Celcuity Presents Updated Data at the 2025 ESMO Congress from Phase 1 Study Evaluating Gedatolisib Plus Darolutamide in Men with Metastatic Castration Resistant Prostate Cancer ("mCRPC")

- *Median radiographic progression free survival ("rPFS") was 9.1 months and the six-month rPFS rate was 67%*

- *No patients discontinued study treatment due to a treatment-related adverse event ("TRAE")*

MINNEAPOLIS, October 18, 2025 — Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced updated clinical results from the Phase 1 portion of a clinical trial evaluating gedatolisib in combination with Nubeqa® (darolutamide), an androgen receptor inhibitor, in men with mCRPC whose disease had progressed on prior treatment with a next generation androgen receptor inhibitor. These data were presented at a poster presentation at the European Society of Medical Oncology (ESMO) today, Saturday, at 6:00 a.m. ET/12:00 p.m. CEST.

In this Phase 1 study, 38 patients with mCRPC were randomly assigned to receive 600 mg darolutamide twice daily combined with either 120 mg gedatolisib in Arm 1 or 180 mg gedatolisib in Arm 2. In both arms, gedatolisib was administered once weekly for three weeks, then one week off. Additionally, all patients received prophylactic treatment for stomatitis. Among the 38 patients enrolled, 61% had received one line of prior systemic therapy and 39% had received at least 2 or more lines of prior therapy. The Phase 1 data set utilized an August 15, 2025 data cut-off. Median duration of follow-up was 9.0 months.

The six-month rPFS rate and median rPFS for patients from both arms combined was 67% and 9.1 months, respectively. For patients treated with 120 mg gedatolisib, the six-month rPFS rate was 74% and median rPFS was 9.5 months. For patients treated with 180 mg gedatolisib, the six-month rPFS rate was 61% and the median rPFS was 7.4 months.

The combination of gedatolisib and darolutamide was generally well tolerated in the trial with mostly low-grade TRAEs. No dose limiting toxicities were observed in either arm. The only Grade 3 TRAEs for patients from both arms combined included rash (5.3%), stomatitis (2.6%), and pruritus (2.6%); no Grade 3 hyperglycemia was reported. Additionally, no Grade 4 or 5 TRAEs were observed, and no patients discontinued study treatment due to a TRAE.

"We are very encouraged by this Phase 1 efficacy and safety data," said Igor Gorbatchevsky, MD, Chief Medical Officer of Celcuity. "The 67% six-month rPFS rate and median rPFS of 9.1 months for this novel combination therapy compares favorably to published data for androgen receptor inhibitors in this setting. We are now enrolling patients in our updated Phase 1/1b portion of this clinical trial to determine the recommended Phase 2 dose."

In the amended Phase 1/1b portion of the clinical trial, up to six patients are planned to be enrolled in each of three arms and treated with different doses. Upon completion of Phase 1, up to an additional 40

patients will be randomly assigned to up to four Phase 1b cohorts to determine the recommended Phase 2 dose ("RP2D"). Dose levels will be selected based on the results from the Phase 1 clinical trial. In the Phase 2 dose expansion study, which will include subjects from the Phase 1/1b clinical trial, up to 18 additional subjects will be enrolled to achieve a total of approximately 30 subjects treated with the RP2D. All patients will also receive standard doses of darolutamide.

About Celcuity

Celcuity is a clinical-stage biotechnology company pursuing development of targeted therapies for treatment of multiple solid tumor indications. The company's lead therapeutic candidate is gedatolisib, a potent, pan-PI3K and mTORC1/2 inhibitor that comprehensively blockades the PAM pathway. Its mechanism of action and pharmacokinetic properties are differentiated from other currently approved and investigational therapies that target PI3Kα, AKT, or mTORC1 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- ABC has completed enrollment and reported topline data for the *PIK3CA* WT cohort and has completed enrollment of patients for the *PIK3CA* mutant cohort. A Phase 3 clinical trial, VIKTORIA-2, evaluating gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with HR+/HER2- ABC is currently enrolling patients. A Phase 1/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer, is ongoing. More detailed information about Celcuity's active clinical trials can be found at ClinicalTrials.gov . Celcuity is headquartered in Minneapolis. Further information about Celcuity can be found at www.celcuity.com . Follow us on LinkedIn and X .

Forward-Looking Statements

This press release contains statements that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including statements relating to the potential therapeutic benefits of gedatolisib; the size, design and timing of our clinical trials; our interpretation of topline clinical trial data; and other expectations with respect to gedatolisib. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "confidence," "encouraged," "potential," "plan," "targets," "likely," "may," "will," "would," "should" and "could," and similar expressions or words identify forward-looking statements. The forward-looking statements included in this press release are based on management's current expectations and beliefs which are subject to a number of risks, uncertainties and factors, including that our topline results are based on a preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial; unforeseen delays in our clinical trials; and unanticipated developments that may impact the design of our clinical trials. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2024, as such risks may be updated in our subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by these cautionary statements, and we undertake no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

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