



Newly FDA-Approved REVTORPYK™ (gedatolisib) Included in the National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines for HR+/HER2- Locally Advanced or Metastatic Breast Cancer

July 30, 2026

REVTORPYK (gedatolisib) in combination with fulvestrant, with or without palbociclib, listed as a preferred Category 1 regimen for second-line or subsequent treatment for tumors without a PIK3CA mutation following progression on or after at least one line of endocrine therapy

MINNEAPOLIS, July 30, 2026 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a biotechnology company focused on developing and commercializing targeted therapies for multiple solid tumor indications, today announced that REVTORPYK™ (gedatolisib) in combination with fulvestrant, with or without palbociclib, is recommended by the National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) as a preferred Category 1 second-line and/or subsequent-line therapy following progression on or after treatment with at least one line of endocrine therapy.

REVTORPYK was granted approval by the U.S. Food and Drug Administration ("FDA") on July 14, 2026, for the treatment of patients with hormone receptor positive ("HR+"), human epidermal growth factor receptor 2 negative ("HER2-"), 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. REVTORPYK is the only inhibitor of class I PI3K isoforms (α , β , δ , γ) and mTOR complexes mTORC1 and mTORC2 to receive FDA approval.

"The inclusion of REVTORPYK in the NCCN Guidelines shortly after FDA approval highlights the clinical relevance of this treatment option for patients with advanced breast cancer," said Igor Gorbachevsky, Chief Medical Officer of Celcuity. "Because the NCCN Guidelines are a foundational resource for oncologists in determining the best course of treatment for patients, we believe these guidelines will increase awareness of REVTORPYK and support informed treatment decision-making for patients with HR+/HER2- locally advanced or metastatic breast cancer."

The approval of REVTORPYK is based on positive clinical results from the *PIK3CA* wild-type cohort of the Phase 3 VIKTORIA-1 trial, an open-label, global, randomized clinical trial evaluating the efficacy and safety of REVTORPYK plus fulvestrant, with or without palbociclib, for the treatment of patients with HR+/HER2- locally advanced or metastatic breast cancer following progression on or after CDK4/6 therapy and an aromatase inhibitor. In the VIKTORIA-1 trial, median progression free survival ("PFS") with the REVTORPYK triplet (REVTORPYK plus palbociclib and fulvestrant) was 9.3 months versus 2.0 months with fulvestrant, an incremental improvement of 7.3 months (HR=0.24; 95% CI: 0.17-0.35; $p<0.0001$). The objective response rate ("ORR") of the REVTORPYK triplet was 32% compared to 1% with fulvestrant, and the median duration of response ("DOR") was 17.5 months. For the REVTORPYK doublet (REVTORPYK plus fulvestrant), the median PFS was 7.4 months versus 2.0 months with fulvestrant, an incremental improvement of 5.4 months (HR=0.33; 95% CI: 0.24-0.48; $p<0.0001$). The ORR of the REVTORPYK doublet was 28%, and the median DOR was 12.0 months. The median DOR was not determinable for fulvestrant because there was only one objective response.

See the following link for additional safety information and full prescribing information: https://www.celcuity.com/wp-content/uploads/2026/04/REVTORPYK_PI_2026.pdf

The NCCN Guidelines® play a pivotal role in decision-making processes for individuals involved in cancer care all over the world, including physicians, nurses, pharmacists, payers, and patients and their families. The guidelines present expert recommendations for cancer screening, diagnosis, and treatment, as well as cancer care options, and are utilized in cancer treatment decision-making to drive positive patient outcomes. NCCN is a not-for-profit alliance of 33 leading cancer centers devoted to patient care, research, and education. NCCN is dedicated to defining and advancing effective, equitable, accessible, and quality cancer care and prevention so all people can live better lives. NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

Based on the company's commitment to ensuring broad patient access to REVTORPYK, Celcuity has created a comprehensive patient support program. REVTORPYK is expected to be commercially available in the U.S. in the late third quarter of 2026. To make REVTORPYK available to patients prior to commercial launch, those who are eligible will be able to enroll in Celcuity's expanded access program. Physician requests for participation in Celcuity's expanded access program may be made by emailing: gedatolisib@tannerpharma.com.

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.^{3,4,5}

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 ($\geq 20\%$) 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 ($\geq 20\%$) 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.

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About Celcuity

Celcuity is a biotechnology company focused on developing and commercializing targeted therapies for the treatment of multiple solid tumor indications. The company's first FDA-approved product is REVTORPYK (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 PI3K α , 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- locally advanced or metastatic breast cancer ("ABC"), supported FDA approval of REVTORPYK for use in patients without a *PIK3CA* mutation detected. Results for the *PIK3CA* mutant cohort of VIKTORIA-1 have been released. VIKTORIA-2 is an ongoing Phase 3 clinical trial incorporating two independent studies, Study 1 and Study 2, in two separate cohorts of patients with ABC who are treatment-naïve in the advanced setting. Study 1 is evaluating gedatolisib plus palbociclib plus fulvestrant as first-line treatment for patients with endocrine-resistant HR+/HER2- ABC. Study 2 is evaluating gedatolisib plus palbociclib plus letrozole as first-line treatment for patients with endocrine-sensitive HR+/HER2- ABC. 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 the Company's clinical trials; the Company's interpretation of clinical trial data; the Company's expectations regarding the timing of and its ability to commercialize gedatolisib; the Company's strategy, marketing and commercialization plans, including the benefits of strategic decisions regarding studies and trials; other expectations with respect to gedatolisib; the Company's anticipated use of cash; and the strength of its balance sheet. 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 submission, and FDA's review of, its supplemental new drug application ("sNDA") for gedatolisib; the Company's ability to obtain regulatory approval of its sNDA and maintain regulatory approvals to commercialize gedatolisib, and the market acceptance of gedatolisib; 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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