Allarity Therapeutics announces that its collaborative Phase 2 trial with the United States Veteran's Administration Combining Stenoparib with Temozolomide in Relapsed Small Cell Lung Cancer is Now Open for Enrollment

- *This is the first trial combining Allarity's stenoparib with another anti-cancer agent*
- *Stenoparib's favorable safety profile supports potential for use in combination regimens*
- *Trial is fully funded by the U.S. Department of Veterans Affairs and is open to enrollment at 11 VA sites throughout the US*

TARPON SPRINGS, Fla., February 3, 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 enrollment is now open for its new Phase 2 clinical trial evaluating the combination of stenoparib and temozolomide for the treatment of recurrent small cell lung cancer (SCLC).

The trial is being conducted in collaboration with the U.S. Department of Veterans Affairs (VA) and is fully funded through the VA's Special Emphasis Panel on Precision Oncology. The trial is officially registered as NCT06681220: Biomarker directed trial of temozolomide and stenoparib in relapsed SCLC and is now open for enrollment at 11 VA sites throughout the US.

This Phase 2 study will assess the safety and efficacy of stenoparib in combination with temozolomide, a DNA-alkylating chemotherapy agent, in patients with recurrent SCLC who have progressed after frontline treatment. Prior studies have shown that PARP inhibitors can enhance the activity of temozolomide, but widespread use has been limited by severe hematologic toxicity. The study includes a blood based biomarker developed in the VA Lung Precision Oncology Program to select patients most likely to benefit from this combination.

"The opening of recruitment marks an important step in exploring stenoparib's potential as a combination agent," said Thomas Jensen, Chief Executive Officer of Allarity Therapeutics.

“Based on clinical data to date from our ongoing trial in ovarian cancer, stenoparib has demonstrated a favorable safety profile, making it a strong candidate for combination therapies — particularly in settings where tolerability has been a limiting factor, as is the case in SCLC. More broadly, we believe stenoparib may offer meaningful clinical benefit in cancers where the WNT signaling pathway plays a key role, which applies to both SCLC and ovarian cancer. We’re particularly enthusiastic about taking this next step in stenoparib’s development as it allows us to explore stenoparib’s enormous potential in other indications and in combination with other agents.”

Shadia Jalal, the study’s Principal Investigator and Professor of Medicine at the Lawrence H. Einhorn Chair in Oncology at Indiana University’s Melvin and Bren Comprehensive Cancer Center said, “We’re excited to explore this novel combination. Patients with relapsed SCLC including veterans have very few effective treatment options. Previous clinical work has shown that the combination of temozolomide with first generation PARP inhibitors is very active but also very limited by the toxicities of the two agents. Stenoparib has not only a unique mechanism of action that could provide benefit to these patients but also has a favorable safety profile that may allow veterans to tolerate this combination therapy and realize meaningful, durable clinical benefit.”

While offering a potentially more favorable safety profile with temozolomide, stenoparib may offer additional anti-tumor benefit through suppression of WNT signaling, a pathway associated with SCLC progression and resistance.

In addition, stenoparib’s ability to cross the blood-brain barrier may offer therapeutic potential for patients with brain metastases, a common and challenging complication in advanced SCLC.

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 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® 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.

Follow Allarity on Social Media

LinkedIn: https://www.linkedin.com/company/allaritytx/

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 clinical development of stenoparib (2X-121) in advanced ovarian cancer and small cell lung cancer; the initiation, enrollment, and expected data readouts from ongoing and future clinical trials; including the trial with the U.S. Department of Veterans Affairs (VA);the potential safety, efficacy, and durability of clinical benefit of stenoparib; stenoparib’s safety and efficacy in combination with temozolomide; the potential for regulatory advancement, including under FDA Fast Track designation; and the expansion and potential commercial application of the Company’s DRP® companion diagnostic platform, including in antibody-based therapies. 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 and regulatory review, including the possibility that future clinical data may not support safety or efficacy claims; delays in patient enrollment or trial completion; reliance on third-party investigators and trial sites; the outcome and timing of decisions by regulatory authorities, including under Fast Track designation; the predictive accuracy and clinical utility of the DRP® platform; and the Company’s ability to secure sufficient funding or partnerships to support its operations and development plans. 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, and our Form 10-Q quarterly reports filed with the SEC on May 9, 2025, August 15, 2025 and November 14, 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.

###

Company Contact:
investorrelations@allarity.com

Media Contact:
Thomas Pedersen
Carrotize PR & Communications
+45 6062 9390
tsp@carrotize.com