Celcuity Presents Updated Results of Phase 1b Study of Gedatolisib in Patients with Advanced Breast Cancer at the 2022 San Antonio Breast Cancer Symposium

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High response rates and encouraging median progression free survival rates were observed in patients regardless of PIK3CA mutation status

Median progression free survival (PFS) of 42.3 months was reported for patients who were treatment naïve in the advanced setting

MINNEAPOLIS, MN / ACCESSWIRE / December 9, 2022 / Celcuity Inc. (Nasdaq:CELC), a clinical-stage biotechnology company focused on development of targeted therapies for oncology, today announced that updated results from a Phase 1b trial evaluating gedatolisib were presented during a Spotlight Poster Discussion at the 2022 San Antonio Breast Cancer Symposium (SABCS).

The presentation reported updated efficacy and safety data and sub-group analysis by *PIK3CA* mutation status in the four expansion arms of the Phase 1b study. Additional analysis of efficacy results from patients who were treatment-naïve in the advanced setting was also performed.

"The comparable efficacy reported in patients with and without *PIK3CA* mutations is very encouraging. We believe these results reflect gedatolisib's unique mechanism of action," said Brian Sullivan, Celcuity's Chief Executive Officer and co-founder. "We are also very encouraged by the median PFS of 42.3 months reported for patients with advanced disease who were treatment naïve. These results compare favorably to published data for current standard-of-care regimens for patients with advanced disease who are treatment naïve. The results warrant further evaluation of gedatolisib in combination with a CDK4/6 inhibitor and endocrine therapy in early line settings, including first-line, neoadjuvant, or adjuvant indications."

A trial-in-progress poster describing Celcuity's Phase 3 clinical trial, VIKTORIA-1, was also presented at SABCS. This poster and the poster presenting updated Phase 1b results are available on the publications page of the Celcuity website.

Phase 1b Study Design and Results

Patients with HR+/HER2- advanced breast cancer were treated with gedatolisib combined with the CDK4/6 inhibitor, palbociclib, and endocrine therapy (either fulvestrant or letrozole). This study included two dose escalation and four dose expansion arms and enrolled a total of 138 patients. Preliminary efficacy and safety results were presented in 2021 (Layman 2021). Updates presented at the 2022 SABCS included efficacy results for patient sub-groups in the four expansion arms according to their *PIK3CA* mutation status (see Table 1).

Table 1: B2151009 Efficacy Summary

Escalation Arms

(N=103)

Expansion Arm	**A**	**B**	**C**	**D**
Prior Therapy	1L CDKi-naive	2L+ CDKi-naive	2L/3L CDKi-pretreated	2L/3L CDKi-pretreated
n (full, evaluable)	31, 27	13, 13	32, 28	27, 27
Study Treatment **(gedatolisib dosing)**	P + L + G (weekly)	P + F + G (weekly)	P + F + G (weekly)	P + F + G (3 wks on / 1 off)

ORR[1] (evaluable)	85%		77%		36%		63%	
mPFS[2] , months (range)	NR[4] (16.9, NR)		12.9 (7.6, 38.3)		5.1 (3.3, 7.5)		12.9 (7.4, 16.7)	
PFS % at 12 months[2]	72%		55%		24%		53%	
***PIK3CA* Status**	**WT**	**MT**	**WT**	**MT**	**WT**	**MT**	**WT**	**MT**
	81% [2,3]	16% [2,3]	69%	31%	75%[2]	25%[2]	56% [2,3]	41% [2,3]
ORR[1] (evaluable)	81%	100%	78%	75%	25%	63%	60%	73%
PFS % at 12 months [2]	74%	60%	50%	67%	22%	29%	49%	60%

(1) Response evaluable analysis set per RECIST v1.1 including uPR; (2) full analysis set; (3) Baseline PIK3CA mutation status missing for one patient; (4) Median follow-up = 33.1 months. 1L= first line, 2L= second line; MT= PIK3CA mutation; NR = Not reached; ORR, objective response rate; PFS, progression free survival; WT=wild type

Additional updates included efficacy results for the 41 patients in the study who did not receive prior therapy for advanced disease. In this combined group of treatment-naïve patients from Escalation Arm A and Expansion Arm A, median PFS was 42.3 months. Treatment discontinuation due to treatment related adverse events was 6.5% in Arm A, 15.4% in Arm B, 9.4% in Arm C and 3.7% in Arm D. Further details on baseline patient characteristics were also included.

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.

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, reversible dual inhibitor that selectively targets all Class 1 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. 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 . 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 clinical trial, the expected or potential results from any ongoing, planned or potential clinical trials, expectations with respect to the potential efficacy of gedatolisib in various patient types alone or in combination with other treatments, and any other expectations with respect to gedatolisib and its 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" 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, those risks set forth in the Risk Factors section in Celcuity's Quarterly Report for the period ended September 30, 2022 filed with the Securities and Exchange Commission on

November 10, 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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