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

March 15, 2023

MINNEAPOLIS, MN / ACCESSWIRE / March 15, 2023 / Celcuity Inc. (NASDAQ:CELC), a clinical-stage biotechnology company focused on development of targeted therapies for oncology, today announced publication of an abstract reporting data from preclinical studies evaluating gedatolisib and other PI3K/AKT/mTOR inhibitors in endometrial, ovarian, and cervical cancer cell lines. A poster will be presented at the 2023 Annual Meeting of the American Association for Cancer Research (AACR), which will be held April 14-19, 2023 in Orlando, Florida.

The abstract and poster presentation describe the potency and efficacy of gedatolisib and other PI3K/AKT/mTOR inhibitors using cell viability, cell proliferation, and flow cytometry assays in endometrial, ovarian, and cervical cancer cell lines.

"We are excited to report preclinical data describing gedatolisib's potent therapeutic effects on gynecological cancer models. These results further demonstrate gedatolisib's differentiated mechanism of action," said Brian Sullivan, Celcuity's Chief Executive Officer and co-founder. "Along with the preclinical data for prostate cancer models presented in February at the ASCO-GU meeting, these results provide support and rationale for our future clinical development plans."

Presentation Details:

Title: Gedatolisib, a well-tolerated pan-PI3K/mTOR inhibitor, exhibits potent therapeutic effects on endometrial cancer models regardless of their PI3K pathway mutational status
Session Title: Novel Antitumor Agents, PI3K/AKT Inhibitors, Proteasome Inhibitors, and Topoisomerases
Date and Time: Tuesday, April 18, 2023, 1:30-5:30 p.m. ET
Location: Poster Section 15
Poster Board Number: 6
Abstract Number: 4928

The abstracts are available online at AACR 2023 in advance of the 2023 AACR Annual Meeting. The poster will be available online on the publications page of the Celcuity website following the poster presentation.

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 patient types alone or in combination with other treatments, and any other expectations with respect to 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 Quarterly Report for the period ended September 30, 2022 filed with the Securities and Exchange Commission on November 10, 2022. 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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