting in downstream inhibition of multiple effectors, including AKT.[4,5,6]

REVTORPYK is in development for the first-line treatment of HR+/HER2- locally advanced or metastatic breast cancer and for the second-line treatment of metastatic castration-resistant prostate cancer.

Indication Statement
REVTORPYK (gedatolisib) is a kinase inhibitor indicated in combination with fulvestrant, with or without palbociclib, for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer without a *PIK3CA* mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Stomatitis: REVTORPYK can cause severe stomatitis, including ulcers and oral mucositis. Stomatitis occurred in 72% of patients treated with REVTORPYK with fulvestrant and palbociclib, including Grade 3 events in 22% of patients. Stomatitis occurred in 58% of patients treated with REVTORPYK with fulvestrant, including Grade 3 events in 12% of patients. Initiate a steroid-containing, alcohol-free mouthwash prior to starting treatment with REVTORPYK and continue prophylactically during treatment. Monitor patients for signs and symptoms of stomatitis. Withhold, reduce dose, or permanently discontinue REVTORPYK based on severity.

Dermatologic Adverse Reactions: REVTORPYK can cause severe rash. Rash occurred in 30% of patients treated with REVTORPYK in combination with fulvestrant and palbociclib, including Grade 3 events in 6% of patients. Rash occurred in 40% of patients treated with REVTORPYK with fulvestrant, including 5% of patients with Grade 3 events. Monitor patients for rash and

infectious sequelae. Instruct patients to limit sun exposure during REVTORPYK treatment. Withhold, reduce dose, or permanently discontinue REVTORPYK based on severity.

Hyperglycemia: REVTORPYK can cause severe hyperglycemia. Monitor fasting glucose prior to initiating treatment with REVTORPYK and periodically during treatment. Monitor HbA1c level if clinically indicated. Increased fasting glucose occurred in 46% of patients receiving REVTORPYK in combination with fulvestrant and palbociclib (Grade 3: 0.9%) and in 57% of patients receiving REVTORPYK in combination with fulvestrant (Grade 3: 1.8%). The safety of REVTORPYK has not been established in patients with Type 1 or uncontrolled Type 2 diabetes mellitus. Patients with well-controlled Type 2 diabetes may require intensified antihyperglycemic therapy and close monitoring of fasting glucose. Manage hyperglycemia with antihyperglycemic medications as clinically indicated. Evaluate fasting blood glucose and HbA1c levels prior to starting and at regular intervals during treatment. Withhold, reduce dose, or permanently discontinue REVTORPYK based on severity.

Embryo-Fetal Toxicity: Based on its mechanism of action, REVTORPYK can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with REVTORPYK and for 2 weeks after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 2 weeks after the last dose.
Advise women not to breastfeed during treatment with REVTORPYK and for 2 weeks after the last dose. When REVTORPYK is used in combination, advise patients to use effective contraception during treatment and for the longest post-treatment duration recommended in the Prescribing Information of any of the individual products. Verify the pregnancy status of females of reproductive potential prior to initiating treatment.

ADVERSE REACTIONS
REVTORPYK in Combination with Fulvestrant and Palbociclib: The most common (≥20%) adverse reactions, including laboratory abnormalities when given in combination with fulvestrant and palbociclib were decreased white blood cells, decreased neutrophils, decreased hemoglobin, decreased lymphocytes, stomatitis, nausea, decreased platelets, increased fasting glucose, fatigue, vomiting, rash, constipation, diarrhea, increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), musculoskeletal pain, decreased sodium, and increased eosinophils.

REVTORPYK in Combination with Fulvestrant: The most common (≥20%) adverse reactions, including laboratory abnormalities when given in combination with fulvestrant were stomatitis, glucose increased, eosinophils increased, hemoglobin decreased, nausea, rash, ALT increased, fatigue, musculoskeletal pain, lymphocytes decreased, vomiting, AST increased, pruritus, and diarrhea.

USE IN SPECIFIC POPULATION
Lactation: Advise women not to breastfeed during treatment with REVTORPYK and for 2 weeks after the last dose. When used in combination, advise patients not to breastfeed during treatment and for the longest post-treatment duration recommended in the Prescribing Information of any of the individual products.

Infertility: Advise females and males of reproductive potential that REVTORPYK may impair fertility.

Please see full Prescribing Information, including Patient Information, for REVTORPYK.

You may report side effects related to Celcuity products to Celcuity Medical Information at 1-877-4-CELCUITY (1-877-423-5284) or to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About Celcuity
Celcuity is a commercial-stage biotechnology company focused on developing and commercializing targeted therapies for the treatment of multiple solid tumor indications. Celcuity's first FDA-approved product is REVTORPYK™ (gedatolisib), a potent pan-PI3K and mTORC1/2 inhibitor that comprehensively blocks 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. Celcuity's Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib plus fulvestrant with or without palbociclib in patients with HR+/HER2- ABC, supported FDA approval of REVTORPYK for use in adult patients without a *PIK3CA* mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting. Results for the *PIK3CA* mutant cohort of the VIKTORIA-1 clinical trial have been released.

Celcuity's Phase 3 clinical trial, VIKTORIA-2, is an ongoing trial incorporating two independent studies, Study 1 and Study 2, in two separate cohorts of patients with ABC who are treatment-naive in the advanced setting. Study 1 is evaluating gedatolisib plus palbociclib and fulvestrant as first-line treatment for patients with endocrine-resistant HR+/HER2- ABC. Study 2 is evaluating gedatolisib plus palbociclib and letrozole as first-line treatment for patients with endocrine-sensitive HR+/HER2- ABC. Celcuity's Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib plus 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, Minnesota. Further information about Celcuity and its products, including important safety information and full prescribing information can be found at https://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 REVTORPYK and the potential therapeutic benefits of gedatolisib; the size, design and timing of the Company's clinical trials; the Company's interpretation of clinical trial data; the status and timing of the FDA's review of the Company's sNDA for REVTORPYK; the market opportunity for gedatolisib; the Company's expectations regarding the timing of and its ability to commercialize REVTORPYK; and the Company's strategy, marketing and commercialization plans, including the benefits of strategic decisions regarding studies and trials. 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 the Company's topline clinical results are based on an ongoing analysis of 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 the Company's clinical trials or the FDA's review of its sNDA for REVTORPYK; the Company's ability to obtain regulatory approval of its sNDA and maintain regulatory approvals to commercialize REVTORPYK in the U.S., and the market acceptance of REVTORPYK; the development of therapies and tools competitive with gedatolisib; and the Company's ability to access capital upon favorable terms. In addition, all forward-looking statements are subject to other risks detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, as such risks may be updated in its 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 the Company undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

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Contacts:

For Investors:
Vicky Hahne, vhahne@celcuity.com
(763) 392-0123
Jodi Sievers, jsievers@celcuity.com
(415) 494-9924

For Media:
Sam Brown LLC
Laura Morgan, lauramorgan@sambrown.com
(951) 333-9110