Celcuity Announces First Patient Dosed in Phase 3 VIKTORIA-1 Clinical Trial of Gedatolisib for the Treatment of HR+/HER2- Advanced Breast Cancer

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First patient dosing enables closing of $100 million PIPE financing and drawdown of $20 million term loan tranche

MINNEAPOLIS, MN / ACCESSWIRE / December 7, 2022 / Celcuity Inc. (Nasdaq:CELC), a clinical-stage biotechnology company developing targeted therapies for oncology, today announced that the first patient has been dosed in its Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib plus fulvestrant with and without palbociclib for the treatment of patients with HR+/HER2- advanced breast cancer. Gedatolisib, the company's lead therapeutic candidate, is a potent, reversible dual inhibitor that selectively targets all Class 1 PI3K isoforms and mTOR.

"We are excited to begin enrolling patients in the VIKTORIA-1 trial and advancing towards our ultimate goal of providing a transformative therapeutic option for patients with breast cancer," said Igor Gorbatchevsky, M.D. Chief Medical Officer of Celcuity. "We look forward to generating robust data with the goal of supporting a future regulatory submission."

"Patients with HR+/HER2- advanced breast cancer whose disease progressed while on treatment with a CDK4/6 inhibitor need better therapeutic options. VIKTORIA-1 is an important and innovative study that has the potential to provide two different treatment regimens for these patients," said Sara Hurvitz, M.D., Professor at the David Geffen School of Medicine at UCLA and a co-principal investigator for the clinical trial.

In July 2022, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to gedatolisib for the treatment of HR+/HER2- advanced breast cancer that has progressed after treatment with a CDK4/6 inhibitor in combination with an aromatase inhibitor. This designation allows for more intensive guidance from the FDA and a potentially accelerated review time if relevant criteria are met. Gedatolisib previously received Fast Track designation from the FDA in January 2022.

Dosing the first patient satisfies the primary closing condition of a $100 million private placement agreement that the company signed in May of this year. Investors participating in the private placement include Venrock Healthcare Capital Partners, Commodore Capital, New Enterprise Associates (NEA), RA Capital Management, Soleus Capital, and Brian Sullivan, the Company's Chief Executive Officer and Co-Founder. Under the terms of the private placement, investors will purchase common stock, preferred stock that may be convertible into common stock, and warrants exercisable for common stock.

Upon the closing of the $100 million private placement and subject to other customary conditions, Celcuity will also be eligible to draw on a $20 million tranche of a term loan under the terms of a $75 million debt facility, as amended in August this year. Additional details regarding the private placement and this debt facility, including the full text of the securities purchase agreement for the private placement and the August amendment of the debt facility, are available with the Company's Current Reports on Form 8-K filed with the Securities and Exchange Commission on May 18, 2022 and August 11, 2022, respectively.

"Closing the private placement and drawing down the additional tranche of our term loan will be important milestones for Celcuity. These financings significantly will strengthen our balance sheet and are expected to provide the capital we need to fund operations through 2025," said Brian Sullivan, CEO and co-founder of Celcuity.

About VIKTORIA-1

VIKTORIA-1 is a Phase 3 open-label, randomized clinical trial to evaluate the efficacy and safety of gedatolisib in combination with fulvestrant with or without palbociclib in adults with HR+/HER2- advanced breast cancer whose disease has progressed after prior CDK4/6 therapy in combination with an aromatase inhibitor. The clinical trial will enroll subjects regardless of *PIK3CA* status while enabling separate evaluation of subjects according to their *PIK3CA* status. Subjects who meet eligibility criteria and do not have confirmed *PI3KCA* mutations (WT) will be randomly assigned (1:1:1) to receive a regimen of either gedatolisib, palbociclib, and fulvestrant (Arm A), gedatolisib and fulvestrant (Arm B), or fulvestrant (Arm C). Up to 351 subjects who are *PIK3CA* WT will be enrolled. Subjects who meet eligibility criteria and have confirmed *PI3KCA* mutations (MT) will be randomly assigned (3:3:1) to receive a regimen of either gedatolisib, palbociclib, and fulvestrant (Arm D), alpelisib and fulvestrant (Arm E), or gedatolisib plus fulvestrant (Arm F). Up to 350 subjects who are *PIK3CA* MT will be enrolled.

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. 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. 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 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, expectations with respect to enrollment of additional patients in, and receiving results from, Celcuity's Phase 3 VIKTORIA-1 clinical trial, expectations with respect to potential results from such trial and the ability of such results to support future regulatory submissions, expectations for the efficacy and safety of gedatolisib, expectations with respect to the closing of Celcuity's $100 million private placement, the $20 million term loan and the impact such financing sources will have on the Company's balance sheet and liquidity needs. 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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