Celcuity Inc. Announces Plan to Initiate a Phase 3 Clinical Trial for Gedatolisib as First-Line Treatment for HR+/HER2- Advanced Breast Cancer and Secures Approximately $62 Million Debt Financing

May 30, 2024

- *The Phase 3 clinical trial will evaluate gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with HR+/HER2- advanced breast cancer who are endocrine therapy resistant*
- *Received an additional term loan of approximately $62 million in conjunction with an amendment to an existing debt facility agreement*

MINNEAPOLIS, May 30, 2024 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced that it plans to initiate a Phase 3 clinical trial to evaluate gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with HR+/HER2- advanced breast cancer ("ABC") who are endocrine therapy resistant. In conjunction with its plan to conduct this study, Celcuity today entered into an amendment to an existing debt facility agreement and received an additional term loan of approximately $62 million.

"There is an urgent need for better first-line treatment options for HR+/HER2- advanced breast cancer patients whose disease progressed while on or within 12 months of completing adjuvant endocrine for early breast cancer," said Igor Gorbatchevsky, MD, Chief Medical Officer of Celcuity. "We are very encouraged by the preliminary clinical data for gedatolisib as first-line treatment in patients with advanced breast cancer. In our Phase 1b trial that evaluated gedatolisib in combination with palbociclib and letrozole, median progression free survival was 48.6 months, and the ORR was 79%. These results highlighted the potential benefit of inhibiting the PI3K/AKT/mTOR pathway in treatment naïve patients."

Phase 3 VIKTORIA-2 Clinical Trial
The Phase 3 VIKTORIA-2 clinical trial will be an open-label, randomized study to evaluate the efficacy and safety of gedatolisib combined with fulvestrant plus a CDK4/6 inhibitor in comparison to fulvestrant plus a CDK4/6 inhibitor as first-line treatment for patients with HR+/HER2- ABC who are endocrine therapy resistant. For the CDK4/6 inhibitor, investigators may choose either ribociclib or palbociclib. The safety profile of gedatolisib combined with fulvestrant and palbociclib is well described, but the investigational combination of gedatolisib with ribociclib has not yet been clinically tested. Therefore, a safety run-in of approximately 12-36 subjects will evaluate the safety profile of gedatolisib combined with ribociclib and fulvestrant. The safety run-in will be completed, and gedatolisib's Phase 3 dose confirmed, before enrolling patients in the Phase 3 portion of the study.

For the Phase 3 study, approximately 638 subjects who meet the eligibility criteria will be assigned to a cohort based on their PIK3CA mutation status. After the investigator selects the CDK4/6 inhibitor for a subject, the subject will then be randomly assigned on a 1:1 basis to either Arm A (gedatolisib, fulvestrant, and Investigator's choice of ribociclib or palbociclib) or Arm B (fulvestrant and Investigator's choice of ribociclib or palbociclib).

The clinical trial primary endpoints are progression free survival ("PFS"), per RECIST 1.1 criteria, as assessed by blinded independent central review. The primary PFS endpoints will be evaluated separately in subjects who are PI3KCA wild type and PI3KCA mutant.

The study's design was reviewed and discussed with the U.S. Food and Drug Administration ("FDA") during a Type C meeting.

This global trial is expected to enroll subjects at up to 200 clinical sites across North America, Europe, Latin America, and Asia. Celcuity expects to enroll the first patient in the second quarter of 2025.

"We are excited to have secured the additional capital so we could accelerate initiation of our second Phase 3 study," said Brian Sullivan, CEO and co-founder of Celcuity. "Allowing investigators to choose between ribociclib or palbociclib as the CDK4/6 inhibitor for their patients, and separately randomizing patients according to their PIK3CA status, are important elements of the trial design. We are pleased that the FDA concurred with our approach."

Amended debt financing agreement with Innovatus Capital Partners, LLC and Oxford Finance LLC
Today, Celcuity also amended its existing debt financing agreement with an affiliate of Innovatus Capital Partners, LLC ("Innovatus") and added Oxford Finance LLC ("Oxford") as a new lender to provide Celcuity with up to $180 million in term loans, a $105 million increase from the current debt financing agreement. At the closing of this amendment to the debt financing agreement, Celcuity will receive $61.7 million and will have $100 million of total debt outstanding. Celcuity will be able to draw an additional tranche of $30 million and an additional tranche of $50 million upon achievement of certain clinical trial and regulatory milestones. The amended debt facility has a 36-month interest only period, which can be extended to a 48-month period if certain conditions are met. The loans will mature on the fifth anniversary of the amended agreement date. The loan agreement includes customary warrant coverage and is secured by all of Celcuity's assets. Armentum Partners LLC acted as sole advisor to Celcuity

on this transaction.

About Celcuity
Celcuity is a clinical-stage biotechnology company focused on development of targeted therapies for treatment of multiple solid tumor indications. 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 enrolling patients. A Phase 3 clinical trial, VIKTORIA-2, evaluating gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with HR+/HER2- advanced breast cancer is expected to begin enrolling patients in the second quarter of 2025. 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 www.celcuity.com. Follow us on LinkedIn and Twitter.

About Innovatus Capital Partners, LLC
Innovatus Capital Partners, LLC, is an independent adviser and portfolio management firm with approximately $1.7B in assets under management. Innovatus adheres to an investment strategy that identifies disruptive and growth opportunities across multiple asset categories with a unifying theme of capital preservation, income generation, and upside optionality. The firm has a dedicated team of life sciences investment professionals with deep experience in healthcare, including life sciences. Innovatus and its principals have significant experience providing debt financing to medical device, diagnostics, and biotechnology companies that address unmet medical needs, improve patient outcomes, and reduce overall healthcare expenditures.

About Oxford Finance
Oxford Finance LLC is a specialty finance firm providing senior secured loans to public and private life sciences and healthcare services companies worldwide. For over 20 years, Oxford has delivered flexible financing solutions to over 700 companies, allowing borrowers to maximize their equity by leveraging their assets. Since 2002, Oxford has originated more than $11 billion in loans. Oxford is headquartered in Alexandria, Virginia, with additional offices serving the greater San Diego, San Francisco, Boston and New York City metropolitan areas.

Cautionary Note Regarding Forward-Looking Statements
This press release contains statements that constitute "forward-looking statements" including, but not limited to, the design of our clinical trials; the timing of initiating and enrolling patients in, and receiving results and data from, our clinical trials; the costs and expected results from any ongoing or planned clinical trials; the market opportunity for gedatolisib; other expectations with respect to gedatolisib and our CELsignia platform; the expected use of proceeds from our recent financing activities; and the strength of our balance sheet. 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 risks, uncertainties, and conditions, many of which are beyond the control of Celcuity. These include, but are not limited to, unforeseen delays in our clinical trials, our ability to obtain and maintain regulatory approvals to commercialize our products, and the market acceptance of such products, the development of therapies and tools competitive with our products, 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, 2023 filed with the Securities and Exchange Commission on March 27, 2024. 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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