Allarity Therapeutics Announces Filing of Form 8-K Regarding Settlement Agreement in Principle with SEC

Boston (January 30, 2025)—Allarity Therapeutics, Inc. (“Allarity” or the “Company”) (NASDAQ: ALLR), a Phase 2 clinical-stage pharmaceutical company dedicated to developing personalized cancer treatments using its proprietary, drug-specific patient selection technology, has filed a Form 8-K with the U.S. Securities and Exchange Commission (“SEC”) regarding its agreement in principle with the SEC staff to resolve the previously disclosed SEC investigation.

The settlement relates to the Company’s disclosures, occurring during or prior to fiscal year 2022, regarding meetings with the United States Food and Drug Administration (the “FDA”) concerning our New Drug Application ("NDA") for Dovitinib or Dovitinib-DRP, which was submitted to the FDA in 2021. This settlement in principle with the SEC staff remains subject to mutual agreement on the final language of the settlement documents and approval by the SEC. Accordingly, the Company emphasizes that there is no assurance that the settlement will be finalized or approved on the terms set forth above, or at all.

“We are pleased to have reached this agreement in principle with the SEC. This settlement allows us to fully focus on advancing stenoparib and delivering a novel therapy to advanced ovarian cancer patients, who currently have very few or no treatment options,” said Thomas Jensen, Chief Executive Officer of Allarity Therapeutics. “As we have previously announced, some patients in our Phase 2 trial have exceeded 14 months on treatment with stenoparib, and this data fills us with optimism about the prospects of this novel molecule and by extension, the prospects for Allarity as well. Our primary objective now is to finalize the design of a follow-on trial that we expect will advance stenoparib toward FDA registration.”

Allarity remains financially positioned to continue its core operations, including the ongoing development of stenoparib, as planned into 2026.

The full Form 8-K filing is available on the SEC’s website at www.sec.gov and on the Company’s website at www.allarity.com/sec-filings.

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. 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 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® companion diagnostic for patient selection in the ongoing phase 2 clinical trial, NCT03878849. 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 anticipated resolution of the SEC investigation, the ongoing development and regulatory progress of stenoparib, and plans to initiate a follow-up clinical trial aimed at FDA registration. 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 finalization and approval of the proposed SEC settlement, the successful execution of clinical trials for stenoparib, securing regulatory approval, and other operational and financial risks that could impact the Company's ability to achieve its goals. 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 S-1/A registration statement filed on April 17, 2024, our Form 10-K annual report on file with the Securities and Exchange Commission (the "SEC") and our Form 10-Q quarterly report filed with the SEC on November 14, 2024, 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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Company Contact:
investorrelations@allarity.com

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