Allarity Therapeutics Announces Two Patients Now Exceeding One Year of Treatment with Stenoparib in Advanced Ovarian Cancer Trial

- Durable Clinical Benefit Observed Beyond a Year on Treatment in Heavily Pre-Treated Patients

Boston (September 16, 2024) — Allarity Therapeutics, Inc. ("Allarity" or the "Company") (NASDAQ: ALLR), a clinical-stage pharmaceutical company dedicated to developing personalized cancer treatments, today announced that two patients enrolled in its Phase 2 clinical trial of stenoparib for advanced, recurrent ovarian cancer have now exceeded one year on therapy.

The patients had been pre-screened using Allarity's Drug Response Predictor (DRP®) companion diagnostic, which identified them as having a high likelihood of benefiting from stenoparib, the Company's novel dual PARP/Tankyrase inhibitor.

This remarkably lengthy treatment period highlights the potential of stenoparib to provide durable clinical benefit, even in heavily pre-treated ovarian cancer patients who have limited treatment options. The trial continues to evaluate stenoparib's safety and efficacy, showing a confirmed, complete response as well as long term disease stability for multiple patients.

Thomas Jensen, CEO of Allarity Therapeutics, commented on this clinical achievement:

"We are incredibly encouraged by the sustained clinical benefit seen in these patients, who have now been on stenoparib for over a year. For heavily pre-treated ovarian cancer patients, extending life by 52 weeks is particularly noteworthy. Stenoparib's unique mechanism of action, as both a PARP and Tankyrase inhibitor, sets it apart from other treatments. These results reinforce our belief in stenoparib's potential as an important new therapy for ovarian cancer patients who have exhausted other treatment options."

Dr. Fernanda B. Musa, Director of Clinical Research in Gynecology Oncology and site Principal Investigator at the Swedish Cancer Institute for the trial added:

"We have been surprised and excited to see a long duration of response to a single-agent oral therapy in patients with ovarian cancer who had failed multiple other types of treatment. I credit the success to personalized medicine: the pairing of the therapy to the patient's specific tumor profile. I look forward to seeing further development of this program!"

Allarity is actively planning the further advancement of its stenoparib program, with a focus on accelerating its path toward regulatory approval. The Company remains dedicated to exploring stenoparib's long-term clinical benefit in DRP®-selected patients and is preparing for the next phase of development. Additional updates on the program's progress and future trials will be shared in the coming months.

Background Information about the Trial

The above-mentioned trial is a Phase 2, prospective open-label, single-arm study with multiple sites in both the US and the UK. Investigators prescreened women with advanced, recurrent ovarian cancer using Allarity's DRP® companion diagnostic (CDx), which comprises a complex transcriptomic signature of 414 mRNA biomarkers indicative of drug response or resistance. Each participant was assigned a DRP score, and those with scores above 50 - suggesting a higher likelihood of benefiting from treatment – were selected to receive stenoparib. The selected patients were administered stenoparib under a revised protocol implemented in Q1 2023, which involved a twice-daily dosing regimen (200 mg in the morning and 400 mg in the evening) instead of the previous once-daily 600 mg dose. This change was made to optimize daily drug exposure and target inhibition.

The patients enrolled have advanced through multiple lines of therapy, including platinum, taxanes, anti-angiogenesis inhibitors, and even the recently approved Antibody Drug Conjugate, Elahere. Importantly, most of the enrolled patients to date have been previously treated with a PARP inhibitor. These patients have few, if any, effective treatment options and typically advance through available therapies after only a few months.

About stenoparib

Stenoparib is an orally available, small-molecule dual-targeted inhibitor of PARP1/2 and Tankyrase 1 and 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 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 proven its ability to provide a statistically significant prediction of the clinical outcome from drug treatment in cancer patients dozens of clinical studies (both retrospective and prospective). The DRP platform, which can be used 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® 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 clinical progress of stenoparib, including the long-term benefit observed in patients, and the Company's plans to advance stenoparib toward regulatory approval]. 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, Allarity’s ability to raise sufficient capital to support its current and anticipated clinical trials,

the risk that early results of a clinical study do not necessarily predict final results and that one or more of the clinical outcomes may materially change following more comprehensive reviews of the data, and as more patient data become available, the risk that results of a clinical study are subject to interpretation and additional analyses may be needed and/or may contradict such results, the receipt of regulatory approval for stenoparib or any of our other therapeutic candidates and companion diagnostics or, if approved, the successful commercialization of such products, the risk of cessation or delay of any of the ongoing or planned clinical trials and/or our development of our product candidates, the risk that the results of previously conducted studies will not be repeated or observed in ongoing or future studies involving our therapeutic candidates]. 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 registration statement filed on October 30, 2023, as amended and our Form 10-K annual report on file with the Securities and Exchange Commission (the “SEC”), 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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