Allarity Therapeutics Announces First Patient Enrolled in New Phase 2 Clinical Trial Protocol of Stenoparib in Advanced Ovarian Cancer

TARPON SPRINGS, Fla., June 2, 2025 -- Allarity Therapeutics, Inc. ("Allarity" or the "Company") (NASDAQ: ALLR), a Phase 2 clinical-stage pharmaceutical company dedicated to developing stenoparib—a differentiated, dual PARP and WNT pathway inhibitor—today announced that the first patient has been enrolled in its new Phase 2 clinical trial protocol of stenoparib for the treatment of advanced, platinum-resistant or platinum-ineligible ovarian cancer.

The newly launched protocol will accelerate the clinical development of stenoparib and its drug-specific Drug Response Predictor (DRP®) companion diagnostic (CDx) toward potential FDA approval. It builds on encouraging data from Allarity's earlier and still ongoing Phase 2 study, which demonstrated that patients on twice-daily stenoparib showed durable clinical benefit and that stenoparib was well tolerated. Two patients remain on treatment and continue to derive benefit after more than 20 months. Reflecting the compelling and durable clinical responses observed in platinum-resistant patients to date, the new trial protocol specifically focuses on evaluating stenoparib in patients with advanced, recurrent, platinum-resistant, or platinum-ineligible ovarian cancer—patients for whom current treatment options are extremely limited and typically involve additional chemotherapy, which is associated with well-documented side effects.

"With the enrollment of the first patient, we are fulfilling our promise to accelerate stenoparib's clinical development as a potentially safer, more effective alternative to chemotherapy for women with advanced, recurrent ovarian cancer," said Thomas Jensen, Chief Executive Officer of Allarity Therapeutics. "This new protocol reflects critical input from leading gynecologic oncologists, and allows us to solidify the importance of DRP for patients who are most likely to receive clinical benefit from stenoparib. This study also allows us to confirm and extend our current findings that show clinical benefit from twice daily dosing."

In addition to assessing overall efficacy and safety, the new trial protocol is designed to further advance the Company's understanding of stenoparib's modulation of the WNT signaling pathway—a key driver of disease progression in ovarian and other cancers. The Company is actively pursuing ways to deepen its insights into the therapeutic importance of

this WNT-modulating activity and how this, in addition to a cleaner safety profile, distinguishes stenoparib from first-generation PARP inhibitors.

Building on the clinical benefit of the current dosing schedule, this updated study design also includes an additional dosing level to explore the optimal dose for enhancing clinical benefit, aligning Allarity with the FDA's Project Optimus initiative to inform the start of pivotal registration trials.

The trial is expected to generate significant clinical data by late summer 2026. Allarity plans to pursue multiple advantaged regulatory pathways to expedite potential approval of both stenoparib and its DRP companion diagnostic (CDx).

About Stenoparib

Stenoparib is an orally available, small-molecule dual-targeted inhibitor of PARP1/2 and tankyrase 1/2. At present, tankyrases are attracting significant attention as emerging therapeutic targets for cancer, principally due to their role in regulating the Wnt signaling pathway. Aberrant Wnt/β-catenin signaling has been implicated in the development and progression of numerous cancers. By inhibiting PARP and blocking Wnt pathway activation, stenoparib's unique therapeutic action shows potential as a promising therapeutic for many cancer types, including ovarian cancer. Allarity has secured exclusive global rights for the development and commercialization of stenoparib, which was originally developed by Eisai Co. Ltd. and was formerly known under the names E7449 and 2X-121.

About the Drug Response Predictor – DRP® Companion Diagnostic

Allarity uses its drug-specific DRP® to select those patients who, by the gene expression signature of their cancer, may have a high likelihood of benefiting from a specific drug. By screening patients before treatment, and only treating those patients with a sufficiently high, drug-specific DRP score, the therapeutic benefit rate may be enhanced. The DRP method builds on the comparison of sensitive vs. resistant human cancer cell lines, including transcriptomic information from cell lines, combined with clinical tumor biology filters and prior clinical trial outcomes. DRP is based on messenger RNA expression profiles from patient biopsies. The DRP® platform has shown an ability to provide a statistically significant prediction of the clinical outcome from drug treatment in cancer patients across dozens of clinical studies (both retrospective and prospective). The DRP platform, which may be useful in all cancer types and is patented for dozens of anti-cancer drugs, has been extensively published in the peer-reviewed literature.

About Allarity Therapeutics

Allarity Therapeutics, Inc. (NASDAQ: ALLR) is a clinical-stage biopharmaceutical company dedicated to developing personalized cancer treatments. The Company is focused on development of stenoparib, a novel PARP/tankyrase inhibitor for advanced ovarian cancer patients, using its DRP® technology to develop a companion diagnostic that can be used to select those patients expected to derive the greatest clinical benefit from stenoparib. Allarity is headquartered in the U.S., with a research facility in Denmark, and is committed to addressing significant unmet medical needs in cancer treatment. For more information, visit www.allarity.com.

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Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements provide the Company's current expectations or forecasts of future events. The words "anticipates," "believe," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predicts," "project," "should," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements include, but are not limited to, statements related to the initiation, conduct, and expected outcomes of the new Phase 2 clinical trial protocol for stenoparib in advanced, platinum-resistant or platinum-ineligible ovarian cancer; the potential for stenoparib to demonstrate improved safety, tolerability, or efficacy compared to existing treatments; the evaluation of WNT pathway modulation as a mechanism of action; the development and potential regulatory approval of the Company's DRP® companion diagnostic; the alignment of the trial design with FDA initiatives such as Project Optimus; and anticipated timing of future clinical data readouts and regulatory submissions. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to multiple risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that stenoparib may not demonstrate sufficient clinical benefit or safety in the updated Phase 2 trial protocol; the risk that patient enrollment, site activation, or data collection may be delayed or disrupted; the risk that earlier clinical observations may not be confirmed in larger patient populations; the possibility that the DRP® companion diagnostic may not be validated, approved, or adopted; and the risk that regulatory pathways or agency feedback may not support accelerated approval or market access. For a discussion of other

risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled “Risk Factors” in our Form 10-K annual report filed with the Securities and Exchange Commission (the “SEC”) on March 31, 2025, available at the SEC’s website at www.sec.gov, and as well as discussions of potential risks, uncertainties and other important factors in the Company’s subsequent filings with the SEC. All information in this press release is as of the date of the release, and the Company undertakes no duty to update this information unless required by law.

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