# Allarity Therapeutics Advances Stenoparib Toward Pivotal Development with Phase 3 Manufacturing Campaign

- *Phase 3 manufacturing campaign on track for completion no later than third quarter 2026, supporting expected pivotal trial in advanced ovarian cancer*

- *Supports accelerating stenoparib toward FDA approval following FDA Fast Track designation*

- *All manufacturing-related payments completed; no additional cash outlays for manufacturing are anticipated*

**TARPON SPRINGS, Fla.,** MAY 5, 2026 – Allarity Therapeutics, Inc. ("Allarity" or the "Company") (NASDAQ: ALLR), a Phase 2 clinical-stage pharmaceutical company dedicated to developing stenoparib (2X-121)—a differentiated, dual PARP and WNT pathway inhibitor—today announced that its active pharmaceutical ingredient (API) manufacturing campaign for stenoparib is progressing in line with the planned timeline for completion no later than the third quarter of 2026 at its world-class contract development and manufacturing organization (CDMO).

This milestone represents a key operational advance as the Company works to secure robust drug supply while preparing for potential pivotal-stage clinical development. The decision to move forward with the campaign reflects the continuously growing confidence in stenoparib's therapeutic potential, based on previously reported data showing extended overall survival in advanced, platinum-resistant ovarian cancer patients.

"With the Phase 3 manufacturing campaign of stenoparib approaching completion, we are taking an important step to ensuring timely advancement into potential pivotal-stage clinical trials," said Thomas Jensen, Chief Executive Officer of Allarity Therapeutics. "This campaign reflects our confidence in the long-term potential of the program, and is particularly important as we work to leverage the FDA Fast Track designation to accelerate the development and potential approval of stenoparib."

The CDMO site, located in Europe, operates in full compliance with GMP (Good Manufacturing Practice) standards set by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Drug manufacturing for late-stage clinical development requires heightened manufacturing standards that go above and beyond the standards necessary for phase 1 and phase 2 clinical development. Triggering this campaign now ensures that the higher standard API is ready when the company is ready to advance a pivotal trial for FDA approval.

From a financial standpoint, the company has completed all payments for the manufacturing and no additional cash outlays for manufacturing are anticipated.

The manufacturing campaign is expected to be completed well in advance of the anticipated generation of critical data from Allarity's ongoing Phase 2 trial in advanced ovarian cancer. The ongoing phase 2 trial continues to enroll patients under the new protocol, generating enthusiastic investigator engagement.

**About Stenoparib/2X-121**

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, Small Cell Lung Cancer and colorectal 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. Allarity has two ongoing Phase 2 trial protocols for stenoparib in Ovarian Cancer patients. In the first, patients who had had 2+ lines of therapy were enrolled on stenoparib and given drug twice daily. This protocol has been closed to further enrollment but continues for the enrolled patients who are still receiving benefit from stenoparib administration. The updated data from this study were presented at the AACR special conference on advances in Ovarian Cancer in September 2025. Note that, as these data are from an ongoing trial, analyses may change as the study fully matures. An amended protocol designed expressly to capitalize on the emerging clinical experience with stenoparib in platinum resistant patients began enrolling patients in the summer of 2025. This amended protocol enrolls only platinum resistant or platinum-ineligible patients and is designed to accelerate the clinical development of stenoparib toward FDA approval. In parallel, a separate Phase 2 trial evaluating stenoparib in combination with temozolomide for relapsed small cell

lung cancer (SCLC) began enrolling patients in early 2026 and is currently enrolling patients across multiple U.S. Veterans Administration (VA) sites.

**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, regarding the Company’s manufacturing readiness and supply strategy for stenoparib, the availability of drug supply to support ongoing and potential future clinical trials, including potential pivotal studies, the timing and progression of late-stage clinical development, future regulatory interactions and submissions, and the potential commercialization of stenoparib. 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 manufacturing execution and scale-up, potential disruptions in the supply of raw materials or drug product, regulatory review and approval processes, the results and timing of ongoing and future clinical trials, the Company’s ability to maintain sufficient financial resources to support development activities, and other operational, clinical, and regulatory risks. 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 30, 2026, 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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