Celcuity Presents Overall Survival Data from Phase 1b Study Evaluating Gedatolisib in Combination with Palbociclib and Endocrine Therapy at the 2024 San Antonio Breast Cancer Symposium

December 11, 2024

Median overall survival (OS) among patients with HR+, HER2- advanced breast cancer who were treatment-naïve in the advanced setting was 77.3 months

Median OS among patients previously treated with a CDK4/6 inhibitor was 33.9 months

MINNEAPOLIS, Dec. 11, 2024 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced overall survival (OS) data from two patient cohorts evaluated in a Phase 1b trial with gedatolisib, a pan-PI3K/mTORC1/2 inhibitor, in combination with palbociclib and either letrozole or fulvestrant, in patients with HR+, HER2-advanced or metastatic breast cancer. Results will be presented in a poster session at the San Antonio Breast Cancer Symposium (SABCS) being held December 10-13 at the Henry B. Gonzalez Convention Center in San Antonio, Texas.

The poster presents overall survival data among patients with HR+, HER2- advanced breast cancer who were either treatment-naïve (N=41) or whose disease progressed during prior treatment with a CDK4/6 inhibitor (N=27). For the treatment-naïve patient cohort (Escalation Arm A and Expansion Arm A), median OS was 77.3 months (95% CI, 50.3 to 89.0). For the patients previously treated with a CDK4/6 inhibitor and who received the Phase 3 dose of gedatolisib (Expansion Arm D), median OS was 33.9 months (95% CI, 17.8 to 52.3).

“The median OS results reported for gedatolisib in combination with palbociclib and endocrine therapy are encouraging and compare favorably to published data for currently available first- or second-line standard-of-care regimens for patients with HR+/HER2- advanced breast cancer,” said Igor Gorbatchevsky, MD, Chief Medical Officer of Celcuity. “These results highlight the promising clinical development strategy of simultaneously blocking the ER, CDK4/6, and PAM (PI3K/AKT/mTOR) signaling pathways. This approach provided the rationale for our two Phase 3 clinical trials, the ongoing VIKTORIA-1 and planned VIKTORIA-2, which are and will be evaluating this treatment strategy in patients with HR+, HER2- advanced breast cancer in the second- and first-line setting, respectively.”

This poster, and two additional posters presenting nonclinical data for gedatolisib at the SABCS, are available on the publications page of the Celcuity website.

About Gedatolisib

Gedatolisib is a potent, reversible inhibitor that selectively targets all Class I PI3K isoforms and mTORC1 and mTORC2 to blockade PI3K/AKT/mTOR signaling activity. Its mechanism of action and pharmacokinetic properties are highly differentiated from other currently approved and investigational therapies that target PI3K, AKT, or mTOR alone or together. Inhibiting all four Class I PI3K isoforms and mTORC1/2 limits the potential development of drug resistance compared with isoform-specific PI3K, AKT 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. Gedatolisib, in combination with palbociclib and fulvestrant, has been granted U.S. Food and Drug Administration (FDA) Breakthrough Therapy designation for the treatment of HR+/HER2- advanced breast cancer that has progressed following treatment with a CDK4/6 inhibitor in combination with an aromatase inhibitor.

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 enrolling patients. A Phase 3 clinical trial, VIKTORIA-2, evaluating gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with HR+/HER2- advanced breast cancer is expected to begin enrolling patients in the second quarter of 2025. Celcuity is headquartered in Minneapolis. Further information about Celcuity can be found at www.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 design of our clinical trials; the timing of initiating and enrolling patients in, and receiving results and data from, our clinical trials; the costs and expected results from any ongoing or planned clinical trials; the market opportunity for gedatolisib; revenue expectations; our strategy, marketing and commercialization plans, including the benefits of strategic decisions regarding studies and trials; other expectations with respect to Celcuity's lead product candidate, gedatolisib, and its CELsignia platform; our anticipated use of cash; and the strength of our balance sheet. 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, unforeseen delays in our clinical trials, our ability to obtain and maintain regulatory approvals to commercialize our products, and the market acceptance of such products, the development of therapies and tools competitive with our products, our ability to access capital upon favorable terms or at all, and those risks set forth in the Risk Factors section in Celcuity's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission on March 27, 2024. 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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