Celcuity Announces Breast Cancer Clinical Trial Collaboration with Sarah Cannon and Pfizer to Study New Drug Regimen

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- Trial will evaluate the efficacy and safety of Pfizer's targeted therapies, VIZIMPRO ® and XALKORI ®, in patients with metastatic HER2-negative breast cancer selected by Celcuity's CELsignia Multi-Pathway Activity Test

- First clinical trial to treat patients diagnosed with hyperactive HER2 and c-Met signaling breast cancers with matching targeted therapies

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 Sarah Cannon Research Institute, the research arm of Sarah Cannon, and Pfizer Inc., a global biopharmaceutical company, to conduct a Phase II clinical trial.

This open-label Phase II trial will evaluate the efficacy and safety of two Pfizer targeted therapies, VIZIMPRO ®, a pan-HER inhibitor, and XALKORI ®, a c-Met inhibitor, in patients with previously treated metastatic HER2-negative breast cancer selected with Celcuity's CELsignia Multi-Pathway Activity Test. Under the agreement, Sarah Cannon Research Institute will serve as the sponsor and Erika Hamilton, MD, a medical oncologist and Director of the Breast Cancer and Gynecologic Cancer Research Program for Sarah Cannon Research Institute at Tennessee Oncology, will serve as the principal investigator of this study. Sarah Cannon Research Institute, one of the world's leading clinical research organizations conducting community-based clinical trials throughout the United States and United Kingdom, has been a clinical trial leader in the majority of approved cancer therapies over the last decade.

"This clinical trial could lay the groundwork for a new treatment paradigm for patients with metastatic HER2-negative breast cancer who stop responding to current standard-of-care drug regimens," said Dr. Hamilton. Added Dr. Hamilton, "We are eager to begin working with Celcuity and exploring their novel CELsignia technology to identify patients whose tumors may respond to these targeted therapies."

Pfizer will supply VIZIMPRO and XALKORI, targeted therapies currently approved by the U.S. Food and Drug Administration to treat metastatic non-small cell lung cancer. Celcuity will provide its CELsignia Multi-Pathway Activity Test to select patients with HER2-negative metastatic breast cancer who have hyperactive HER2 and c-Met signaling pathways for the trial and will fund the patient-related trial costs. Based on Sarah Cannon's estimate of patient enrollment rates, Celcuity expects to obtain interim results 12 to 15 months after the protocol is activated and final results 12-15 months later. Celcuity expects enrollment to begin in the second quarter of 2021.

Celcuity believes there is significant clinical interest in finding new diagnostic tests and targeted therapies for patients with metastatic HER2-negative breast cancer whose disease progressed on prior therapies. The anti-tumor effect of blocking EGFR/HER1, HER2, HER3, and c-Met pathways when the HER2 and c-Met pathways are hyperactive has been demonstrated in animal models. [1]

This study represents Celcuity's fourth clinical trial collaboration with a leading cancer research organization and a pharmaceutical company, and the second one announced in the past month. In December, Celcuity announced a clinical trial collaboration with Massachusetts General Hospital, UCLA, and Vanderbilt to evaluate Puma Biotechnology's pan-HER inhibitor, NERLYNX, in patients with hormone receptor-positive, HER2-negative breast cancer. Each of the four collaborations rely on a CELsignia Pathway Activity test to select patients who have a dysregulated oncogenic pathway not associated with a corresponding genomic or proteomic mutation.

"We are excited about the opportunity to collaborate with Dr. Hamilton, Sarah Cannon Research Institute, and Pfizer on this important clinical trial," said Brian Sullivan, CEO and co-founder of Celcuity. "This will be our first collaboration that uses our CELsignia Multi-Pathway Activity Test to select patients who have both HER2 and c-Met hyperactive signaling tumors for a clinical trial. According to our studies, approximately 20% of HER2-negative breast cancers have hyperactive HER2 and c-MET signaling. For this group of 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 Sarah Cannon Research Institute

Sarah Cannon Research Institute is the research arm of HCA Healthcare's global cancer institute, Sarah Cannon. Focused on advancing therapies for patients, it is one of the world's leading clinical research organizations conducting community-based clinical trials throughout the United States and United Kingdom. A leader in drug development, Sarah Cannon has led more than 450 first-in-human clinical trials since its inception in 1993 and has been a clinical trial leader in the majority of approved cancer therapies over the last 10 years. Additionally, Sarah Cannon offers management, regulatory, and other research support services for drug development and industry sponsors as well as strategic investigator sites through its contract research organization (CRO), Sarah Cannon Development Innovations.

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 Multi-Pathway 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. Laing, L, et al., Evaluating contribution of hyperactive c-Met and ErbB signaling to tumor progression in mouse breast tumor xenografts: an in vivo study of c-Met and ErbB targeted therapies. Cancer Research;79 (4 Supplement) P3-10-15

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