

## **Allarity Therapeutics Presents New Phase 2 Clinical Data for Stenoparib/2X-121 Showing Landmark Median Overall Survival Has Now Surpassed 25 Months**

- *Kaplan-Meier analyses show for the first time that median Overall Survival exceeds 25 months for Platinum Resistant and Refractory Ovarian Cancer Patients receiving stenoparib/2X-121 twice daily*
- *Two patients continue on therapy now more than 24 months*
- *Clinical Benefit Evident in patients with BRCAwt as well as BRCAmut genetics*
- *Data presented at the American Association for Cancer Research (AACR) 7<sup>th</sup> Biennial Special Conference on Ovarian Cancer, Denver CO*

**TARPON SPRINGS, Fla.**, September 22, 2025 – 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 Dr Jeremy Graff, President and Chief Development Officer for Allarity Therapeutics, presented new and updated clinical data from the ongoing Phase 2 clinical trial in advanced ovarian cancer patients at the American Association for Cancer Research (AACR) 7th Biennial Special Conference on Ovarian Cancer, held September 19–21, 2025, at the Grand Hyatt Denver in Denver, Colorado. The poster is available via the Scientific Publications section of the Company’s website.

The presentation showcased the first Kaplan-Meier analysis for median Overall Survival (mOS) from the Company’s ongoing Phase 2 trial that enrolled patients with advanced ovarian cancer, all of whom had either platinum-resistant or refractory disease and had tumors showing a Stenoparib-specific Drug Response Predictor (DRP<sup>®</sup>) score above 50. Notably, these data provide the first evidence that stenoparib, when given twice daily, may extend patient survival. The mOS has not been formally reached yet and now exceeds 25 months. Two patients actively remain on therapy now more than 24 months, with one of these two patients carrying a wild-type BRCA gene—a genetic background that typically precludes benefit from PARP inhibitors. Notably, one patient with primary platinum-refractory disease

remains alive more than two years after enrollment—a clinical outcome that is highly uncommon in this population.

“These emerging clinical results presented at the AACR Special Conference on Ovarian Cancer suggest that stenoparib may offer meaningful extended survival benefit for patients with advanced, platinum-resistant ovarian cancer (PROC)—a population with historically poor outcomes and limited treatment options,” said Thomas Jensen, Chief Executive Officer of Allarity Therapeutics. “Importantly, the durability of clinical benefit—including in BRCA wild-type and heavily pre-treated patients—underscores stenoparib’s unique mechanism of action as a dual inhibitor of both PARP and the WNT pathway. Given the FDA’s recent proclamations emphasizing the need to assess Overall Survival, we are particularly excited that the median Overall Survival in this trial has not yet been reached and exceeds 25 months—that’s nearly 10 months longer than the mOS reported for the most recent FDA approvals and advances in therapy for PROC patients. We look forward to further exploring the game-changing potential of stenoparib through the ongoing enrollment of patients in our new Phase 2 trial protocol expressly enrolling PROC or platinum-ineligible patients. These data will help deepen and solidify the durable clinical benefit and extended overall survival stenoparib may provide and will support our attempts to accelerate stenoparib toward FDA approval.”

A preliminary Kaplan-Meier (K-M) analysis of overall survival presented at this conference indicates that mOS has not yet been reached, with the current K-M estimate now exceeding 25 months, based on a median follow-up time of nearly 22 months. For context, the most recent clinical advances and FDA approved therapies for the treatment of PROC patients have shown mOS of approximately 16-16.5 months, an improvement versus the 11.5-13 months mOS of standard chemotherapy. This underscores stenoparib’s potential to meaningfully improve patient outcomes and dovetails with the FDA’s recently published draft guidance (Approaches to Assessment of Overall Survival in Oncology Clinical Trials, August 2025), which reaffirms overall survival as the most meaningful and objective endpoint for oncology drug approval.

The study population includes heavily pre-treated patients, many of whom had previously received PARP inhibitors, chemotherapy, immunotherapy, and antibody-drug conjugates (ADCs). Stenoparib continues to show a favorable safety profile, with significantly less myelotoxicity than typically observed with earlier-generation PARP inhibitors. This is especially relevant in light of the 2022 market withdrawal of first-generation PARP inhibitors in heavily pre-treated ovarian cancer, due to lack of demonstrated long-term survival benefit—emphasizing the need for therapies that may meaningfully extend overall survival. Moreover, the updated clinical data continue to show that stenoparib may provide clinical benefit in

patients regardless of BRCA status, possibly reflecting the dual inhibition of PARP1/2 and the WNT pathway and distinguishing stenoparib from 1<sup>st</sup> generation PARP inhibitors.

### **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/ $\beta$ -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. 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 this AACR special conference on advances in Ovarian Cancer. 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 this summer. This amended protocol enrolls only platinum resistant or platinum-ineligible patients and is designed to accelerate the clinical development of stenoparib toward FDA approval.

### **About the Drug Response Predictor – DRP<sup>®</sup> Companion Diagnostic**

Allarity uses its drug-specific DRP<sup>®</sup> 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<sup>®</sup> 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](http://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 potential efficacy, safety, clinical benefit, and regulatory advancement of stenoparib (2X-121); the Company’s expectations for its ongoing and future clinical trials, including patient enrollment and data readouts; and the potential for FDA approval or other regulatory milestones. 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 clinical development, including the risk that future clinical results may not be consistent with prior data; delays or difficulties in patient enrollment; the Company’s reliance on third parties to conduct its trials; regulatory decisions by the FDA or other authorities; the Company’s ability to obtain and maintain regulatory approvals; and the sufficiency of the Company’s capital resources and need for additional financing. 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](http://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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