Celcuity Announces Clinical Trial Collaboration and Supply Agreement with Pfizer to Provide Ibrance(R) (palbociclib) for Planned Phase 3 Clinical Trial

MINNEAPOLIS, MN / ACCESSWIRE / November 15, 2021 / 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 it has entered into a clinical trial collaboration and supply agreement with Pfizer to provide Ibrance® (palbociclib) for use in Celcuity's Phase 3 clinical trial at no cost to Celcuity.

As previously disclosed, Celcuity expects to initiate a Phase 3 clinical trial in the first half of 2022 to evaluate gedatolisib, the company's pan-PI3K/mTOR inhibitor, in combination with palbociclib, a CDK4/6 inhibitor, and Faslodex® (fulvestrant), a selective endocrine receptor degrader, in patients with ER+/HER2- advanced breast cancer. Further details about the design of the clinical trial will be provided once feedback is obtained from the U.S. Food and Drug Administration (FDA).

"We are excited that Pfizer is providing palbociclib for this important Phase 3 clinical trial," said Brian Sullivan, Chief Executive Officer and co-founder of Celcuity. "Our goal is to address the significant unmet need for new therapeutic options for patients who progressed on their first line of treatment for ER+/HER2- advanced breast cancer."

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 PI3K isoforms, as gedatolisib does, limits the potential confounding effect of isoform interaction that may occur 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 favorable safety profile 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.

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 strategy. The company's therapeutic efforts are focused on 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**.

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 clinical trials, 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.

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