Celcuity to Present Additional Data for Gedatolisib at the 2022 San Antonio Breast Cancer Symposium

November 22, 2022

MINNEAPOLIS, MN / ACCESSWIRE / November 22, 2022 / Celcuity Inc. (NASDAQ:CELC), a clinical-stage biotechnology company focused on development of targeted therapies for cancer treatment, today announced that an abstract accepted for a Spotlight Poster presentation at the 2022 San Antonio Breast Cancer Symposium (SABCS) is now available on the SABCS website. The 2022 San Antonio Breast Cancer Symposium (SABCS) is being held virtually and in-person from December 6-10, 2022.

The presentation will include updated efficacy and safety data and sub-group analysis by PIK3CA mutation status in the four expansion arms of a Phase 1b study of gedatolisib (a dual PI3K/mTOR inhibitor) plus palbociclib (a CDK4/6 inhibitor) and endocrine therapy in women with hormone receptor positive advanced breast cancer. The primary endpoint was investigator assessed objective response rate (ORR). Secondary endpoints included safety, duration of response and progression free survival (PFS). Promising ORR and PFS were seen in all arms, regardless of PIK3CA mutation status. Arm D, which treated patients whose disease progressed on a CDK4/6 inhibitor, reported ORR of 63% overall, 73% in PIK3CA-mutation patients, and 60% in PIK3CA-wild type patients; overall PFS was 12.9 months. Arm A, which evaluated patients who were treatment-naïve in the advanced disease setting, reported ORR of 85% overall, 81% in PIK3CA-wild type patients, and 100% in PIK3CA-mutations patients; median PFS was not reached after a median follow-up period of 33.1 months.

These preliminary findings demonstrate promising activity for gedatolisib plus palbociclib and endocrine therapy in patients who were CDK4/6 inhibitor-naïve and in those whose disease progressed on or after treatment with a CDK4/6 inhibitor, regardless of PIK3CAmutation status. Arm D results provide a strong rationale for Celcuity's Phase 3 clinical trial (VIKTORIA-1) in patients with advanced breast cancer whose disease progressed on or after CDK4/6 therapy. The encouraging results in treatment-naïve advanced breast cancer patients warrant further evaluation of gedatolisib in combination with a CDK4/6 inhibitor and endocrine therapy in early line settings, including front-line, neoadjuvant, or adjuvant indications.

Poster presentation details are provided below.

Poster Title: "Updated results of a Phase 1b study of gedatolisib plus palbociclib and endocrine therapy in women with hormone receptor positive advanced breast cancer: Subgroup analysis by PIK3CA mutation status"
Author: Robert Wesolowski, et al.
Poster ID: PD13-05
Poster Session: Spotlight Poster Discussion Session 13
Presentation Time: December 8, 2022, 5 - 6:15 p.m. CT (6 - 7:15 p.m. ET)

Additional data will be presented at the Spotlight 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, reversible dual inhibitor that selectively targets all Class 1 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. The company has activated the Phase 3 VIKTORIA-1 clinical trial to evaluate gedatolisib in patients with HR+/HER2- advanced breast cancer. More detailed information about the VIKTORIA-1 study can be found at ClinicalTrials.gov. Its 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 enrolling patients in, and receiving results from, Celcuity's Phase 3 VIKTORIA-1 clinical trial, expectations with respect to potential results from such trial, and expectations for the efficacy and safety of gedatolisib. 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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