Celcuity Presents Preclinical Data on Therapeutic Effects of Gedatolisib in Gynecological Cancer Models at AACR Annual Meeting 2023

April 18, 2023

Gedatolisib demonstrated superior anti-proliferative potency and efficacy in endometrial, ovarian and cervical cancer cell lines compared to other PAM inhibitors evaluated regardless of PTEN, P13K, or AKT mutational status

MINNEAPOLIS, MN / ACCESSWIRE / April 18, 2023 / Celcuity Inc. (Nasdaq:CELC), a clinical-stage biotechnology company focused on development of targeted therapies for oncology, today presented data from preclinical studies evaluating gedatolisib and other PI3K/AKT/mTOR (PAM) inhibitors in endometrial, ovarian, and cervical cancer cell lines. The poster was presented at the 2023 Annual Meeting of the American Association for Cancer Research (AACR), which is being held April 14-19, 2023 in Orlando, Florida.

"Gedatolisib's ability to induce anti-tumor activity regardless of PAM pathway mutational status in preclinical gynecological models is reflective of our prior findings in other hormonally driven cancers, including breast and prostate models," said Brian Sullivan, Celcuity's Chief Executive Officer and co-founder. "The findings further demonstrate gedatolisib's differentiated mechanism of action and potential to treat various solid tumor types."

The presentation titled, "Gedatolisib, a well-tolerated pan-PI3K/mTOR inhibitor, exhibits potent therapeutic effects on gynecological cancer models regardless of their PI3K pathway mutational status," described in vitro and in vivo studies that evaluated the potency and efficacy of gedatolisib and other PAM inhibitors using cell viability, cell proliferation, and flow cytometry assays. The PI3K/mTOR pathway has been implicated in many hormonally driven tumor types such as breast, prostate, endometrial, and ovarian cancers.

In each of these studies, gedatolisib demonstrated superior potency and efficacy relative to other PAM inhibitors in endometrial, ovarian, and cervical cancer lines, regardless of PTEN, PI3K, or AKT mutational status. In addition, gedatolisib demonstrated robust tumor growth inhibition in vivo in endometrial cancer xenograft models with different PAM pathway mutational status.

The poster is available on the publications page of the Celcuity website.

About Gedatolisib

Gedatolisib is an investigational, pan-PI3K and mTOR inhibitor with low nanomolar potency for all Class I PI3K isoforms and mTORC1 and mTORC2. Its mechanism of action and pharmacokinetic properties are highly differentiated from other 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 to isoform-specific PI3K or mTOR specific inhibitors. A robust response rate and a manageable side effect profile were reported for a Phase 1b clinical trial that evaluated gedatolisib in combination with palbociclib and endocrine therapy in patients with HR+/HER2- advanced breast cancer. 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.

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. 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. Celcuity is headquartered in Minneapolis. 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 timing of initiating and enrolling patients in, and receiving results from, clinical trials, such as Celcuity's Phase 3 VIKTORIA-1 clinical trial, the expected or potential results from any ongoing, planned or potential clinical trials, expectations with respect to the potential efficacy of gedatolisib in various tumor types alone or in combination with other treatments, the potency and efficacy of gedatolisib relative to other PAM inhibitors, and any 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, 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. 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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