Celcuity Enters into a Clinical Trial Collaboration and Supply Agreement with Bayer to Provide Nubeqa® (darolutamide) for Planned Phase 1b/2 Clinical Trial

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MINNEAPOLIS, Aug. 22, 2023 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced that it has entered into a clinical trial collaboration and supply agreement with Bayer AG for Celcuity's Phase 1b/2 clinical trial of gedatolisib and Nubeqa® (darolutamide) in patients with metastatic castration resistant prostate cancer (mCRPC). As part of the supply agreement, Bayer will provide Nubeqa to Celcuity at no cost.

Celcuity expects to initiate a Phase 1b/2 clinical trial in the first quarter of 2024 to evaluate gedatolisib, the company's pan-PI3K/mTOR inhibitor, in combination with darolutamide, an androgen receptor inhibitor, in patients with mCRPC who progressed on their first line of androgen receptor treatment for mCRPC.

"We are excited that Bayer is providing darolutamide for this important Phase 1b/2 clinical trial," said Brian Sullivan, Chief Executive Officer and co-founder of Celcuity. "Darolutamide is structurally unique to other ARI's, with an excellent efficacy and differentiated tolerability profile coupled with minimal drug-drug interactions, making it an ideal combination partner for gedatolisib. Our goal is to address the significant need for new therapeutic options for patients with metastatic castration resistant prostate cancer."

About Gedatolisib
Gedatolisib is a potent 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.

About Celcuity
Celcuity is a clinical-stage biotechnology company pursuing development of targeted therapies for oncology. The company's lead therapeutic candidate is gedatolisib, a potent, pan-PI3K and mTOR inhibitor. 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. A Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with HR+/HER2- advanced breast cancer is currently enrolling patients. More detailed information about the VIKTORIA-1 study can be found at ClinicalTrials.gov . A Phase 1b/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer, is planned to begin enrolling patients in the first quarter of 2024. The company's 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 Celcuity.com . Follow us on LinkedIn and Twitter .

Forward-Looking Statements

This press release contains statements that constitute "forward-looking statements" including, but not limited to, the timing of initiating and enrolling patients in, and receiving results from, clinical trials, such as Celcuity's Phase 3 VIKTORIA-1 and Phase 1b/2 CELC-G-201 clinical trial, the costs and expected results from ongoing and planned clinical trials, the impact on gedatolisib and Celcuity of preliminary clinical trial results, the market opportunity for gedatolisib in the prostate cancer market, and other expectations with respect to Celcuity's lead product candidate, gedatolisib, and Celcuity's CELsignia platform. In some cases, you can identify forward-looking statements by terminology such as "may," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "intends," "goal," 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 risks, uncertainties, and conditions, many of which are beyond the control of Celcuity. These include, but are not limited to, Bayer's continued performance under the terms of our clinical trial collaboration and supply agreement and those risks set forth in the Risk Factors section in Celcuity's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 23, 2023, and our subsequent Quarterly Reports on Form 10-Q. 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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