



Celcuity Presents Updated Data from a Phase 1b/2 Study Evaluating Gedatolisib Plus Darolutamide in Men with Metastatic Castration-Resistant Prostate Cancer at the ESMO Congress 2026

October 23, 2026

Median radiographic progression free survival ("rPFS") was 15.7 months and the six-month rPFS rate ("rPFS6") was 82.2% in patients who received prior abiraterone

Median rPFS was 9.1 months and rPFS6 was 62.5% in patients who received prior enzalutamide

The Phase 2 portion of the study evaluating gedatolisib plus darolutamide is expected to begin in the first half of 2027

MINNEAPOLIS, Oct. 23, 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 updated clinical results from the Phase 1b/2 study evaluating gedatolisib in patients with metastatic castration-resistant prostate cancer ("mCRPC"). These data were presented at the European Society of Medical Oncology (ESMO) Congress 2026 today, Friday, October 23, 2026, at 9:15 a.m. EDT/3:15 p.m. CEST at a poster presentation:

Poster 2237P: [A phase 1/2, open-label, randomized, dose-finding and dose expansion study of gedatolisib in combination with darolutamide in metastatic castration-resistant prostate cancer \(mCRPC\)](#)

In this Phase 1b/2 study, 45 patients with mCRPC were randomly assigned to receive 600 mg darolutamide twice daily combined with either 120 mg gedatolisib in Arm 1 (n=19), 180 mg gedatolisib in Arm 2 (n=19) and 240 mg gedatolisib in Arm 3 (n=7). In all arms, gedatolisib was administered intravenously on days 1, 8, and 15 of a 28-day cycle, then two weeks off. Additionally, all patients received prophylactic treatment for stomatitis. Baseline characteristics were generally consistent across dose cohorts; over 50% had bone disease, 33% had phosphatase and tensin hemolog ("PTEN") loss. Data was analyzed as of an August 14, 2026 cut-off date.

Key results reported included:

- Median rPFS was 15.7 months with an rPFS6 rate of 82.2% in patients with prior abiraterone exposure (n=22).
- Median rPFS was 9.1 months with an rPFS6 rate of 62.5% in patients with prior enzalutamide exposure (n=18).
- PSA $\geq$ 50% decreases from baseline ("PSA50") were observed across all dose levels; response rates were 36%, 47% and 67% at the 120-, 180-, and 240-mg gedatolisib dose levels, respectively, in patients with prior exposure to either abiraterone or enzalutamide.
- Exploratory analyses of patients according to their PTEN status suggest activity is independent of PTEN status.
- Gedatolisib plus darolutamide demonstrated a manageable safety profile across the evaluated dose levels (120 mg, 180 mg, 240 mg) with one dose limiting toxicity (Grade 3 rash), no Grade 4/5 treatment related adverse events ("TRAEs"), and no TRAEs leading to treatment discontinuation or death. Grade 3 TRAEs occurred in 9 (20%) patients with only rash (n=4) and pruritus (n=2) occurring in more than one patient.

"We are highly encouraged by these results and believe combining gedatolisib with an androgen receptor inhibitor is a promising new approach for patients with mCRPC," said Igor Gorbachevsky, Chief Medical Officer of Celcuity. "The 82.2% six-month PFS rate and median rPFS of 15.7 months is remarkable in patients who had received prior abiraterone and compares favorably to published data for AR inhibitors in this setting. We look forward to initiating the Phase 2 portion of the study and further evaluating this combination in more patients."

The randomized Phase 2 study is expected to evaluate two different groups of patients (Groups 1 and 2) with the objective of determining the recommended phase 3 dose level. Subjects in Group 1 will be those who received prior abiraterone for either hormone sensitive or castration resistant prostate cancer. Subjects in Group 2 will be those who received prior enzalutamide or apalutamide for either hormone sensitive or castration resistant prostate cancer. Celcuity anticipates initiating this study in the first half of 2027 after completion of the Phase 1b part of the study.

About Prostate Cancer

Prostate cancer is the second most commonly occurring cancer in men with 1.5 million cases diagnosed in 2024 and the fourth most commonly occurring cancer overall worldwide.¹ The American Cancer Society estimates approximately 333,830 men will be diagnosed with prostate cancer in 2026 and over 36,000 will die annually in the U.S.² For men diagnosed with metastatic

castration-resistant prostate cancer, the 5-year survival rate is 32% and there is a significant need for better treatment options, as median progression-free survival is currently between 6.7 – 5.5 months in the second line setting following AR therapy.³⁻⁵

About Celcuity

Celcuity is a commercial-stage 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 (PI3K/AKT/mTOR) 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 U.S. Food and Drug Administration 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. 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 clinical strategy, including the benefits of strategic decisions regarding studies and trials; and other expectations with respect to gedatolisib, including potential future indications for gedatolisib regimens. 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; 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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