Celcuity Presents Updated Results of Phase 1b Study of Gedatolisib in Combination with Palbociclib and Endocrine Therapy for ER+ Advanced Breast Cancer (ABC) at the 2021 San Antonio Breast Cancer Symposium

December 10, 2021

78% ORR in 3rd line patients and 63% ORR overall in patients treated with three weeks on/one week off gedatolisib dosing schedule (Arm D)

MINNEAPOLIS, MN / ACCESSWIRE / December 10, 2021 / Celcuity Inc. (Nasdaq:CELC), a clinical-stage biotechnology company pursuing an integrated therapeutic and companion diagnostic strategy for treating patients with cancer, today presented a poster at the 2021 San Antonio Breast Cancer Symposium (SABCS) with updated results from a four-arm Phase 1b expansion study. This study evaluated gedatolisib, a first-in-class pan-PI3K/mTOR inhibitor, in combination with palbociclib, a CDK4/6 inhibitor and endocrine therapy (either letrozole or fulvestrant) in women with ER+/HER2- advanced breast cancer (ABC). The poster presented data as of a May 10, 2021 data cutoff. Preliminary data from this Phase 1b study was presented earlier this year with results as of a January 11, 2021 data cut-off.

Consistent with the previously released results, the addition of gedatolisib to palbociclib and endocrine therapy demonstrated promising antitumor activity in both first and later line settings for ER+/HER2- ABC that compared favorably to historical controls. A significant objective response rate (ORR) was also observed in patients refractory to their last treatment or who had received two or more lines of prior treatment for advanced breast cancer. Gedatolisib was well tolerated with manageable toxicity and a low number of patients discontinued treatment due to an adverse event.

"The updated data we presented at SABCS for this Phase 1b study provides additional information about the characteristics of enrolled patients, the impact of the dosing schedule on efficacy, time to first response, and duration of treatment," said Brian Sullivan, Celcuity's Chief Executive Officer and co-founder. "The favorable antitumor activity and safety profile observed in patients treated with the three weeks on/one week off gedatolisib regimen supports use of this dosing schedule in future studies. We are especially encouraged about the 78% objective response rate observed in patients who had received two or more prior lines of therapy in Arm D. The significantly higher duration of treatment relative to immediate prior therapy in Arm D patients who progressed on their last line of therapy in less than 12 months was also very encouraging. We are continuing to plan for the initiation of a Phase 3 trial evaluating gedatolisib in patients with ER+/HER2- advanced breast cancer in the first half of 2022."

The poster presented at SABCS is available on the publications page of Celcuity's website.

Phase 1B Study Design and Results

Patients with ER+/HER2- advanced breast cancer (N=103) were treated in one of four arms. Palbociclib, letrozole, and fulvestrant were administered at standard doses. Gedatolisib 180 mg was intravenously administered weekly in Arms A, B, and C and three weeks on/one week off in Arm D. The primary endpoint was ORR and secondary endpoints were safety, duration of response, and progression free survival (PFS). Patient assessment was conducted by the investigator.

A summary of key results follows below:

- Arm A (n=31): Patients who were treatment naive in the ABC setting (1st line)
  - ORR: 85%
  - PFS: 31.1 months
- Arm B (n=13): Patients who received prior endocrine therapy without a CDK4/6 inhibitor (2nd line)
  - ORR: 77%
  - PFS: 11.9 months
- Arm C (n=32): Patients who received prior treatment with a CDK4/6 inhibitor (2nd/3rd line)
  - ≥2 prior therapies for ABC: 66% of patients
  - ORR: 32%
  - PFS: 5.1 months
- Arm D (n=27) - Patients who received prior treatment with a CDK4/6 inhibitor (2nd/3rd line)
  - ≥ 2 prior therapies for ABC: 33% of patients
  - ORR: 63%
  - PFS: 12.9 months

Results from an exploratory comparative and a longitudinal intrapatient analysis were also presented for two sub-groups of Arm C and Arm D patients: 1) patients who had the same number of prior lines of treatment; and 2) patients who had similar durations of treatment with their immediate prior therapy. The two analyses were performed to isolate the effect of the different gedatolisib

schedules used in Arm C (weekly) and Arm D (3 weeks on/1 week off) on patient response. Key findings from the analyses are presented below:

- The ORR in Arm D relative to Arm C was superior irrespective of the number of prior therapies for ABC.
  - Patients who had received one prior line of therapy were 1.7 times more likely to report an objective response in Arm D than Arm C (56% vs. 33%).
  - Patients who had received 2 or more prior lines of therapy were 2.4 times more likely to report an objective response in Arm D than Arm C (78% vs. 32%).
- The median duration of treatment with gedatolisib was significantly longer in Arm D relative to Arm C, irrespective of the treatment period of their immediate prior therapy.
  - For patients who had progressed on their prior treatment in less than six months, the median duration of treatment for Arm D patients was 3.33 times longer than patients in Arm C (270 vs. 81 days). The ORR for this sub-group of Arm D and C patients was 71% and 0% respectively.
  - For patients who had progressed on their prior treatment in less than 12 months, Arm D patients remained on treatment 2.10 times longer than patients in Arm C (276 vs. 131 days). The ORR for this sub-group of Arm D and C patients was 73% and 15% respectively.
- Because duration of treatment tends to decline in subsequent lines of therapy, a longitudinal intrapatient analysis was performed to compare the efficacy of the gedatolisib regimen to the immediate prior regimen for the sub-group of Arm C and D patients who remained on their prior therapy less than six and 12 months. The analysis was performed using duration of treatment because progression free survival data was not available for patients' immediate prior therapy.
  - For Arm D patients who progressed on their prior therapy in less than six months, the median duration of gedatolisib treatment was 2.6 times longer than their immediate prior treatment period (270 vs. 106 days). For Arm C patients, the ratio between the time on gedatolisib versus immediate prior therapy was 0.8 (81 vs. 97 days).
  - For Arm D patients who had progressed on prior therapy in less than 12 months, the median duration of gedatolisib treatment was 1.8 times longer than their immediate prior treatment period (276 vs. 155 days). For Arm C patients, the ratio between time on gedatolisib versus immediate prior therapy duration was 0.9 (131 vs. 146 days).

Overall, this exploratory analysis of ORR and duration of treatment found significantly higher ORR and longer duration of treatment in Arm D vs. Arm C patients who progressed within six months and within 12 months on their prior therapy. In addition, ORR was superior in Arm D relative to Arm C in patients irrespective of the number of prior therapies for ABC. This suggests that Arm D's gedatolisib/palbociclib synchronized dosing schedule (three weeks on/1 week off) may have played a significant role in the different outcomes between the Arms.

The study of gedatolisib in combination with palbociclib and endocrine therapy also demonstrated that the treatment was well tolerated with side effects managed by available standards of care. No Grade 5 event occurred; the most common (≥20%) Grade 3-4 adverse events were stomatitis and neutropenia. Less than 10% of all patients, and only one patient (3.7%) in Arm D, discontinued treatment due to an adverse event. Fewer patients experienced Grade 3-4 adverse events associated with PI3K/mTOR inhibition compared to data reported for other products in this class. Across all study arms, Grade 3-4 hyperglycemia was observed in ≤7% of patients, AST and ALT elevation in ≤10% of patients, diarrhea and colitis in ≤7% of patients, pneumonitis in ≤4% of patients. These results reflect gedatolisib's differentiated pharmacokinetic properties and indicate that gedatolisib can be safely combined with other targeted agents.

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.

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, including our planned Phase 3 clinical trial, 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 November 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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