



Celcuity Inc. Reports Fourth Quarter and Full Year 2021 Financial Results, Pivotal Phase 3 Trial Design for Gedatolisib in the Treatment of Advanced Breast Cancer, and Business Updates

March 23, 2022

- **Finalized pivotal Phase 3 trial design following formal meetings with FDA**
- **Received FDA Fast Track designation for gedatolisib in HR+/HER2- metastatic breast cancer**
- **Presented updated Phase 1b data during a Spotlight Poster-Discussion Session at the 2021 San Antonio Breast Cancer Symposium in December 2021**
- **Entered into a clinical collaboration and supply agreement with Pfizer for planned Phase 3 clinical trial evaluating gedatolisib in combination with Ibrance® and Faslodex® in advanced breast cancer (ABC)**
- **Management to host webcast and conference call today, March 23, 2022, at 4:30 p.m. ET**

MINNEAPOLIS, MN / ACCESSWIRE / March 23, 2022 / Celcuity Inc. (NASDAQ:CELC), a clinical-stage biotechnology company pursuing an integrated therapeutic and companion diagnostic strategy for treating patients with cancer, today announced financial results for the fourth quarter and full year ended December 31, 2021, the design for its pivotal Phase 3 trial for gedatolisib, an investigational pan-PI3K/mTOR inhibitor, and other recent business progress.

The pivotal Phase 3 clinical trial, which is named VIKTORIA-1, will be an open-label, randomized study to evaluate the efficacy and safety of gedatolisib in combination with fulvestrant with or without palbociclib in adults with HR+/HER2- advanced breast cancer whose disease has progressed after prior CDK4/6 therapy in combination with an aromatase inhibitor. Prior to finalizing the Phase 3 trial design, Celcuity conducted two formal meetings with the U.S. Food and Drug Administration (FDA) to obtain their feedback.

The clinical trial will enroll subjects regardless of *PIK3CA* status while enabling separate evaluation of subjects according to their *PIK3CA* status. Subjects who meet eligibility criteria and do not have confirmed *PIK3CA* mutations (WT) will be randomly assigned (1:1:1) to receive a regimen of either gedatolisib, palbociclib, and fulvestrant (Arm A), gedatolisib and fulvestrant (Arm B), or fulvestrant (Arm C). Up to 351 subjects who are *PIK3CA* WT will be enrolled. Subjects who meet eligibility criteria and have confirmed *PIK3CA* mutations (MT) will be randomly assigned (1:1) to receive a regimen of either gedatolisib, palbociclib, and fulvestrant (Arm D) or alpelisib and fulvestrant (Arm E). Up to 300 subjects who are *PIK3CA* MT will be enrolled.

The primary endpoints for this pivotal study are progression free survival (PFS), per RECIST 1.1 criteria, as assessed by blinded independent central review (BICR). The primary PFS endpoints will be evaluated separately in subjects who are *PIK3CA* WT and *PIK3CA* MT.

This multi-center, international trial is expected to enroll up to 651 subjects at approximately 175 clinical sites across the U.S., Europe, and Asia. Celcuity expects to initiate the clinical trial in the first half of 2022.

"We are excited to finalize the trial design for our pivotal Phase 3 study following productive meetings with the FDA," said Brian Sullivan, CEO and co-founder of Celcuity. "This design, we believe, provides us with an opportunity to generate data that could support the future submission to the FDA of a New Drug Application for gedatolisib to treat a broad patient population."

"There is an urgent need for better treatment options for HR+/HER2- metastatic breast cancer patients whose disease has progressed after treatment with a CDK4/6 inhibitor and endocrine therapy," said Igor Gorbachevsky, MD, Chief Medical Officer of Celcuity. "We are very encouraged by the clinical data for gedatolisib and determined to advance its development for patients as quickly as possible."

