



Celcuity Announces Multiple Presentations At The European Society For Medical Oncology (ESMO) Congress 2026

October 5, 2026

Rapid oral presentation of additional sub-group analyses from the VIKTORIA-1 PIK3CA mutant-type cohort

Poster presentation of a comparative analysis of data for the gedatolisib triplet from the PIK3CA wild-type cohort of VIKTORIA-1 and other regimens evaluated in patients with HR+/HER2- advanced breast cancer

Poster presentation of sub-group analyses from the Phase 1b trial of gedatolisib plus darolutamide in patients with mCRPC

MINNEAPOLIS, Oct. 05, 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 that a late breaking rapid oral presentation and three poster presentations will be featured at the upcoming European Society for Medical Oncology ("ESMO") Congress 2026 being held October 23-27, 2026, in Madrid, Spain. Data from its clinical trials of gedatolisib in hormone receptor positive ("HR+"), human epidermal growth factor receptor 2 negative ("HER2-") locally advanced or metastatic breast cancer ("ABC") and metastatic castration-resistant prostate cancer ("mCRPC") will be presented.

Late Breaking Rapid Oral Presentation Details:

Title: 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)

Presentation Number: LBA 16

Speaker: Barbara Pistilli, MD

Session Title: Rapid oral 1: Breast cancer, advanced stage

Room: Almeria Auditorium - Hall 9

Date: Saturday, October 24, 2026

Time: 10:15 –11:45 a.m. CEST

Poster Presentation Details:

Title: 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)

Presentation Number: 2237P

Presenting Author: Adam Sharp, MD, PhD

Session Title: Poster Display session, Metastatic prostate cancer

Date: Friday, October 23, 2026

Time: 3:15 p.m. – 4:00 p.m. CEST

Title: 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)

Presentation Number: 1873P

Presenting Author: Sara Tolaney, MD

Session Title: Poster Display session, HR+ breast cancer

Date: Saturday, October 24, 2026

Time: 12:00 p.m. – 12:45 p.m. CEST

Title: A Randomized, Open-Label, Phase 3 Study Evaluating Efficacy and Safety of Gedatolisib with Endocrine Therapy (ET) and Palbociclib vs ET and Ribociclib as First-Line (1L) Treatment in Patients With HR-Positive (HR+) HER2-Negative (HER2-) Advanced Breast Cancer (ABC) (VIKTORIA-2)

Presentation Number: 57TiP

Presenting Author: Giuseppe Curigliano, MD, PhD

Session Title: Poster Display session, Advanced breast cancer, other

Date: Saturday, October 24, 2026

Time: 12:00 p.m. – 12:45 p.m. CEST

Abstracts will be published online via the ESMO website at 12:05 a.m. CEST on October 19, 2026. The posters will be presented in the Poster Area – Hall 5. Electronic versions will also be available on the ESMO 2026 virtual platform.

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 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- ABC, 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](#).

Contacts:

For Investors:

Brian Sullivan, bsullivan@celcuity.com

Vicky Hahne, vhahne@celcuity.com

(763) 392-0123

For investors and media:

Jodi Sievers, jsievers@celcuity.com

(415) 494-9924