Celcuity Announces FDA Approval of REVTORPYK™ (gedatolisib) for the Treatment of HR+/HER2-, PIK3CA Wild-Type Locally Advanced or Metastatic Breast Cancer

July 14, 2026

- *REVTORPYK is the first and only FDA-approved therapy that inhibits all class I PI3K isoforms (α, β, δ, γ) and mTOR complexes mTORC1 and mTORC2*

- *In the Phase 3 VIKTORIA-1 trial, REVTORPYK combined with palbociclib and fulvestrant and REVTORPYK combined with fulvestrant reduced the risk of disease progression or death by 76% and 67%, respectively, compared to fulvestrant among patients with PIK3CA wild-type advanced or metastatic breast cancer*

- *Celcuity to host webcast and conference call today Tuesday, July 14, 2026, at 5:30 p.m. EDT*

REVTORPYK (gedatolisib)

REVTORPYK (gedatolisib) vial and box

MINNEAPOLIS, July 14, 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 the U.S. Food and Drug Administration ("FDA") approved 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 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 PI3K/AKT/mTOR, or PAM, pathway is one of the most important targets in cancer, but comprehensively inhibiting it has stymied researchers and drug developers for nearly two decades," said Brian Sullivan, CEO and co-founder of Celcuity. "REVTORPYK addressed this 20-year challenge by becoming the first pan-PI3K, mTORC1/2 inhibitor approved by the FDA. We are thankful for the opportunity to make this important new therapy available to patients with HR+/HER2- locally advanced or metastatic breast cancer."

HR+/HER2- breast cancer is the most common subtype of breast cancer, accounting for approximately 70% of all breast cancers.[1] Among this breast cancer subtype, approximately 60% have *PIK3CA* wild-type disease.[2]

"For patients with HR+/HER2- locally advanced or metastatic breast cancer, there is an urgent need for new treatment options that can meaningfully increase the likelihood of survival without disease progression or death," said Sara Hurvitz, MD, Senior Vice President, Clinical Research Division, Fred Hutchinson Cancer Center, Smith Family Endowed Chair in Women's Health and Professor and Head, Division of Hematology and Oncology, University of Washington, School of Medicine and co-principal investigator for the VIKTORIA-1 trial. "With the approval of REVTORPYK, oncologists now have an effective new treatment option for these patients."

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 locally advanced or metastatic HR+/HER2- 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.

"Today's approval of REVTORPYK addresses a significant unmet need for the thousands of patients affected each year by HR+/HER2-, *PIK3CA* wild-type locally advanced or metastatic breast cancer whose disease has progressed after endocrine therapy," said Igor Gorbatchevsky, MD, Chief Medical Officer of Celcuity. "We are deeply grateful to the patients and their

caregivers, investigators and clinical study teams, and Celcuity team members who made this advancement possible."

Celcuity anticipates commercial launch in late Q3 2026. Based on the company's commitment to ensuring broad, affordable, and unrestricted patient access to REVTORPYK, we have designed a comprehensive patient support program. 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.

Celcuity plans to submit in Q3 2026 a supplemental New Drug Application ("sNDA") to the FDA for REVTORPYK for the treatment of HR+/HER2-, *PIK3CA* mutated, locally advanced or metastatic breast cancer, following at least one line of endocrine therapy based on results from the mutant cohort of the Phase 3 VIKTORIA-1 trial. Results for this study were recently presented in a late-breaking abstract oral session at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting. Following the sNDA submission, Celcuity intends to submit VIKTORIA-1 data for marketing authorization of gedatolisib to other regulatory authorities around the world.

REVTORPYK is also being studied in the ongoing Phase 3 VIKTORIA-2 clinical trial incorporating two independent studies evaluating two separate patient cohorts with HR+/HER2- locally advanced or metastatic breast cancer who are treatment-naive in the advanced setting.

Webcast and Conference Call Information

The Celcuity management team will host a live webcast and conference call on Tuesday, July 14, 2026, at 5:30 p.m. EDT / 4:30 p.m. CDT to discuss the FDA approval of REVTORPYK. Those who would like to participate may access the live webcast here, or register in advance for the teleconference here. A replay of the webcast will be available on the Celcuity website.

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 fastingblood 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 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 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- 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-naive 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 status and timing of the submission, and the FDA’s review, of the Company’s sNDA for gedatolisib, and for making comparable filings with other regulatory authorities outside the U.S.; the market opportunity for gedatolisib; 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, including subcutaneous formulations to support potential future indications for gedatolisib regimens; 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 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.

References:

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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/297d1d12-584a-4733-ae4f-15748ef91345