Celcuity Announces Clinical Trial Collaboration with Massachusetts General Hospital and Puma Biotechnology

December 23, 2020

- UCLA Jonsson Comprehensive Cancer Center and Vanderbilt-Ingram Cancer Center will also participate

- Study will evaluate the efficacy and safety of NERLYNX® and FASLODEX® in metastatic HR-positive, HER2-negative breast cancer patients selected by the CELsignia® Test

MINNEAPOLIS, MN / ACCESSWIRE / December 23, 2020 / Celcuity Inc. (NASDAQ:CELC), a clinical stage biotechnology company utilizing its 3rd generation companion diagnostics to identify new targeted therapeutic options for cancer patients, today announced a clinical trial collaboration with Massachusetts General Hospital and Puma Biotechnology, a biopharmaceutical company, to conduct a Phase II clinical trial.

This open-label Phase II trial will evaluate the efficacy and safety of Puma's drug, NERLYNX(neratinib), and FASLODEX(fulvestrant), an AstraZeneca drug, in previously treated metastatic HR-positive (HR+), HER2-negative (HER2-) breast cancer patients selected with Celcuity's CELsignia HER2 Activity Test. Under the agreement, Massachusetts General Hospital will serve as the sponsor and Dr. Aditya Bardia, a medical oncologist at Massachusetts General Hospital and assistant professor at Harvard Medical School, will serve as the principal investigator of this study, while the UCLA Jonsson Comprehensive Cancer Center and the Vanderbilt-Ingram Cancer Center will serve as co-sponsors. Each of these institutions is amongst the United States' 51 NCI-Designated Comprehensive Cancer Centers tasked with developing new approaches to diagnosing and treating cancer.

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 HR+, HER2- metastatic breast cancer patients 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 the protocol is activated and final results 12 to 15 months later. Celcuity expects enrollment to begin in the second quarter of 2021.

The goal of the trial is to demonstrate that previously treated HR+, HER2- metastatic breast cancer patients who have hyperactive HER2 signaling tumors, as identified by the CELsignia test, respond to treatment with NERLYNX in combination with FASLODEX, a hormonal therapy that targets the estrogen receptor. Celcuity believes there is significant clinical interest in finding new diagnostic tests and targeted therapies for metastatic HR+, HER2- breast cancer patients whose disease progressed on prior therapies. Of particular interest are new therapeutic combinations that can overcome resistance to anti-estrogen therapies like FASLODEX. The blockade of estrogen receptor and HER2 pathways when the HER2 pathway is hyperactive using a combination of NERLYNX and FASLODEX has been demonstrated in animal models.[1]

"We are excited about the opportunity to collaborate with Dr. Bardia, Massachusetts General Hospital, UCLA, Vanderbilt, 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 selected for treatment using our CELsignia HER2 Activity Test. Our two current clinical trials are studying the efficacy of anti-HER2 therapies in early-stage breast cancer patients. Approximately 20% of the 280,000 HER2- breast cancer patients receiving drug treatment annually have tumors with hyperactive HER2 signaling, according to our studies.[2] For these patients, this trial represents a critical step towards a potential new therapeutic option."

About Celcuity
Celcuity is a clinical stage biotechnology company translating discoveries of new cancer sub-types into pioneering companion diagnostics and expanded therapeutic options for cancer patients. Celcuity's 3rd generation diagnostic platform, CELsignia, analyzes living tumor cells to untangle the complexity of the cellular activity driving a patient's cancer. This allows Celcuity to discover new cancer sub-types molecular diagnostics cannot detect. Celcuity is driven to improve outcomes for patients and to transform how pharmaceutical companies define the patient populations for their targeted therapies. Celcuity is headquartered in Minneapolis, MN. Further information about Celcuity can be found at www.celcuity.com.

About the Massachusetts General Hospital
Massachusetts General Hospital, founded in 1811, is the original and largest teaching hospital of Harvard Medical School. The Mass General Research Institute conducts the largest hospital-based research program in the nation, with annual research operations of more than $1 billion and comprises more than 9,500 researchers working across more than 30 institutes, centers and departments. In August 2020, Mass General was named #6 in the *U.S. News & World Report* list of "America's Best Hospitals."

Forward-Looking Statements
This press release contains statements that constitute "forward-looking statements." In some cases, you can identify forward-looking statements by terminology such as "may," "can," "could," "expects," "estimates," or "plans," 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 in this release include, without limitation, expectations with respect to commencement of patient enrollment, patient enrollment rates and timing of expected results, and beliefs regarding clinical interest of the trial, the use of new diagnostic tests and targeted therapies in treating cancer patients, and the potential role of the trial and the CELsignia HER2 Activity Test in developing new treatment options for cancer patients. Forward-looking statements are subject to numerous conditions, many of which are beyond the control of Celcuity, which include, but are not limited to, those set forth in the Risk Factors section in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission on March 13, 2020. 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 release, except as required by law.

1. Crooessmann S., Combined blockade of activating ERBB2 mutations and ER results in synthetic lethality of ER+/HER2 mutant breast cancer, Clin Cancer Res. 2019 Jan 1: 25(1): 277-289
2. Laing, L, et al. New HER2-negative breast cancer subtype responsive to anti-HER2 therapy identified. Journal of Cancer Research and Clinical Oncology 2020; 146:605-619

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