Celcuity Announces Clinical Trial Collaboration with University of Rochester Wilmot Cancer Center and Puma to Study Patients with Breast Cancer Brain Metastases

October 18, 2021

- *Study will evaluate the efficacy and safety of NERLYNX® plus XELODA® in patients selected by the CELsignia® Test who have metastatic HER2-negative breast cancer with brain metastases*
- *The unique tumor insights CELsignia generates enable identification of new potential applications for targeted therapies and development of potential first-in-class drugs*

Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing an integrated companion diagnostic and therapeutic strategy for treating patients with cancer, today announced a clinical trial collaboration with the University of Rochester Wilmot Cancer Center and Puma Biotechnology (Nasdaq: PBYI), a biopharmaceutical company, to conduct a Phase 2 clinical trial.

This open-label Phase 2 trial will evaluate the efficacy and safety of Puma's drug, NERLYNX (neratinib), and Xeloda (capecitabine), a Genentech/Roche drug, in previously treated patients selected with Celcuity's CELsignia HER2 Activity Test who have metastatic HER2-negative breast cancer. Under the agreement, The University of Rochester Wilmot Cancer Center will serve as the sponsor and Ajay Dhakal, M.D., a medical oncologist at the University of Rochester Medical Center, will serve as the principal investigator of this study. The University of Rochester Wilmot Cancer Center is one of the 51 NCI-Designated Comprehensive Cancer Centers in the U.S. tasked with developing new approaches to diagnosing and treating cancer.

“This clinical trial could play a key role in creating a new treatment paradigm for metastatic HER2-negative breast cancer patients with brain metastases,” said Dr. Dhakal. “We are eager to begin working with Celcuity’s cutting-edge CELsignia technology to identify a new subset of patients who may respond to NERLYNX.”

Puma will supply NERLYNX, its pan-HER inhibitor currently approved by the U.S. Food and Drug Administration (FDA) for early and late-stage HER2-positive breast cancer. Celcuity will provide its CELsignia HER2 Activity Test to select HER2-negative metastatic breast cancer patients with brain metastases who have hyperactive HER2-driven signaling pathways for the trial and will fund the patient-related trial costs. Based on its estimates of patient enrollment rates, Celcuity expects to obtain interim results 12 to 15 months after initiation of the trial followed by the final results 12 to 15 months later. Celcuity expects enrollment to begin by early to mid-2022.

The goal of the trial is to demonstrate that previously treated HER2-negative metastatic breast cancer patients with brain metastases who have hyperactive HER2 signaling tumors, as identified by the CELsignia test, respond to treatment with NERLYNX in combination with XELODA, a chemotherapy commonly used in metastatic breast cancer patients. Celcuity believes there is significant clinical interest in finding new diagnostic tests and targeted therapies for metastatic HER2- negative breast cancer patients with brain metastases.

"We are excited about the opportunity to collaborate with Dr. Dhakal, The University of Rochester Wilmot Cancer Center, and Puma Biotechnology on this important clinical trial," said Brian Sullivan, CEO and co-founder of Celcuity. "This will be our first collaboration to study metastatic breast cancer patients with brain metastases selected for treatment using our CELsignia HER2 Activity Test. Patients with HER2-negative breast cancer who have brain metastases have few good options today. Approximately 20% of the 280,000 HER2-negative breast cancer patients receiving drug treatment annually have tumors with hyperactive HER2 signaling. [1] For these patients, this trial represents a critical step towards a potential new therapeutic option."

About Celcuity

Celcuity is a clinical-stage biotechnology company seeking to extend the lives of cancer patients by pursuing an integrated companion diagnostic and therapeutic strategy. 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. Its therapeutic efforts are focused on in-licensing and developing molecularly targeted therapies that address the same cancer driver its companion diagnostics can identify. Celcuity is headquartered in Minneapolis. Further information about Celcuity can be found at www.celcuity.com .

Forward-Looking Statements

This press release contains statements that constitute "forward-looking statements" that involve risks and uncertainties including, but not limited to, expectations with respect to commencement of clinical trial patient enrollment and the rates of such enrollment, timing of clinical trial results, the actual results of such clinical trials and interest from outside parties in such clinical trials, the results and any new treatment paradigms that may result therefrom. 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 conditions, many of which are beyond the control of Celcuity, which include, but are not limited to, the unknown impact of the COVID-19 pandemic on Celcuity's business and those other risks set forth in the Risk Factors section in Celcuity's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission on February 16, 2021 and in Exhibit 99.4 to Celcuity's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 8, 2021. 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.

1. MacNeil IA, Burns DJ, Rich BE, Soltani SM, Kharbush S, Osterhaus NG, Sullivan BF, Hawkins DM, Pietruska JR, Laing LG. New HER2-negative breast cancer subtype responsive to anti-HER2 therapy identified. J Cancer Res Clin Oncol. 2020 Mar;146(3):605-619.

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