Celcuity Presents Data at AACR Annual Meeting Assessing Gedatolisib, a pan-PI3K/mTOR Inhibitor, in HER2-negative Breast and Ovarian Cancer Patient Tumors with Hyperactive RAS Network Signaling

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- Inhibition of hyperactive RAS network signaling is nine times more effective with gedatolisib than with a PI3K-α inhibitor -
- Synergistic cooperation between PI3K/mTOR and BCL signaling detected, suggesting potential patient benefit of combining gedatolisib with a BCL inhibitor -

MINNEAPOLIS, MN / ACCESSWIRE / April 12, 2021 / Celcuity Inc. (NASDAQ:CELC), a clinical-stage biotechnology company pursuing an integrated companion diagnostic (CDx) and therapeutic strategy for treating patients with cancer, presented results of studies evaluating gedatolisib (a pan-PI3K/mTOR inhibitor), inavolisib (a PI3K-*α* inhibitor), and navitoclax (a BCL inhibitor) in breast and ovarian patient tumors. Results were presented in two e-posters at the American Association for Cancer Research (AACR) Annual Meeting.

The CELsignia RAS Network Activity test for breast and ovarian cancer identifies patients whose tumors have hyperactive RAS network signaling. The posters presented at AACR describe studies using this CELsignia test to characterize the role RAS network nodes, PI3K, mTOR, and BCL, play in phospholipid-initiated signaling activity via the lysophosphatidic acid (LPA) receptor family of GPCRs in breast and ovarian patient tumor cells and cell lines. Key findings included:

- Hyperactive RAS network signaling is more effectively inhibited with a pan-PI3K/mTOR inhibitor (gedatolisib) than a PI3K-*α* inhibitor (inavolisib).
- Gedatolisib inhibited nine times more signaling test activity in tumors with hyperactive RAS network signaling, on average, than inavolisib, when evaluated at equal concentrations with the CELsignia test.
- Gedatolisib at one-fifth the concentration of inavolisib (30 nM vs. 150 nM) inhibited five times more signaling activity as quantified by the CELsignia test.
- Synergistic cooperation between BCL and PI3K/mTOR inhibitors was detected, suggesting that addition of a BCL inhibitor like navitoclax to a pan-PI3K/mTOR inhibitor like gedatolisib may induce a greater anti-tumor effect.

"Results obtained during the development of our CELsignia RAS Network Activity test, such as those we presented at AACR this weekend, revealed the potential advantage of inhibiting all Class 1 PI3K isoforms and mTOR, not just PI3K-*α* signaling, when treating PI3K-involved signaling tumors," said Brian Sullivan, CEO and co-founder of Celcuity.

The e-poster is available on the AACR website at www.aacr.org and on the publication page of the Celcuity corporate website.

About Gedatolisib

Gedatolisib is a potent, reversible dual inhibitor that selectively targets PI3K (isoforms *α*, β, γ, δ, including isoforms with *α*-mutations) and mTOR. Celcuity licensed exclusive global rights to gedatolisib from Pfizer Inc. in April 2021. An on-going Phase 1b trial evaluated patients with ER+/HER2- metastatic breast cancer. Based on the favorable preliminary results reported to date from the Phase 1b trial, we intend to initiate, subject to feedback from the FDA, a Phase 2/3 clinical trial evaluating gedatolisib in combination with palbociclib and an endocrine therapy in patients with ER+/HER2- advanced or metastatic breast cancer in the first half of 2022.

About Celcuity

Celcuity is a clinical-stage biotechnology company seeking to extend the lives of cancer patients by pursuing an integrated companion diagnostic and therapeutic strategy. Our CELsignia companion diagnostic platform is uniquely able to analyze live patient tumor cells to identify new groups of cancer patients likely to benefit from targeted therapies. This enables a CELsignia CDx to support advancement of new indications for already approved targeted therapies. Our therapeutic efforts are focused on in-licensing and developing molecularly targeted therapies that address the same cancer driver our companion diagnostics can identify. By pursuing an integrated companion diagnostic and therapeutic strategy, we believe we are uniquely positioned to achieve our goal of helping cancer patients receive the therapeutic best suited to treat their cancer driver. 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." 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 in this press release include, without limitation, expectations with respect to the results from the e-poster presentations at AACR, the expected benefits of gedatolisib, initiation of a Phase 2/3 clinical trial for gedatolisib, and other statements regarding the future of Celcuity's business and results of operations. 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 April 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.

Contacts:

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

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

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