Celcuity Reports Preliminary Data from Phase 1b Trial of Gedatolisib plus Ibrance® and Endocrine Therapy for Patients with ER+/HER2- Metastatic Breast Cancer and Provides Corporate Update

April 8, 2021

Preliminary Phase 1b Data

- 53 of the 88 evaluable patients (60%) had an objective response -

- Gedatolisib showed a potentially differentiated safety and tolerability profile -

Corporate Update

- Entered $25 million debt financing agreement with Innovatus Capital Partners -

- Proceeds from first $15 million tranche increase cash-on-hand to $44 million -

- Drug development capabilities and team broadened and expanded -

- Conference call and webcast scheduled for today, April 8 at 5 p.m. Eastern Time -

Celcuity Inc. (Nasdaq:CELC), a clinical-stage biotechnology company pursuing an integrated companion diagnostic and therapeutic strategy for treating patients with cancer, today reported preliminary data for the 103 patients enrolled in the expansion portion of an ongoing Phase 1b clinical trial evaluating gedatolisib, a first-in-class PI3K/mTOR inhibitor, plus Ibrance and endocrine therapy, in ER+/HER2- advanced or metastatic breast cancer patients. As of the January 11, 2021 data cut-off date, 53 of the 88 evaluable patients (60%) had an objective response. Gedatolisib was also generally well tolerated, with the majority of treatment-related adverse events (TRAE) being Grade 1 or 2. The most common Grade 3 or 4 TRAEs related to gedatolisib were stomatitis and rash.

“We are very encouraged by this preliminary data for gedatolisib from our ongoing Phase 1b trial in patients with breast cancer,” said Brian Sullivan, CEO and Co-Founder of Celcuity. “The robust response rate and the observed tolerability profile are particularly compelling given the need for a therapeutic regimen that can address endocrine therapy resistance. We look forward to sharing additional data from the study at a future medical conference in 2021. Developing a therapeutic such as gedatolisib allows us to more fully leverage our CELsignia cellular analysis platform.“

Preliminary Phase 1b Data for Gedatolisib:

The preliminary Phase 1b data set for the 103 patients enrolled utilized a January 11, 2021 data cut-off. Patients were enrolled in one of four expansion arms (A, B, C, D), according to their prior treatment history for metastatic breast cancer. All patients received gedatolisib in combination with standard doses of palbociclib and endocrine therapy (either letrozole or fulvestrant). In Arms A, B, and C, patients received an intravenous dose of 180 mg of gedatolisib once weekly. In Arm D, patients received an intravenous dose of 180 mg gedatolisib on a four-week cycle of three weeks-on, one week-off. The primary endpoint was objective response as determined using Response Evaluation Criteria in Solid Tumors v1.0, or RECIST v1.0.

The preliminary efficacy and safety analysis showed:

- 53 of the 88 evaluable patients (60%) had an objective response.
- 66 of the 88 evaluable patients (75%) had a clinical benefit, defined as either a confirmed objective response or stable disease for at least 24 weeks.
- Gedatolisib was also generally well tolerated, with the majority of treatment related adverse events (TRAE) being Grade 1 or 2. The most common Grade 3 or 4 TRAEs associated with gedatolisib were stomatitis and rash. Gedatolisib was discontinued in 10% of patients.
- 22 patients were continuing to receive gedatolisib in combination with the other study drugs, 17 of whom have been on study treatment for more than two years.

In light of these encouraging results, Celcuity is planning 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.

Corporate Update

Management team expanded in key areas

With the in-licensing of gedatolisib, Celcuity has broadened and deepened its management team with experienced pharmaceutical development and regulatory affairs experts.

Arthur DeCillis, M.D., Chief Medical Officer

Dr. DeCillis was the Chief Medical Officer for Eleven Biotherapeutics (now known as Sesen Bio Inc.) and VP Clinical Research for Exelixis. Prior to that, he served in senior drug development roles at Novartis and Bristol-Myers Squibb. Arthur has been involved in the development of several commercialized oncology drugs, including SPRYCEL® (dasatinib), AFINITOR® (everolimus), FARYDAK® (panobinostat), and CABOMETYX® (cabozantinib).

