Celcuity Presents Preclinical Data on Therapeutic Effects of Gedatolisib in Prostate Cancer at ASCO GU Cancers Symposium

February 16, 2023

Gedatolisib demonstrated superior potency and efficacy in prostate cancer cell lines compared to other PI3K/AKT/mTOR inhibitors evaluated regardless of PI3K or PTEN status

MINNEAPOLIS, MN / ACCESSWIRE / February 16, 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 inhibitors in prostate cancer cell lines. The poster was presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU), which is being held February 16-18, 2023.

The presentation titled "Therapeutic effect of gedatolisib, a pan-PI3K/mTOR inhibitor, on prostate cancer models with PI3K or PTEN mutational status" demonstrated gedatolisib's superior potency and efficacy across different prostate cancer cell lines relative to other PI3K/AKT/mTOR inhibitors of PTEN or PI3K status.

"The findings further demonstrate gedatolisib's differentiated mechanism of action and potential to treat various solid tumor types," said Brian Sullivan, Celcuity's Chief Executive Officer and co-founder. "The results suggest that gedatolisib may help overcome or prevent development of resistance to androgen receptor inhibitors, which is particularly relevant in metastatic castration resistant prostate cancer (mCRPC)."

This 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 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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