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Celcuity Provides Update on Status of the *PIK3CA* Mutated Cohort of Phase 3 VIKTORIA-1 Trial and Releases Additional Data Analysis From Phase 1b Clinical Trial

- *PIK3CA mutant cohort of the Phase 3 VIKTORIA-1 clinical trial is fully enrolled*

- *Additional analysis of data from a Phase 1b clinical trial that included all patients treated with gedatolisib combined with fulvestrant and palbociclib showed median progression-free survival ("PFS") of 14.6 months in patients with HR+/HER2-/PIK3CA-mutated advanced breast cancer ("ABC")*

MINNEAPOLIS, October 18, 2025 — Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced updates on the status of the *PIK3CA* mutant cohort of the Phase 3 VIKTORIA-1 clinical trial evaluating gedatolisib plus fulvestrant with and without palbociclib versus alpelisib and fulvestrant in adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *PIK3CA* mutant ("MT") tumors, locally advanced or metastatic breast cancer, following progression on, or after, treatment with a CDK4/6 inhibitor and an aromatase inhibitor. Analysis of data from a Phase 1b clinical trial that evaluated gedatolisib combined with palbociclib and fulvestrant in the same population was also provided.

"We are pleased to announce that the *PIK3CA* mutant cohort of the VIKTORIA-1 study is 100% enrolled," said Brian Sullivan, CEO and co-founder of Celcuity. "Based on our current forecast of reaching the event threshold that will trigger primary analysis in the *PIK3CA* mutant cohort, we expect to report topline data sometime in late Q1 2026 or during Q2 2026."

Updated Analysis of Data from the Phase 1b Trial

In a presentation of results from the *PIK3CA* wild-type ("WT") cohort of the VIKTORIA-1 study at the European Society for Medical Oncology ("ESMO") Congress, additional data from a Phase 1b clinical trial that evaluated gedatolisib in patients with HR+/HER2- ABC was included. The analyses reported efficacy data from patients who were treated with the same drug regimen evaluated in the VIKTORIA-1 study, gedatolisib combined with fulvestrant and palbociclib.[1] This included patients from Escalation Arm B and Expansion Arms B, C and D of the Phase 1b study.

Patients in Escalation Arm B and Expansion Arms B and C received a 180 mg dose of gedatolisib once weekly ("weekly dose"). Patients in Expansion Arm D received a 180 mg dose of gedatolisib on days 1, 8, and 15 of a four-week cycle ("intermittent dose"), which was the same dose regimen patients in the VIKTORIA-1 study received. The proportion of patients who received the intermittent dose of gedatolisib was 37% for those with *PIK3CA* MT tumors and 25% for those with *PIK3CA* WT tumors. The proportion of patients who received prior treatment with a CDK4/6 inhibitor was 73% for those with *PIK3CA* WT tumors, and 71% for those with *PIK3CA* MT tumors.

Median PFS and the objective response rate ("ORR") were assessed in sub-groups of patients according to their *PIK3CA* status (Table 1). For all analyzed patients with *PIK3CA* MT tumors (n=30), median PFS was 14.6 months and the ORR in response evaluable patients was 48%. Median PFS was 19.7 months and the ORR was 64% in patients with *PIK3CA* MT tumors who received the intermittent dose of gedatolisib used in the VIKTORIA-1 study. For patients with *PIK3CA* WT tumors (n=60), median PFS was 9.0 months and the ORR in response evaluable patients was 41%. Median PFS was 9.1 months and the ORR was 53% in patients with *PIK3CA* WT tumors who received the intermittent dose of gedatolisib used in the VIKTORIA-1 study.

Table 1: Efficacy Analysis of Phase 1b Patients Treated with Gedatolisib Plus Palbociclib Plus Fulvestrant

	***PIK3CA* MT**		***PIK3CA* WT**	
	All	**Intermittent Dose**	**All**	**Intermittent dose**
N	30	11	60	15
Median PFS (months)	14.6	19.7	9.0	9.1
ORR	48%	64%	41%	53%

"We are very encouraged by the median PFS of 14.6 months found in the entire *PIK3CA* mutant patient subgroup," said Igor Gorbatchevsky, MD, Chief Medical Officer of Celcuity. "While the sample size is small, the median PFS from patients whose tumors had *PIK3CA* mutations and who received the Phase 3 intermittent gedatolisib dose is promising and consistent with the results from the overall group. We are looking forward to reporting Phase 3 data for this patient subgroup in 2026."

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, including the release of topline data; 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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Reference:

1. Layman R., Lancet Oncol. 2024;25:474-8

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