Fourth Quarter 2021 Business Highlights and Other Recent Developments

- Celcuity obtained formal feedback from the FDA regarding the design of its proposed Phase 3 clinical trial, and the trial design has been finalized.
- In January, the FDA granted Fast Track designation to Celcuity's lead drug candidate, gedatolisib, for the treatment of patients with HR+/HER2- metastatic breast cancer after progression on CDK4/6 therapy.
- In November 2021, Celcuity and Pfizer entered into a Clinical Trial Collaboration and Supply Agreement. Under this agreement, Pfizer will supply Ibrance for Celcuity's pivotal Phase 3 clinical trial for gedatolisib at no cost.
- Updated data from Celcuity's ongoing Phase 1b clinical trial for patients with HR+/HER2- advanced breast cancer (ABC) was presented at the San Antonio Breast Cancer Symposium in December 2021. 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 HR+/HER2- ABC that compared favorably to published data for available therapeutic options. 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.

- Celcuity entered into a clinical trial collaboration agreement with the University of Rochester Wilmot Cancer Center and Puma Biotechnology in October 2021.
- Enrollment in the FACT-1 and FACT-2 trials evaluating CELsignia selected patients who have early-stage HR+/HER2- breast cancer was impacted by COVID-19 related delays during the fourth quarter and early 2022. Hospitalizations of patients with COVID-19 increased dramatically during this period which led hospitals to reduce clinical trial related activities. Interim results are now expected to be available in the first half of 2023.

Fourth Quarter and Full Year 2021 Financial Results

Unless otherwise stated, all comparisons are for the fourth quarter and full year ended December 31, 2021, compared to the fourth quarter and full year ended December 31, 2020.

Total operating expenses were \$6.3 million for the fourth quarter of 2021, compared to \$2.6 million for the fourth quarter of 2020. Operating expenses for the full year 2021 were \$28.4 million, compared to \$9.6 million for the full year 2020.

Research and development (R&D) expenses were \$5.5 million for the fourth quarter of 2021, compared to \$2.1 million for the fourth quarter of 2020. R&D expenses for the full year 2021 were \$25.8 million, compared to \$7.7 million for the prior year. The approximately \$18.1 million increase during the full year 2021, compared to the full year 2020, resulted primarily from a \$10.0 million upfront license fee related to the execution of the Pfizer license agreement, which included \$5.0 million of non-cash expense for issuance of common stock. The remaining \$8.1 million increase primarily resulted from expenses initially associated with the transfer of gedatolisib-related activities from Pfizer to Celcuity and subsequently the continued support and development of gedatolisib.

General and administrative (G&A) expenses were \$0.8 million for the fourth quarter of 2021, compared to \$0.4 million for the fourth quarter of 2020. G&A expenses for the full year 2021 were \$2.6 million, compared to \$1.9 million for the prior year. The approximately \$0.7 million increase during the full year 2021, compared to the full year 2020, resulted primarily from a \$0.4 million increase in compensation related expenses, including approximately \$0.3 million of non-cash stock-based compensation.

Net loss for the fourth quarter of 2021 was \$6.8 million, or \$0.45 per share, compared to a net loss of \$2.6 million, or \$0.25 per share for 2020. Net loss for the full year 2021 was \$29.6 million, or \$2.21 per share, compared to \$9.5 million, or \$0.92 per share in 2020. Non-GAAP adjusted net loss for the fourth quarter of 2021 was \$5.6 million, or \$0.37 per share, compared to non-GAAP adjusted net loss of \$2.1 million, or \$0.21 per share, for the fourth quarter of 2020. Non-GAAP adjusted net loss for the full year 2021 was \$21.4 million, or \$1.60 per share, compared to non-GAAP adjusted net loss of \$7.7 million, or \$0.75 per share, for 2020. Non-GAAP adjusted net loss excludes stock-based compensation expense, issuance of common stock and non-cash interest. Because these items have no impact on Celcuity's cash position, management believes non-GAAP adjusted net loss better enables Celcuity to focus on cash used in operations. For a reconciliation of financial measures calculated in accordance with generally accepted accounting principles (GAAP) in the United States to non-GAAP financial measures, please see the financial tables at the end of this news release.

