Allarity Therapeutics Granted FDA Fast Track Designation for Stenoparib for the Treatment of Advanced Ovarian Cancer

TARPON SPRINGS, Fla., August 26, 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 and WNT pathway inhibitor—today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to stenoparib, its investigational treatment for patients with advanced ovarian cancer.

The FDA's Fast Track designation is intended to expedite the development and review of drugs that treat serious conditions and fill an unmet medical need. This designation enables more frequent interactions with the FDA throughout the drug development process and potentially provides eligibility for accelerated approval, priority review, and rolling review if relevant criteria are met.

"We are very pleased that the FDA has granted Fast Track designation to stenoparib," said Thomas Jensen, Chief Executive Officer of Allarity Therapeutics. "This recognition underscores the significant unmet need facing women with advanced ovarian cancer and reflects the potential of stenoparib to meaningfully improve treatment outcomes. We look forward to engaging closely with the FDA as we advance this program."

Allarity recently began patient enrollment under a new Phase 2 clinical trial protocol evaluating stenoparib in advanced, recurrent, platinum-resistant or platinum-ineligible ovarian cancer. The first patient was enrolled in early June 2025, and several patients have already been dosed. The trial is designed to accelerate clinical development of stenoparib and its DRP® companion diagnostic and builds on prior encouraging Phase 2 data showing durable clinical benefit, including patients who remain on treatment now for over 22 months.

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, 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, statements regarding the regulatory advancement of stenoparib; anticipated interactions with the FDA under Fast Track designation; expected timelines and outcomes of the ongoing Phase 2 trial in advanced ovarian cancer; and the potential impact of the DRP® companion diagnostic on patient selection and treatment outcomes. 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 future development and regulatory approval of stenoparib; the outcome of FDA interactions and potential reliance on Fast Track-related incentives; uncertainties in clinical trial enrollment, execution, and data interpretation; and the Company's ability to successfully validate and deploy its DRP® companion diagnostic. 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, 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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