



Celcuity Presents Updated Results from the PIK3CA MT Cohort of the Phase 3 VIKTORIA-1 Study in Patients with HR+/HER2- Advanced Breast Cancer at the ESMO Congress 2026

October 24, 2026

Median PFS was 21.5 months with the gedatolisib triplet and 11.5 months with the gedatolisib doublet versus 9.1 months with alpelisib + fulvestrant in patients who had no liver metastases

ORR and median duration of response was 59% and 19.4 months for the gedatolisib triplet and 43% and 27.8 months for the gedatolisib doublet, respectively, compared to 33% and 7.5 months for alpelisib + fulvestrant

The discontinuation rate for gedatolisib due to treatment-emergent adverse events was 5% and 4% with the gedatolisib triplet and doublet, respectively, compared to 19% for alpelisib

MINNEAPOLIS, Oct. 24, 2026 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a biotechnology company focused on developing and commercializing targeted therapies for the treatment of multiple solid tumor indications, today announced new subgroup analyses from the PIK3CA mutant ("MT") cohort of the Phase 3 VIKTORIA-1 study evaluating gedatolisib in patients with HR+/HER2- locally advanced or metastatic breast cancer ("ABC"). These data were presented by Dr. Barbara Pistilli, Head of the Breast Cancer Unit, Gustave Roussy, at the European Society of Medical Oncology (ESMO) Congress 2026 today, Saturday, October 24, 2026, at 4:15 a.m. EST/10:15 a.m. CEST during a late breaking rapid oral presentation:

Presentation LBA 16: [VIKTORIA-1: Updated results of a randomized, open-label, phase 3 study of gedatolisib \(geda\) + fulvestrant \(fulv\) ± palbociclib \(palbo\) vs standard of care in patients with HR+/HER2- advanced breast cancer \(ABC\) \(Study 2\)](#)

Gedatolisib plus fulvestrant with palbociclib ("gedatolisib triplet") or without palbociclib ("gedatolisib doublet") significantly improved median progression-free survival ("PFS") compared with alpelisib plus fulvestrant in HR+/HER2-, PIK3CA mutant ABC patients with and without liver metastases and those with or without visceral metastases:

Subgroup	Gedatolisib Triplet	Gedatolisib Doublet	Alpelisib + Fulvestrant
No Liver metastases, n	77	28	76
mPFS, mos. (95% CI)	21.5 (11.4-NR)	11.5 (9.2-NR)	9.1 (5.6-16.9)
HR (90% CI) vs. control	0.46 (0.30-0.72)	0.71 (0.41-1.25)	
p-value	0.0016	0.1627	
Liver Metastases, n	78	24	79
mPFS, mos. (95% CI)	9.1 (5.7-11.1)	11.1 (3.7-NR)	4.6 (3.7-5.6)
HR (90% CI) vs. control	0.47 (0.34-0.65)	0.38 (0.23-0.62)	
p-value	<0.0001	0.0006	
Subgroup	Gedatolisib Triplet	Gedatolisib Doublet	Alpelisib + Fulvestrant
No Visceral Metastases, n	38	13	37
mPFS, mos. (95% CI)	21.5 (9.6 – NR)	NR (1.6-NR)	9.2 (3.9-16.9)
HR (90% CI) vs. control	0.38 (0.21-0.73)	0.40 (0.15-1.1)	
p-value	0.0059	0.0703	
Visceral Metastases, n	117	39	118
mPFS, mos (95% CI)	9.8 (7.5-12.9)	11.3 (7.4-22.1)	5.6 (4.6-7.2)
HR (90% CI) vs. control	0.52 (0.39-0.70)	0.53 (0.35-0.79)	

p-value	<0.0001	0.0042	
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* NR, not reached

In patients with evaluable disease, the gedatolisib-based regimens induced higher objective response rates (“ORR”) (confirmed and unconfirmed) and longer median durations of response in both the *PIK3CA* mutant and wild-type cohorts compared to the control:

Study 2 (<i>PIK3CA</i> Mutant Cohort)			
Endpoint	Gedatolisib Triplet (n=133)	Gedatolisib Doublet (n=42)	Alpelisib + Fulvestrant (n=127)
Objective Response Rate, n (%)	78 (59%)	18 (43%)	42 (33%)
Median Duration of Response, mos. (95% CI)	19.4 (11.1-25.1)	27.8 (9.2-NR)	7.5 (5.6 – 16.6)

Study 1 (<i>PIK3CA</i> Wild-type Cohort)			
	Gedatolisib Triplet (n=124)	Gedatolisib Doublet (n=113)	Fulvestrant (n=105)
Objective Response Rate, n (%)	48 (39%)	38 (34%)	1 (1%)
Median Duration of Response, mos. (95% CI)	19.2 (10.7-NR)	13.8 (9.4-NR)	Not evaluable

In the *PIK3CA* mutant cohort, the discontinuation rate of gedatolisib due to treatment-emergent adverse events (“TEAEs”) was 5% and 4% for the gedatolisib triplet and doublet, respectively, compared to a 19% discontinuation rate due to TEAEs for alpelisib. Grade 3 stomatitis with gedatolisib was transient. By the second cycle of treatment, less than 3% of patients had Grade 3 stomatitis, and all grade 3 events improved within 1-2 weeks. Discontinuations due to stomatitis for the gedatolisib triplet and gedatolisib doublet were minimal, 1% and 0%, respectively.

“The additional data from Study 2 of VIKTORIA-1 show consistent and significant clinical benefit for important sub-groups of breast cancer patients treated with gedatolisib regimens,” said Igor Gorbachevsky, Chief Medical Officer of Celcuity. “For patients who do not have liver metastases and received the gedatolisib triplet, the median progression-free survival was approximately 21 months, versus approximately 9 months for the alpelisib regimen. This is a particularly important result since patients with no liver metastases represent approximately 60%-70% of all patients treated in this setting.”

“Additionally, the median duration of response was over 19 months for the gedatolisib triplet in both the *PIK3CA* wild-type cohort, or Study 1, and the *PIK3CA* mutant cohort, or Study 2, compared to not evaluable for fulvestrant in the *PIK3CA* wild-type cohort and 7.5 months for alpelisib plus fulvestrant in the *PIK3CA* mutant cohort. To our knowledge, the gedatolisib triplet in each study demonstrated the longest median duration of response results ever reported for a therapeutic regimen used in the primary analysis for a Phase 3 trial in the second-line HR+/HER2- advanced breast cancer setting.”

VIKTORIA-1 *PIK3CA* Wild-Type Cohort Comparative Analysis

Dr. Sara Tolaney, Chief of the Division of Breast Oncology at Dana-Farber Cancer Institute, presented a comparative analysis of data for the gedatolisib regimens from the *PIK3CA* wild-type cohort of VIKTORIA-1 and other regimens evaluated in patients with HR+/HER2- advanced breast cancer.

Poster 1873P: [Gedatolisib \(Ged\) vs Other Regimens Post-CDK4/6i and Endocrine Therapy \(ET\) in *PIK3CA* Wild-Type \(WT\) HR+/HER2- Advanced Breast Cancer \(aBC\): A Network Meta-Analysis \(NMA\)](#)

Eight studies were included in this network meta-analysis comparing progression-free survival outcomes in randomized controlled trials of systemic treatments evaluated among patients with HR+/HER2- advanced breast cancer with CDK4/6 inhibitor experience and *PIK3CA* wild-type tumors. This analysis found that the gedatolisib triplet and doublet each demonstrated statistically significant or numerically superior improvement in PFS and in progression-free survival rate at 6 months relative to the non-gedatolisib regimens evaluated. Of note, the analysis found that patients treated with the gedatolisib triplet and doublet were a statistically significant 2x and 1.5x more likely to survive without disease progression or death compared to imlunestrant plus abemaciclib, respectively.

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

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), pan-PI3K and mTORC1/2 inhibitor that comprehensively blockades the PAM (PI3K/AKT/mTOR) 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, supported FDA approval of REVTORPYK for use in 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 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](https://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; 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; and the development of therapies and tools competitive with gedatolisib. 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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2. National Cancer Institute. Surveillance, Epidemiology and End Results Program (accessed July 2025). <https://seer.cancer.gov/statfacts/html/breast-subtypes.html>

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