Net cash used in operating activities for the fourth quarter of 2021 was \$6.1 million, compared to \$2.1 million for the fourth quarter of 2020.

At December 31, 2021, Celcuity had cash and cash equivalents of \$84.3 million, compared to cash and cash equivalents of \$11.6 million at December 31, 2020.

Anticipated Milestones

Celcuity expects to achieve the following potential milestones over the next twelve months:

- Initiate a pivotal Phase 3 clinical trial to evaluate gedatolisib in combination with palbociclib and fulvestrant in patients with HR+/HER2- advanced breast cancer in the first half of 2022.
- Provide an update on lifecycle development priorities for gedatolisib in the first half of 2022.
- Initiate two Phase 2 clinical trials to evaluate gedatolisib in HR+/HER2- breast cancer patients selected with a CELsignia PI3K Pathway Test.
- Obtain interim results from the FACT-1 and FACT-2 trials in the first half of 2023.

Webcast and Conference Call Information

The Celcuity management team will host a webcast/conference call at 4:30 p.m. ET today to discuss the fourth quarter and full year 2021 financial results and provide a corporate update. To participate in the teleconference, domestic callers should dial (877) 407-0784 and international callers should dial (201) 689-8560. A live webcast presentation can also be accessed using this weblink: https://viavid.webcasts.com/starthere.jsp?ei=1535102&tp_key=d9da71b7fd. A replay of the webcast will be available on the Celcuity website following the live event.

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 in-licensing and 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, the timing, costs and results of Celcuity's expected clinical trials, Celcuity's expectations with respect to planned clinical collaborations, clinical trials and the timing and content of updates on the gedatolisib life cycle development plan and results of ongoing clinical trials. 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, 2021 filed with the Securities and Exchange Commission on March 23, 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.

Contacts:

Celcuity Inc.
 Brian Sullivan, bsullivan@celcuity.com
 Vicky Hahne, vhahne@celcuity.com
 763-392-0123

ICR Westwicke
 Robert Uhl, robert.uhl@westwicke.com
 619-228-5886

Celcuity Inc. Balance Sheets

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 84,286,381	\$ 11,637,911
Deposits	22,009	22,009
Deferred transaction costs	22,144	-
Payroll tax receivable	298,764	190,000
Prepaid assets	<u>722,677</u>	<u>317,040</u>
Total current assets	85,351,975	12,166,960
Property and equipment, net	312,444	558,876
Operating lease right-of-use assets	<u>241,901</u>	<u>230,911</u>
Total Assets	<u>\$ 85,906,320</u>	<u>\$ 12,956,747</u>
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	\$ 1,507,099	\$ 217,377
Finance lease liabilities	5,850	5,810
Operating lease liabilities	189,858	187,518

Accrued expenses	802,893	774,612
Total current liabilities	2,505,700	1,185,317
Finance lease liabilities	2,449	8,299
Operating lease liabilities	61,771	60,861
Note payable, non-current	14,625,923	-
Total Liabilities	17,195,843	1,254,477
Total Stockholders' Equity	68,710,477	11,702,270
Total Liabilities and Stockholders' Equity	\$ 85,906,320	\$ 12,956,747

