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FDA approves first pan-PI3K / mTOR inhibitor gedatolisib in metastatic breast cancer

Market Event Summary

Glenda Walker, Ph.D. | July 2026

Gedatolisib advances treatment of *PIK3CA* wild-type metastatic breast cancer

- **The FDA approved the first inhibitor targeting all class I PI3K isoforms and both mTOR complexes.** Celcuity's gedatolisib (Revtorpyk) was approved in July 2026 for *PIK3CA wild-type* HR-positive / HER2-negative advanced or metastatic breast cancer following progression on endocrine therapy + a CDK4/6 inhibitor in the metastatic setting.
- **The Phase 3 VIKTORIA-1 trial** assessed gedatolisib + fulvestrant ± palbociclib versus fulvestrant in previously treated *PIK3CA wild-type* HR-positive / HER2-negative metastatic breast cancer.
- **Gedatolisib + fulvestrant ± palbociclib showed a significant improvement in median PFS** compared with fulvestrant alone.

Treatment	Median PFS vs. fulvestrant
Gedatolisib + fulvestrant + palbociclib	• **9.3 months vs. 2.0 months** (hazard ratio 0.24, P < 0.0001)
Gedatolisib + fulvestrant	• **7.4 months vs 2.0 months** (hazard ratio 0.33, P < 0.0001)

Background

- **HR-positive / HER2-negative breast cancer** accounts for ~70% of all breast cancer cases across the major markets. Around 60% of these tumors are *PIK3CA* wild-type—a large segment with a **high unmet need** following **frontline CDK4/6 inhibitor therapy**.
- Despite recent successes, **PI3K / AKT / mTOR (PAM)-pathway inhibitors** were restricted to **biomarker-selected patient subgroups** before these results.
- **Regulatory filings** based on VIKTORIA-1 data in the United States (in *PIK3CA*-mutant disease) and Europe (in *PIK3CA*-mutant and *PIK3CA* wild-type disease) are expected in Q3 2026 and Q4 2026, respectively.

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Clarivate's takeaways

Novel option for *PIK3CA* wild-type disease

Gedatolisib is a first-in-class pan-PI3K / mTOR inhibitor developed specifically for *PIK3CA wild-type* HR-positive / HER2-negative advanced or metastatic breast cancer in a post-CDK4/6 inhibitor-treated population, a population with a high unmet need. Celcuity expects gedatolisib to launch in the U.S. market in Q3 2026.

Clinically meaningful efficacy differentiates gedatolisib

The PFS improvements reported in VIKTORIA-1 are among the strongest observed for endocrine-based regimens in this setting, positioning gedatolisib as a potential new standard of care following progression on frontline endocrine therapy plus a CDK4/6 inhibitor. While initially targeting patients with *PIK3CA* wild-type disease, anticipated filings in *PIK3CA*-mutant disease are supported by superior efficacy versus alpelisib, expanding its opportunity into the established biomarker-selected market.

Uptake may be moderated by its weekly IV administration, treatment-related toxicities, the high cost of gedatolisib-based combinations, and increasing competition from multiple agents in this setting.

Positioned for blockbuster status

The VIKTORIA clinical program (VIKTORIA-1 and VIKTORIA-2) will support expansion in both later-line and first-line HR-positive / HER2-negative metastatic breast cancer, driving blockbuster sales for gedatolisib and strengthening the role of PAM-pathway inhibition in breast cancer.

About the author

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Dr. Walker has more than 12 years' experience in the pharmaceutical field. She has authored thought-leadership articles covering a broad range of pharmaceutical-industry-relevant topics and therapeutic areas, including the flagship Drugs to Watch article. She holds a Ph.D. in cell biology and genetics from the University of Manchester and was a Wellcome postdoctoral fellow at the University College London Institute of Healthy Ageing.

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- Breast Cancer | Disease Landscape & Forecast | G7
- Breast Cancer | Current Treatment: Physician Insights | US, exploring the current prescribing trends among medical oncologists treating breast cancer
- Breast Cancer | Current Treatment: Treatment Sequencing | US, presenting surveyed medical oncologists' most frequent treatment sequences for breast cancer
- Metastatic HR-Positive / HER2-Negative Breast Cancer | Unmet Need

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