Celcuity Announces Appointment of Dr. Igor Gorbatchevsky as VP of Clinical Development and Jill Krause as VP of Clinical Operations

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MINNEAPOLIS, MN / ACCESSWIRE / June 9, 2021 / Celcuity Inc. (NASDAQ:CELC), a clinical-stage biotechnology company pursuing an integrated companion diagnostic and therapeutic strategy for treating patients with cancer, today announced the addition of two new senior executives to its clinical drug development and operations team. Igor Gorbatchevsky, MD, joined Celcuity as VP of Clinical Development and Jill Krause joined as VP of Clinical Operations.

"We are very excited to have Igor and Jill join Celcuity and lead our clinical development and clinical operations teams. Each has very relevant experience at both large pharmaceutical and small biopharma companies," said Celcuity's Chairman and Chief Executive Officer, Brian Sullivan. "Igor has over two decades of hands-on oncology drug development experience, including successful regulatory IND and NDA/BLA filings across several drug classes. Jill brings deep clinical operations expertise, including over nine years of experience managing and executing trials in breast cancer."

Prior to joining Celcuity, Dr. Gorbatchevsky worked for MEI Pharma (MEI), an oncology focused biopharmaceutical company, where he was the VP of Clinical Development. MEI's pipeline included zandelisib, an oral PI3K-delta inhibitor. He had previously served as the VP of Clinical Science at Iovance Biotherapeutics, as a Global Clinical Leader at Bayer Pharmaceuticals, and as a Senior Medical Director at Daiichi-Sankyo a global pharmaceutical company. At Bayer, his responsibilities included leadership of the Global Clinical Development Team for ALIQOPA (copanlisib), a pan-PI3K inhibitor approved by the FDA for treatment of patients with follicular lymphoma.

Dr. Gorbatchevsky commented, "Gedatolisib is well positioned to become a first-in-class PI3K/mTOR inhibitor. It uniquely combines low nanomolar potency against all Class I PI3K isoforms and mTOR with a compelling pharmacokinetic profile. The clinical safety data obtained so far suggests gedatolisib is much better tolerated compared to other targeted agents in this class. The opportunity to develop gedatolisib for patients with ER+/HER2-negative metastatic breast cancer and other tumor types is very exciting."

Prior to joining Celcuity, Ms. Krause worked for Odonate Therapeutics, a developer of an oral chemotherapy to treat breast cancer, where she served as VP of Clinical Operations Quality as well as VP of Study Management and Medical Affairs. She also served in a variety of different clinical operations roles at Pfizer for over 10 years and led clinical operations teams at several clinical research organizations.

Ms. Krause commented, "I am excited to join Celcuity and continue my work managing breast cancer clinical trials and supporting the clinical development of gedatolisib."

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, Celcuity intends to initiate, subject to feedback from the FDA, a Phase 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 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 expected impact of 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 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.

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