Celcuity Receives FDA Fast Track Designation for Gedatolisib in HR+ / HER2- Metastatic Breast Cancer and Provides Corporate Update

January 18, 2022

- ***FDA's Fast Track Designation for the pan-PI3K/mTOR inhibitor highlights potential to address the urgent need for new treatment options for breast cancer patients***
- ***On track to finalize Phase 3 clinical trial design for gedatolisib with FDA feedback in first quarter***
- ***Planning to initiate two studies in breast cancer to evaluate gedatolisib in patients selected with a CELsignia test***

MINNEAPOLIS, MN / ACCESSWIRE / January 18, 2022 / Celcuity Inc. (NASDAQ:CELC), a clinical-stage biotechnology company pursuing an integrated therapeutic and companion diagnostic strategy for treating patients with cancer, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the Company's lead drug candidate, gedatolisib, for the treatment of patients with HR+/HER2- metastatic breast cancer after progression on CDK4/6 therapy.

"There is an urgent need for better treatment options for HR+/HER2- metastatic breast cancer patients whose disease progressed after treatment with a CDK4/6 inhibitor and endocrine therapy," said Brian Sullivan, CEO and co-founder of Celcuity. "We are very encouraged by the clinical data for gedatolisib and believe that Fast Track designation will facilitate our efforts to advance its development for patients as quickly as possible."

Fast Track designation is granted by the FDA for products that are intended for the treatment of serious or life-threatening disease or conditions and which demonstrate the potential to address an unmet medical need. The designation offers the opportunity for frequent interactions with the FDA to discuss the drug's development plan and to ensure collection of appropriate data needed to support drug approval, as well as eligibility for rolling submission of a New Drug Application.

Celcuity remains on track to obtain feedback from the FDA and to finalize the design and protocol of its Phase 3 clinical trial in the first quarter of 2022. Site identification and feasibility activities for the Phase 3 clinical trial are on-going.

Additionally, Celcuity announced plans to initiate two Phase 2 clinical trials to evaluate gedatolisib in HR+/HER2- breast cancer patients selected with a CELsignia PI3K Pathway Test. One trial will evaluate gedatolisib in combination with fulvestrant in up to 25 patients with metastatic breast cancer. The second trial will evaluate up to 15 patients with early-stage breast cancer with gedatolisib in combination with palbociclib and letrozole. These clinical trials will be initiated at sites which are already participating in a trial that is screening patients with the CELsignia HER2 Pathway Test. Screened patients who provide a tumor biopsy will receive a CELsignia HER2 and PI3K Test. Patients found to have hyperactive HER2 signaling will be eligible to receive treatment with an anti-HER2 therapy and those with hyperactive PI3K signaling will be eligible to receive gedatolisib in combination with other targeted therapies. Patient enrollment is expected to begin for the two trials in late 2022.

Celcuity believes that conducting these CELsignia studies in parallel will enhance screening activities for potentially eligible patients. Based on the prevalence of hyperactive HER2 and PI3K signaling, Celcuity estimates that approximately 40%-45% of patients receiving a CELsignia test would potentially be eligible to enroll in one of the clinical trials. Patients providing tumor for CELsignia testing would thus be twice as likely to be eligible for participation in a CELsignia clinical study, potentially a significant benefit.

"Initiating clinical trials to evaluate gedatolisib in CELsignia selected patients in parallel with other CELsignia studies is very synergistic," stated Brian Sullivan. "First, we believe this will enhance the enrollment activities for each study. Secondly, these studies provide an efficient opportunity for Celcuity to evaluate gedatolisib in CELsignia PI3K test selected patients. Finally, it allows optimization of our overall CELsignia trial strategy. We concluded that the patients eligible for PI3K therapies may significantly overlap with the patients eligible for our clinical trial evaluating the pan-HER inhibitor, dacomitinib, and the c-MET inhibitor, crizotinib. In addition, a gedatolisib based regimen offers, we believe, a significantly more favorable safety profile than the combination of dacomitinib and crizotinib. Since we have another clinical trial evaluating a pan-HER and c-MET inhibitor, we concluded the FACT-3 clinical trial was redundant, and we have decided to discontinue it."

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

About Gedatolisib
Gedatolisib is a potent, reversible dual inhibitor that selectively targets all Class I isoforms of PI3K 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. Inhibiting all four Class I PI3K isoforms, as gedatolisib does, limits the potential development of drug resistance compared with isoform-specific PI3K inhibitors. Inhibiting mTOR also addresses potential resistance mechanisms that can result when PI3K isoforms are targeted in the absence of mTOR inhibition. A robust response rate and a well-tolerated treatment with manageable side effects were observed in an on-going Phase 1b clinical trial that evaluated gedatolisib in combination with palbociclib and endocrine therapy in patients with ER+/HER2- advanced breast cancer. Based on these results, a Phase 3 clinical trial is planned.

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 receiving FDA feedback, plans to provide further details about clinical trial design, plans to commence our Phase 3 clinical trial, including expected patient screening and enrollments, and clinical trial 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.

CONTACT:
Celcuity Inc.
Brian Sullivan, bsullivan@celcuity.com
Vicky Hahne, vhahne@celcuity.com

ICR Westwicke
Robert Uhl, robert.uhl@westwicke.com
(619) 228-5886

SOURCE: Celcuity Inc.

View source version on accesswire.com:

https://www.accesswire.com/684239/Celcuity-Receives-FDA-Fast-Track-Designation-for-Gedatolisib-in-HR-HER2-Metastatic-Breast-Cancer-and-Provides-Corporate-Update