



Celcuity to Present Preclinical Data for Gedatolisib at the 2023 San Antonio Breast Cancer Symposium

December 1, 2023

MINNEAPOLIS, Dec. 01, 2023 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced that an abstract accepted for a poster presentation at the 2023 San Antonio Breast Cancer Symposium (SABCS) is now available on the SABCS website. The 2023 San Antonio Breast Cancer Symposium (SABCS) is being held virtually and in-person from December 5-9, 2023.

The presentation will include potency and efficacy data evaluating the effects of gedatolisib, a pan-PI3K/mTOR (PAM) inhibitor, and approved PAM inhibitors (PAMi) on breast cancer cell lines with mutated or non-mutated PAM pathway genes. Compared to the other PAMi, gedatolisib exhibited more potent and efficacious anti-proliferative and cytotoxic effects, regardless of the cell lines' PI3K pathway mutational status. Mechanistically, gedatolisib decreased both DNA and protein synthesis more effectively than the other PAMi tested.

These findings demonstrate that gedatolisib may more effectively address potential drug resistance mechanisms associated with the approved PAM inhibitors. A Phase 3 VIKTORIA-1 trial evaluating gedatolisib plus fulvestrant with and without palbociclib is underway in adults with HR+, HER2- advanced breast cancer.

Poster presentation details are provided below.

Poster Title: "Gedatolisib, a pan-PI3K inhibitor shows superior potency & efficacy relative to other PI3K/AKT/mTOR pathway inhibitors in breast cancer models"

Author: Rossetti S et al.

Poster ID: PO1-24-04

Poster Session: Poster Session 1

Presentation Time: December 6, 2023, 12:00 p.m. - 2:00 p.m. CT (1:00 p.m. - 3:00 p.m. ET)

Additional data will be presented at the Poster Discussion, and the poster will be available on Celcuity's website after the poster is presented.

For more details about SABCS please visit: <https://www.sabcs.org/>.

About Celcuity

Celcuity is a clinical-stage biotechnology company focused on development of targeted therapies for treatment of multiple solid tumor indications. The company's lead therapeutic candidate is gedatolisib, a potent, pan-PI3K and mTOR inhibitor. Its mechanism of action and pharmacokinetic properties are highly differentiated from other currently approved and investigational therapies that target PI3K or mTOR 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- advanced breast cancer is currently enrolling patients. More detailed information about the VIKTORIA-1 study can be found at [ClinicalTrials.gov](https://clinicaltrials.gov). A Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer, is expected to be initiated in the first quarter of 2024. The company's CELsignia companion diagnostic platform is uniquely able to analyze live patient tumor cells to identify new groups of cancer patients likely to benefit from already approved targeted therapies. Further information about Celcuity can be found at [Celcuity.com](https://celcuity.com). Follow us on [LinkedIn](https://www.linkedin.com/company/celcuity) and [Twitter](https://twitter.com/celcuity).

Forward-Looking Statements

This press release contains statements that constitute "forward-looking statements" including, but not limited to, the efficacy and potential applications of Celcuity's lead product candidate, gedatolisib, the timing of clinical trial activities, and other expectations with respect to gedatolisib and Celcuity's CELsignia platform. In some cases, you can identify forward-looking statements by terminology such as "may," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "intends" or "continue," and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. Forward-looking statements are subject to numerous risks, uncertainties, and conditions, many of which are beyond the control of Celcuity. These include, but are not limited to, unexpected delays or results relating to our clinical trials or regulatory approvals, and the risks set forth in the Risk Factors section in Celcuity's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission on March 23, 2023, as may be updated by our quarterly reports on Form 10-Q. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Celcuity undertakes no obligation to update these statements for revisions or changes after the date of this press release, except as required by law.

[View source version of release on GlobeNewswire.com](#)

Contacts:

Celcuity Inc.

Brian Sullivan, bsullivan@celcuity.com

Vicky Hahne, vhahne@celcuity.com

(763) 392-0123

ICR Westwicke

Maria Yonkoski, maria.yonkoski@westwicke.com

(203) 682-7167



News Provided by GlobeNewswire via QuoteMedia