Celcuity to Host Virtual Science Day for Investors

September 7, 2023

- *Leading key opinion leaders to review the treatment landscape in breast and prostate cancer and the importance of targeting the PI3K/mTOR pathway in hormonally driven tumor types*
- *Discussion of the planned Phase 1b/2 trial for gedatolisib in combination with Nubeqa ® (darolutamide) in patients with mCRPC*
- *Event to be webcast from 10:00 a.m. – 12:00 p.m. ET on September 21, 2023*

MINNEAPOLIS, Sept. 07, 2023 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced that it will host a Virtual Science Day for analysts and investors from 10:00 a.m. – 12:00 p.m. ET on Thursday, September 21, 2023. During this informative event, Celcuity will provide an in-depth overview of its lead compound, the equipotent pan-PI3K/mTOR inhibitor gedatolisib, discuss the importance of comprehensive, rather than selective, inhibition of the PI3K/mTOR pathway, and review its anticipated clinical development strategy in breast and prostate cancer.

The Phase 3 (VIKTORIA-1) global registration trial with gedatolisib is currently enrolling patients with HR+/HER2- advanced breast cancer whose disease progressed while receiving a CDK4/6 inhibitor. In early 2024, Celcuity expects to initiate the Phase 1b/2 CELC-G-201 trial of gedatolisib in combination with the androgen receptor inhibitor Nubeqa ® (darolutamide) in metastatic castration resistant prostate cancer.

“We look forward to providing additional insights about gedatolisib’s highly differentiated mechanism of action and how, we believe, this MOA can enable gedatolisib to potentially obtain several blockbuster indications,” said Brian Sullivan, Chief Executive Officer and co-founder of Celcuity.

Key opinion leaders speaking at Celcuity’s Virtual Science Day will include two leading oncologists:

- **Sara Hurvitz, M.D.** , *Head of the Division of Hematology and Oncology at the University of Washington Department of Medicine, Senior Vice President, Clinical Research Division at Fred Hutchinson Cancer Center. Formerly, she was the Director of the Breast Cancer Clinical Trials Program at UCLA.*
- **Karim Fizazi, M.D., Ph.D.** , *Professor of Oncology at the University of Paris-Saclay, and former head of the department of oncology medicine at Gustav Roussy specializing in the treatment of prostate cancer.*

Registration Information

Celcuity’s Virtual Science Day for analysts and investors will take place on Thursday, September 21, 2023, from 10:00 a.m. to 12:00 p.m. ET. To register for the event, please click here . A replay of the webcast will be available on the “Events & Presentations” section of Celcuity’s website following the event.

About the Phase 1b/2 CELC-G-201 Trial

The CELC-G-201 Phase 1b/2 clinical trial is designed to evaluate gedatolisib plus darolutamide, an androgen receptor (AR) inhibitor, in patients previously treated with an AR inhibitor as a first-line treatment for metastatic castration resistant prostate cancer (mCRPC). In the Phase 1b portion of the study, Celcuity expects that 36 participants will be randomly assigned to receive 600 mg darolutamide combined with either 120 mg gedatolisib in Arm 1, or 180 mg gedatolisib in Arm 2. An additional 12 participants will then be enrolled in the Phase 2 portion of the trial at the recommended Phase 2 dose (RP2D) to enable evaluation of 30 participants treated with the RP2D of gedatolisib. The primary objectives of the Phase 1b portion of the trial include assessment of the safety and tolerability of gedatolisib in combination with darolutamide and determination of the RP2D of gedatolisib. The primary objective of the Phase 2 portion of the trial is to assess the radiographic progression-free survival (rPFS) at six months of patients who received the RP2D.

About Gedatolisib

Gedatolisib is a potent inhibitor that selectively targets all Class I isoforms of PI3K 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. Inhibiting all four PI3K isoforms, as gedatolisib does, limits the potential confounding effect of isoform interaction that may occur with isoform-specific PI3K inhibitors. Inhibiting mTOR also addresses potential resistance mechanisms that can result when PI3K isoforms are targeted in the absence of mTOR inhibition.

About Celcuity

Celcuity is a clinical-stage biotechnology company pursuing development of targeted therapies for oncology. 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 planned to begin enrolling patients in the first quarter of 2024. 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 and Phase 1b/2 CELC-G-201 clinical trial, the costs and expected results from ongoing and planned clinical trials, the impact on gedatolisib and Celcuity of preliminary clinical trial results, the market opportunity for gedatolisib in the prostate and breast cancer markets, and other expectations with respect to Celcuity's lead product candidate, 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," "goal," 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, delays, disruptions or adverse results in our clinical trials 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, 2022, filed with the Securities and Exchange Commission on March 23, 2023, and our subsequent Quarterly Reports on Form 10-Q. 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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