Celcuity Announces Breast Cancer Clinical Trial Collaboration with MD Anderson, Novartis, and Puma Biotechnology to Study New Drug Regimen

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- Trial will evaluate the efficacy and safety of Novartis' targeted therapy TABRECTA ® and Puma's NERLYNX ® in patients with metastatic HER2-negative breast cancer selected by Celcuity's CELsignia Multi-Pathway Activity Test

- This is Celcuity's second clinical trial to treat patients diagnosed with hyperactive HER2 and c-Met signaling breast cancers with matching targeted therapies

- Five clinical trial collaborations are now in place and include ones with Genentech, Pfizer, Novartis and Puma

Celcuity Inc. (Nasdaq: CELC), a clinical stage biotechnology company utilizing its 3 rd generation companion diagnostics to identify new targeted therapeutic options for cancer patients, today announced a clinical trial collaboration with the MD Anderson Cancer Center, one of the world's most respected cancer centers, Novartis AG, a global biopharmaceutical company, and Puma Biotechnology, Inc., a biopharmaceutical company, to conduct a Phase II clinical trial.

This open-label Phase II trial will evaluate the efficacy and safety of two targeted therapies, TABRECTA ®, a c-Met inhibitor, and NERLYNX ® a pan-HER inhibitor, in patients with previously treated metastatic HER2-negative breast cancer selected with Celcuity's CELsignia Multi-Pathway Activity Test. Under the agreement, MD Anderson will serve as the sponsor and Bora Lim MD, a medical oncologist at Baylor College of Medicine, and Rachel Layman MD, a medical oncologist at MD Anderson, will serve as the co-principal investigators of this study. MD Anderson is ranked No. 1 for cancer care in U.S. News & World Report's "Best Hospitals" survey. It has ranked as one of the nation's top two hospitals for cancer care since the survey began in 1990 and has ranked first 16 times in the last 19 years.

"This trial is evaluating a very exciting drug combination," said Dr. Lim. "My research has focused on mechanisms of resistance that occur when a breast cancer tumor is under therapeutic pressure, and key pathways, including HER2 and c-Met, are activated. Celcuity's studies have demonstrated how the c-Met pathway and HER-family pathways can cooperate to promote tumorigenesis. We hope that this novel combination therapy study will help us demonstrate a new way of treating breast cancers with normally expressed HER2 by combining a c-Met inhibitor and a HER2 inhibitor. This has never been tested before, and we will learn so much about the hidden biology of breast cancer."

Novartis will supply TABRECTA ® and Puma will supply NERLYNX ®, targeted therapies currently approved by the U.S. Food and Drug Administration to treat non-small cell lung cancer and HER2-positive breast cancer, respectively. 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 MD Anderson'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 to 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 fifth clinical trial collaboration with a leading cancer research organization and a pharmaceutical company, and the third one announced in the past three months. In January, Celcuity announced a clinical trial collaboration with the Sarah Cannon Research Institute to evaluate two drugs from Pfizer, a global pharmaceutical company, in patients with metastatic HER2-negative breast cancer. Each of the five 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 Drs. Lim and Layman, MD Anderson, Novartis and Puma on this important clinical trial," said Brian Sullivan, CEO and co-founder of Celcuity. "This will be our second 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, these trials represent a critical step towards a potential new therapeutic option.

"Our other collaboration discussions also continue to progress, including one involving a PI3K targeted therapy. Dysregulated PI3K signaling is implicated in a wide variety of human cancers. In breast cancer, activation of the PI3K/mTOR pathway is a common mechanism of resistance to endocrine inhibitors. Broader use of PI3K targeted therapies may thus create, we believe, a substantial opportunity to improve the standard-of-care for many breast cancer patients."

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 MD Anderson

The University of Texas MD Anderson Cancer Center in Houston ranks as one of the world's most respected centers focused on cancer patient care, research, education and prevention. The institution's sole mission is to end cancer for patients and their families around the world. MD Anderson is one of only 51 comprehensive cancer centers designated by the National Cancer Institute (NCI). MD Anderson is ranked No. 1 for cancer care in U.S. News & World Report's "Best Hospitals" survey. It has ranked as one of the nation's top two hospitals for cancer care since the survey began in 1990 and has ranked first 16 times in the last 19 years.

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, 2020 filed with the Securities and Exchange Commission on February 16, 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 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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