Celcuity Presents Preclinical Data on Therapeutic Effects of Gedatolisib in Breast Cancer Models at the 2023 San Antonio Breast Cancer Symposium

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MINNEAPOLIS, Dec. 06, 2023 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today presented data from preclinical studies evaluating gedatolisib and other PI3K/AKT/mTOR (PAM) inhibitors in breast cancer cell lines during a poster session at the 2023 San Antonio Breast Cancer Symposium (SABCS).

The preclinical studies evaluated gedatolisib, a pan-PI3K/mTOR inhibitor, and PAM inhibitors that selectively target single PAM nodes (PI3Kα, AKT, and mTORC1) to compare the functional effect of inhibiting multiple vs. single PAM pathway nodes in a panel of breast cancer cell lines. In cell viability and proliferation analyses, gedatolisib was found to be more cytotoxic and at least 300-fold more potent, on average, compared to the single node PAM inhibitors. Mechanistically, gedatolisib decreased cell survival, DNA replication, protein synthesis, glucose consumption, lactate production and oxygen consumption more effectively than the other PAM inhibitors. In vivo studies confirmed that pan-PI3K/mTOR inhibition by gedatolisib reduced tumor cell growth more effectively than single node inhibitors in breast cancer patient derived xenograft models with and without PAM pathway mutations.

“These findings indicate that gedatolisib is more effective than single node PAM inhibitors at controlling key cellular functions required by cancer cells for energy production, molecule biosynthesis, and cell proliferation,” said Brian Sullivan, Celcuity’s Chief Executive Officer and co-founder. “We believe this data reinforces the relevance of gedatolisib’s highly differentiated mechanism of action.”

The poster will be available in the publications page of the Celcuity website after the poster session.

About Gedatolisib

Gedatolisib is a potent, reversible dual inhibitor that selectively targets all Class I PI3K isoforms and mTOR. 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. Inhibiting all four Class I PI3K isoforms and mTOR limits the potential development of drug resistance compared with isoform-specific PI3K or mTOR specific inhibitors. A robust response rate and a manageable side effect profile were reported for the Phase 1b clinical trial that evaluated gedatolisib in combination with palbociclib and endocrine therapy in patients with HR+/HER2- advanced breast cancer.

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 . 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 . Follow us on LinkedIn and Twitter .

Forward-Looking Statements

This press release contains statements that constitute "forward-looking statements" including, but not limited to, the adequacy of Celcuity’s cash on hand to fund research and development expenses and other general corporate expenses, the timing of initiating and enrolling patients in, and receiving results from, clinical trials, such as Celcuity's Phase 3 VIKTORIA-1 clinical trial and Phase 1b/2 CELC-G-201 clinical trial, the costs and expected results from any ongoing or planned clinical trials, the impact on gedatolisib and Celcuity of preliminary clinical trial results, any potential benefits resulting from Breakthrough Therapy designation for gedatolisib, and other expectations with respect to Celcuity's lead product candidate, gedatolisib and its 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, those 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.

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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