John R. MacDonald, Ph.D., DABT, Senior Vice President of R&D

Dr. MacDonald led the preclinical and clinical R&D efforts at MGI Pharma, an oncology-focused pharmaceutical company until its sales to Eisai Co. He has over 30 years of experience in all aspects of pharmaceutical drug development and licensing. Prior to MGI, he worked for Warner-Lambert (now Pfizer).

Sheri Smith, Head of Clinical Operations (Acting)

Ms. Smith was the former Senior Director of Clinical Operations at MGI Pharma, where she was responsible for all clinical operations. For the past 17 years, she has served as President of Courante Oncology, a specialty clinical research services company serving pharmaceutical and medical device companies.

Bernhard Lampert, Ph.D., Head of CMC

Dr. Lampert has extensive drug development experience in the pharmaceutical and biotech industries, including ten years in large, fully integrated pharmaceutical companies, including Gilead and GSK. He received his Ph.D. in Medicinal Chemistry from the University of Georgia in 1989.

Marie DeGayner Kuker, Head of Regulatory

Ms. Kuker has more than 35 years of experience in the pharmaceutical industry, most recently as head of global regulatory affairs for 3M Pharmaceuticals and Drug Delivery Systems before founding her consultancy in 2007. Marie is an appointed Fellow of the Regulatory Affairs Professionals Society.

Celcuity announces $25 million debt financing agreement with Innovatus Capital Partners, LLC

Celcuity has entered into a debt financing agreement with Innovatus Capital Partners, LLC (Innovatus) to provide Celcuity with up to $25 million in term loans with the first $15 million tranche funded at closing. Celcuity will be able to draw on two additional tranches of $5 million each upon the achievement of certain clinical trial and financing milestones. Celcuity is entitled to make interest only payments for 36 months or up to 48 months if certain conditions are met. The loans will mature on the fifth anniversary of the initial funding date. Innovatus has the right to convert up to 20% of the outstanding principal amount into shares of Celcuity common stock until the third anniversary of the loan agreement. 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.

Webcast Presentation and Conference Call Information

The Celcuity management team will host a webcast/conference call today, April 8, 2021, at 5:00 p.m. ET to discuss the gedatolisib license agreement and provide a corporate update. To participate in the call, dial 1-877-407-8035. A live webcast presentation can be accessed using this weblink: https://www.webcaster4.com/Webcast/Page/2678/40570 or via Celcuity's website at https://celcuity.com/home/investors/events-webcasts/ . A replay of the webcast will be available on the Celcuity website for a limited time following the event.

About the Phase 1b Gedatolisib Clinical Trial

The B2151009 trial is a multicenter, open-label, on-going Phase 1b study in patients with ER+/HER2- metastatic breast cancer. Four dose expansion arms enrolled 103 patients to determine if the triplet combination of gedatolisib plus palbociclib and letrozole or gedatolisib plus palbociclib and fulvestrant produced a superior objective response (OR), compared to historical control data of the doublet combination (palbociclib plus endocrine therapy). More information about the trial is available at NCT02684032 .

About Gedatolisib

Gedatolisib is a potent, reversible dual inhibitor that selectively targets PI3K and mTOR. Gedatolisib was originally developed by Wyeth and clinical development was continued by Pfizer after it acquired Wyeth. Celcuity licensed exclusive global rights to gedatolisib from Pfizer in April 2021. An on-going Phase 1b trial evaluating patients with ER+/HER2- metastatic breast cancer was initiated in 2016 and subsequently enrolled 138 patients. Patient enrollment for the four expansion arms of the trial is complete. 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 .

Innovatus Capital Partners, LLC

Innovatus Capital Partners, LLC, is an independent adviser and portfolio management firm with approximately $1.54B 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. Further information can be found at www.innovatuscp.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 the results from the B2151009 Phase 1b clinical trial, the timing of launching a Phase 2/3 clinical trial, the expected benefits of gedatolisib, the growth of Celcuity's management team, 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. 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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