Celcuity Inc.
Statements of Operations

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 5,491,041	\$ 2,107,272	\$ 25,758,006	\$ 7,683,522
General and administrative	829,851	444,064	2,597,909	1,872,642
Total operating expenses	<u>6,320,892</u>	<u>2,551,336</u>	<u>28,355,915</u>	<u>9,556,164</u>
Loss from operations	<u>(6,320,892)</u>	<u>(2,551,336)</u>	<u>(28,355,915)</u>	<u>(9,556,164)</u>
Other income (expense)				
Interest expense	(438,067)	(26)	(1,262,350)	(120)
Interest income	5,459	469	13,262	82,109
Loss on sale of fixed assets	-	-	(263)	-
Other income (expense), net	<u>(432,608)</u>	<u>443</u>	<u>(1,249,351)</u>	<u>81,989</u>
Net loss before income taxes	<u>(6,753,500)</u>	<u>(2,550,893)</u>	<u>(29,605,266)</u>	<u>(9,474,175)</u>
Income tax benefits	-	-	-	-
Net loss	<u>\$ (6,753,500)</u>	<u>\$ (2,550,893)</u>	<u>\$ (29,605,266)</u>	<u>\$ (9,474,175)</u>
Net loss per share, basic and diluted	\$ (0.45)	\$ (0.25)	\$ (2.21)	\$ (0.92)
Weighted average common shares outstanding, basic and diluted	14,910,963	10,279,535	13,382,553	10,266,884

Cautionary Statement Regarding Non-GAAP Financial Measures

This press release contains references to non-GAAP adjusted net loss and non-GAAP adjusted net loss per share. Management believes these non-GAAP financial measures are useful supplemental measures for planning, monitoring, and evaluating operational performance as they exclude stock-based compensation expense, issuance of common stock and non-cash interest from net loss and net loss per share. Management excludes these items because they do not impact Celcuity's cash position, which management believes better enables Celcuity to focus on cash used in operations. However, non-GAAP adjusted net loss and non-GAAP adjusted net loss per share are not recognized measures under GAAP and do not have a standardized meaning prescribed by GAAP. As a result, management's method of calculating non-GAAP adjusted net loss and non-GAAP adjusted net loss per share may differ materially from the method used by other companies. Therefore, non-GAAP adjusted net loss and non-GAAP adjusted net loss per share may not be comparable to similarly titled measures presented by other companies. Investors are cautioned that non-GAAP adjusted net loss and non-GAAP adjusted net loss per share should not be construed as

alternatives to net loss, net loss per share or other statements of operations data (which are determined in accordance with GAAP) as an indicator of Celcuity's performance or as a measure of liquidity and cash flows.

Celcuity Inc.

**Reconciliation of GAAP Net Loss to Non-GAAP Adjusted Net Loss and
GAAP Net Loss Per Share to Non-GAAP Adjusted Net Loss Per Share**

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
GAAP net loss	\$ (6,753,500)	\$ (2,550,893)	\$ (29,605,266)	\$ (9,474,175)
Adjustments:				
Stock-based compensation				
Research and development ⁽¹⁾	627,497	241,996	1,645,353	1,055,094
General and administrative ⁽²⁾	293,106	185,094	964,582	708,785
Issuance of common stock, licensing agreement ⁽³⁾	-	-	5,000,000	-
Non-cash interest expense ⁽⁴⁾	198,114	-	567,822	-
Non-GAAP adjusted net loss	\$ (5,634,783)	\$ (2,123,803)	\$ (21,427,509)	\$ (7,710,296)
GAAP net loss per share - basic and diluted	\$ (0.45)	\$ (0.25)	\$ (2.21)	\$ (0.92)
Adjustment to net loss (as detailed above)	0.08	0.04	0.61	0.17
Non-GAAP adjusted net loss per share	\$ (0.37)	\$ (0.21)	\$ (1.60)	\$ (0.75)
Weighted average common shares outstanding, basic and diluted	14,910,963	10,279,535	13,382,553	10,266,884

(1) To reflect a non-cash charge to operating expense for Research and Development stock-based compensation.

(2) To reflect a non-cash charge to operating expense for General and Administrative stock-based compensation.

(3) To reflect a non-cash charge to operating expense for the Issuance of common stock related to a licensing agreement.

(4) To reflect a non-cash charge to other expense for amortization of debt issuance and discount costs and PIK interest related to the issuance of a note payable.

SOURCE: Celcuity Inc.

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