Allarity Therapeutics Announces Expansion of Phase 2 Clinical Trial to Accelerate Development of Stenoparib in Advanced Ovarian Cancer

Boston (February 6, 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/Wnt pathway inhibitor—as a personalized cancer treatment using its proprietary, drug-specific patient selection technology—the Drug Response Predictor (DRP®)—today announced plans for the next step in advancing the clinical development of stenoparib toward FDA approval in advanced ovarian cancer. With this new phase 2 protocol, Allarity will capitalize and expand on the ongoing phase 2 clinical trial data to optimize the dose of stenoparib and to refine the DRP® patient selection criteria in order to maximize the clinical benefit from stenoparib.

An in-depth review of Allarity's maturing clinical data, in collaboration with leading clinical investigators, prompted Allarity to design this new Phase 2 protocol to enable a more aggressive push of stenoparib toward regulatory approval. The protocol will enable new enrollment expressly focusing on patients with advanced, recurrent, platinum-resistant disease, a group that has shown durable clinical benefit from stenoparib in the current phase 2 trial and who have only limited treatment options following standard chemotherapy. In addition to expanding and deepening the clinical data set necessary for regulatory approval, this trial is also designed to enhance the understanding of stenoparib's unique therapeutic mechanism of action. Of particular interest will be the impact of stenoparib treatment on the Wnt pathway, a key cellular pathway repeatedly shown to be involved in advanced ovarian cancers as well as many other advanced cancer types, most notably colon cancers. A richer understanding of stenoparib's potential for controlling the Wnt pathway—a key aspect of the newly designed trial—could further distinguish stenoparib as a unique investigational cancer treatment.

The protocol will also further refine Allarity's understanding of the stenoparib-DRP® for identifying patients most likely to benefit from stenoparib treatment. As part of the trial, a DRP score will be assessed for all enrolled patients to generate the deeper, more robust data set necessary to refine the DRP cut-off that would ring-fence patients most likely to benefit from

stenoparib. These data will be fundamental for supporting any regulatory approval for the stenoparib-DRP as a companion diagnostic (CDx) specific to stenoparib.

The Company has previously announced long-lasting clinical benefit for advanced, recurrent ovarian cancer patients, with some of these patients continuing on therapy for more than 14 months. Based upon these encouraging clinical benefit data, Allarity intends to pursue an advantaged regulatory path toward approval to further enable stenoparib's clinical development.

Patient enrollment is expected to begin in the first half of 2025, subject to final protocol review by regulatory authorities. Recruitment will commence at leading U.S. trial sites, with the potential inclusion of additional sites in the U.K. as warranted.

"Until now, patients receiving stenoparib have had diverse and often extensive treatment histories, with many being very heavily pretreated. Based on data we have gathered to date from our clinical trials, and through in-depth analysis and consultation with leading gynecologic oncologists, we have developed a new clinical trial protocol focused on a well-defined, commercially significant patient population in desperate need of newer, safer treatment options beyond more chemotherapy, which comes with well-documented side effects," said Thomas Jensen, CEO of Allarity Therapeutics. "We are therefore pleased to have submitted this trial design and are eager to begin patient enrollment as soon as we receive the final green light from the regulatory authorities, including the FDA."

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, are found to 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 significantly increased. 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 in dozens of clinical studies (both retrospective and prospective). The DRP platform, which may be useful in all cancer types and is patented for more than 70 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 selelct 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 continued development and regulatory progress of stenoparib, as well as plans to implement a new clinical protocol. 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 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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