

Allarity Therapeutics Announces CLIA Certification, Clearing the Path for Advancing DRP[®] Testing for FDA Registration

- *Allarity Therapeutics is now poised to run its DRP[®] testing in-house in a CLIA-certified laboratory environment*
- *The FDA requires that biomarker testing to select patients for registration trials must be performed in a CLIA-certified laboratory environment*
- *CLIA certification for the Allarity Therapeutics Medical Laboratory is a critical strategic initiative to streamline the development of Allarity's lead agent, stenoparib*
- *Positions Allarity Therapeutics Medical Laboratory as a preferred CLIA-certified partner for European companies pursuing U.S. clinical trials or commercialization*

TARPON SPRINGS, Fla., July 7, 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 it has obtained a Certificate of Registration under the Clinical Laboratory Improvement Amendments (CLIA) for its in-house laboratory.

With a wholly owned CLIA-certified facility located in Horsholm, Denmark, Allarity will now be able to do all necessary testing in-house to support the acceleration of stenoparib toward FDA registration. Importantly, Allarity will no longer need to rely on external partner labs to do this testing. This transition will significantly reduce turnaround times for DRP[®] analyses, streamline communication with clinical trial sites, and create significant long-term cost savings for developing stenoparib. In addition, Allarity Therapeutics Medical Laboratory will now be positioned as a preferred CLIA-certified laboratory partner in Northern Europe, capable of providing DRP[®] and additional laboratory services for potential partner companies seeking to conduct clinical trials in the U.S. or support products commercialized in the U.S. market.

Strategically, Allarity has sought to develop this capability in-house to control DRP[®] testing in advance of a potential pivotal, registrational trial of stenoparib in advanced, platinum-resistant or platinum-ineligible ovarian cancer. The CLIA initiative also represents an

important step toward the potential future commercialization of the DRP® companion diagnostic in the U.S.—both as part of Allarity’s internal clinical programs and as a potential regulated service offering to other biopharmaceutical companies interested in leveraging the Company’s DRP® platform in the development of precision oncology therapies in U.S.-based clinical trials.

“Achieving CLIA certification for our own lab is transformative, allowing us to bring DRP testing under our direct control for both clinical and commercial use in the U.S.,” said Thomas Jensen, Chief Executive Officer of Allarity Therapeutics. “We are pleased to have successfully completed this prudent step as we set the stage to accelerate stenoparib toward FDA registration, while also creating a broader opportunity to serve biotechnology and pharmaceutical companies in Northern Europe that require CLIA-compliant testing for U.S. clinical trials or commercialized products. We believe this capability can make Allarity Therapeutics Medical Laboratory a natural partner of choice for companies looking to bridge European innovation with the U.S. clinical and commercial market.”

CLIA certification, administered by the U.S. Centers for Medicare & Medicaid Services (CMS), is a regulatory requirement for laboratories conducting diagnostic testing on human samples for use in U.S.-based clinical trials. Under its CLIA Certificate of Registration, Allarity’s Danish laboratory is authorized to perform DRP® testing for U.S. studies, including a pivotal, registrational trial of stenoparib in advanced ovarian cancer.

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, especially drug-resistant 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 completed its first Phase 2 trial for stenoparib in advanced ovarian cancer patients. That trial showed promising and durable clinical benefit in ovarian cancer patients who had 2+ lines of therapy and were given stenoparib twice daily. The updated data from this study were presented at the AACR special conference on advances in ovarian cancer in September 2025. Note that analyses may change as the study fully matures. A new



protocol was designed expressly to capitalize on this emerging clinical experience with stenoparib in platinum resistant patients and 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 VA sites in the US.

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's principal operations are located in Denmark and its U.S. business address is in Florida 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 Company’s ability to maintain its CLIA Certificate of Registration and obtain and maintain any additional certificates, licenses or regulatory approvals required for its planned laboratory activities; the anticipated use of the Company’s in-house laboratory to perform DRP® testing in connection with U.S.-based clinical trials, including a potential pivotal trial of stenoparib in advanced, platinum-resistant or platinum-ineligible ovarian cancer; the expected operational efficiencies, reduced turnaround times, improved communication and long-term cost benefits associated with bringing DRP® testing in-house; the potential use and commercialization of the DRP® companion diagnostic in the United States; and the Company’s ability to provide DRP® and other laboratory services to third-party biopharmaceutical companies supporting U.S. clinical trials or commercialized products.. 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 Company’s ability to maintain its CLIA Certificate of Registration and obtain and maintain any additional certificates, licenses or regulatory approvals required for its planned laboratory activities; delays, costs, operational challenges, inspection findings or regulatory requirements associated with establishing and operating a CLIA-regulated laboratory outside the United States; the Company’s ability to validate, implement and perform DRP® testing in compliance with applicable regulatory, quality and laboratory standards; the possibility that the anticipated operational efficiencies, cost savings or commercial opportunities may not be realized; the regulatory acceptance and clinical utility of the DRP® companion diagnostic; and the Company’s ability to use the DRP® prospectively for patient selection in a potential pivotal trial of stenoparib.. 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, and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, filed with the SEC on May 15, 2026, available at the SEC’s website at www.sec.gov, 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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