



Celcuity Announces FDA Breakthrough Therapy Designation for Gedatolisib for Treatment of HR+/HER2- Metastatic Breast Cancer

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MINNEAPOLIS, MN / ACCESSWIRE / July 18, 2022 / Celcuity Inc. (Nasdaq:CELC), a clinical-stage biotechnology company focused on development of targeted therapies for hormonally driven cancers, today announced that the U.S. Food and Drug Administration (FDA) has granted gedatolisib Breakthrough Therapy designation for the treatment of patients with HR+/HER2- metastatic breast cancer whose disease progressed during treatment with a CDK4/6 therapy and a non-steroidal aromatase inhibitor. Gedatolisib is a potential first-in-class pan-PI3K/mTOR inhibitor.

Breakthrough Therapy Designation is granted by the FDA to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition. The criteria for Breakthrough Therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on one or more clinically significant endpoints over available therapy. The benefits of Breakthrough Therapy Designation include more intensive guidance from the FDA on an efficient development program, access to a scientific liaison to help accelerate review time, and potential eligibility for priority review if relevant criteria are met. Gedatolisib previously received Fast Track designation from the FDA in January 2022.

Celcuity's breakthrough application was supported by data from a Phase 1b study that assessed the safety, tolerability and clinical activity of gedatolisib in combination with palbociclib and fulvestrant in patients with HR+/HER2- metastatic breast cancer whose disease progressed during treatment with a CDK4/6 therapy and an aromatase inhibitor.

"Breakthrough Therapy designation marks an important development milestone for gedatolisib and for patients with metastatic breast cancer whose disease progresses during treatment with a CDK4/6 inhibitor," said Brian Sullivan, CEO and co-founder of Celcuity. "There is an urgent need for additional therapeutic options for these patients. We look forward to continued collaboration with the FDA as we strive to advance development of gedatolisib."

About Gedatolisib

Gedatolisib is a potent, reversible dual inhibitor that selectively targets all Class I PI3K isoforms 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 and mTOR limits the potential development of drug resistance compared with isoform-specific PI3K or mTOR specific inhibitors. A robust response rate and a manageable side effect profile were reported for the Phase 1b clinical trial that evaluated gedatolisib in combination with palbociclib and endocrine therapy in patients with HR+/HER2- advanced breast cancer. The company expects to initiate a Phase 3 trial evaluating gedatolisib in patients with HR+/HER2- advanced breast cancer in 2022.

About Celcuity

Celcuity is a clinical-stage biotechnology company focused on development of targeted therapies for hormonally driven cancers. The company's lead therapeutic candidate is gedatolisib, a potent, reversible dual inhibitor that selectively targets all Class I PI3K isoforms 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. The company expects to initiate a Phase 3 study evaluating gedatolisib in patients with HR+/HER2- advanced breast cancer in 2022. 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.

Forward-Looking Statements

This press release contains statements that constitute "forward-looking statements" that involve risks and uncertainties including, but not limited to, the timing of initiating and enrolling patients in clinical trials and receiving results from such trials, including without limitation, Celcuity's planned Phase 3 clinical trial (VIKTORIA-1). 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, 2021 filed with the Securities and Exchange Commission on March 23, 2022. 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.

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