Allarity Therapeutics to Begin Enrollment for New Phase 2 Protocol to Advance Stenoparib Toward FDA Approval in Advanced Ovarian Cancer Patients

- *Patient enrollment set to begin at leading U.S. clinical trial sites, new drug product already delivered*

- *Trial will advance stenoparib and the stenoparib-DRP Companion Diagnostic toward FDA approval*

- *Two patients in the ongoing phase 2 trial have now exceeded 17 months on stenoparib treatment*

Boston (February 24, 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/Wnt pathway inhibitor—as a personalized cancer treatment using its proprietary, drug-specific patient selection technology—the Drug Response Predictor (DRP®)—today announced that the new protocol for its Phase 2 clinical trial of stenoparib in ovarian cancer is set to begin and will be expected to provide critical data by end of summer 2026 for a pivotal registration trial.

The new protocol design was constructed following in-depth review of the Company's ongoing Phase 2 clinical data in collaboration with key ovarian cancer thought leaders and treating physicians, including the gynecologic oncologists who have been treating patients with stenoparib in the ongoing phase 2 study. This comprehensive review revealed compelling evidence for stenoparib's durable clinical benefit in platinum-resistant, advanced ovarian cancer patients, including a complete, confirmed response as well as two patients remaining on therapy without progression for more than 17 months. The protocol reflects the feedback of these gynecologic oncology experts as well as input from the FDA. The protocol has now also been approved by the Institutional Review Board of the first trial sites, paving the way for the trial to begin patient enrollment immediately. Anticipating IRB approval, to advance stenoparib, Allarity recently completed a new drug manufacturing campaign and has readied finished drug product for delivery to sites to expedite patient enrollment.

”The intensive review and finalization of this new protocol, with feedback from the FDA, the IRB and our treating physicians marks a critical milestone in our effort to accelerate stenoparib as a potentially safer, more effective alternative to additional lines of chemotherapy,” said Thomas Jensen, CEO of Allarity Therapeutics. “Importantly, this new protocol simultaneously allows us to accelerate the development of stenoparib alongside the stenoparib-DRP as a companion diagnostic. Pushing both in parallel will generate the critical data needed to support timely, connected regulatory approval for both. We are very excited about the thoughtful, unique design of this new protocol as it allows us to quickly and effectively get stenoparib into the hands of the world’s best gynecologic oncologists, benefiting patients who need safer and more effective treatment options than the toxic chemotherapy options they would otherwise have to rely upon. We are particularly excited about the prospects of this trial advancing stenoparib’s journey toward commercialization.”

This new protocol was designed expressly to enrich the understanding of clinical benefit in a well-defined ovarian cancer patient population with significant unmet medical need. In addition to further deepening the clinical experience for stenoparib, this trial will allow for the evaluation of the impact of stenoparib on the Wnt pathway, a critical cellular signaling pathway implicated in advanced ovarian cancer and multiple other malignancies, including colon cancer. A deeper understanding of stenoparib’s role in modulating the Wnt pathway would further differentiate stenoparib in the $9B+ PARP inhibitor market. The ongoing Phase 2 study was the first stenoparib study to assess twice-daily dosing and showed clear evidence for clinical benefit. The new protocol will build upon this clinical experience with the current dose while introducing an additional dose level to assess whether clinical benefit can be further enhanced. Ultimately, this trial will allow Allarity to address the FDA’s recent “Project Optimus” guidelines and will set the stage for pivotal registration studies.

Allarity expects to pursue multiple advantaged regulatory pathways to expedite approval in the first half of 2025. Allarity will also be presenting key data, with abstracts now accepted, at multiple upcoming scientific and clinical conferences. Details will be announced as embargo policies for these conferences allow.

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, are found to 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 significantly increased. 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 in dozens of clinical studies (both retrospective and prospective). The DRP platform, which may be useful in all cancer types and is patented for more than 70 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 regarding the continued development and regulatory progress of stenoparib, as well as plans to implement a new clinical protocol, including collaboration with leading U.S. clinical trial sites. 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, risks related to the successful execution of clinical trials for stenoparib, securing regulatory approval, and other operational and financial risks that could impact the Company's ability to achieve its goals. 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 S-1/A registration statement filed on April 17, 2024, our Form 10-K annual report on file with the Securities and Exchange Commission (the "SEC") and our Form 10-Q quarterly report filed with the SEC on November 14, 2024, 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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