



Allarity Therapeutics' Dual PARP/Tankyrase Inhibitor, Stenoparib, Continues to Show Extended Clinical Benefit in Advanced Ovarian Cancer

- *Multiple patients have now exceeded 30 weeks on treatment*

Boston (June 25, 2024)—Allarity Therapeutics, Inc. (“Allarity” or the “Company”) (NASDAQ: ALLR), a Phase 2 clinical-stage pharmaceutical company dedicated to developing personalized cancer treatments, today announced that multiple patients in its Phase 2 clinical trial of stenoparib for advanced recurrent ovarian cancer have been on treatment for more than 30 weeks.

The continued durability of clinical benefit further bolsters the Company’s announcement in early May 2024 that stenoparib had shown clear clinical benefit, including significant tumor shrinkage and long-term disease stability, in patients who had been heavily pre-treated for their ovarian cancer and otherwise have limited life expectancy. These results provided clinical proof of concept for stenoparib as a treatment in this patient population, prompting the company to halt patient enrollment to focus its resources on developing a follow-on trial designed to accelerate the path for stenoparib toward regulatory approval.

Kathleen N. Moore, MD, MS, Deputy Director of the Stephenson Cancer Center, Professor of the Section of Gynecologic Oncology and the Virginia Kerley Cade Chair in Developmental Therapeutics, serves as the Principal Investigator for the current Allarity trial: “Inhibition of poly-ADP-ribose polymerase or PARP has been transformational for the treatment of ovarian cancer with first-generation agents significantly improving progression-free and overall survival especially among patients with biomarkers for their use. However, there are a significant number of patients who either don’t benefit at all from inhibition of PARP or only modestly and for them, continual development of next-generation agents remains a high priority. The promising results observed with stenoparib - particularly with the tolerability demonstrated so far, warrant further development of this drug. I look forward to continuing the discussions with the team at Allarity to refine the future trial design and subsequently continue to investigate the potential of this novel PARP/Tankyrase inhibitor.”

“The continued durability of clinical benefit from stenoparib furthers our enthusiasm for stenoparib for patients who traditionally have limited treatment options and often only a few months of continued life expectancy. We continue to see patients maintain their quality of life with minimal side effects for extended periods,” stated Allarity Therapeutics CEO Thomas

Jensen. He elaborated, “Not only does the safety profile stand out when compared to chemotherapies, which is often the alternative for this patient group, but the safety metrics are indeed also favorable when compared to first-generation PARP inhibitors. As we see it, stenoparib may represent the next-generation alternative for advanced ovarian cancer patients. Therefore, we are aggressively working with Dr. Moore and other leading experts to design a trial that will help advance and quicken stenoparib’s clinical progress toward registration with the FDA.”

After conducting a detailed review of the stenoparib monotherapy trial data, including the data announced today, the Company has concluded that these data may be of significant interest among key oncologists, potential commercial partners, and other relevant stakeholders and therefore warrant presentation within a high-level scientific conference. Further release of these clinical data is intended to be staged to comply with the common rules of scientific conferences, which do not allow data to be published before the event.

The PARP inhibitor market saw a major shift in 2022 as rucaparib, olaparib, and niraparib were withdrawn for heavily pretreated ovarian cancer patients, underscoring the need for new, effective PARP inhibitors with a more favorable safety profile. The PARP inhibitor market is expected to reach \$22 billion in revenue by 2028, and has historically seen significant partnerships and acquisitions. Recent interest in the market has focused on the development of PARP inhibitors with improved tolerability and safety profiles, leading to notable activity in the sector. For example, one significant acquisition included a multi-asset deal potentially totaling \$1.5 billion, which featured an advanced PARP inhibitor. Stenoparib is orally available and also shares an advantaged safety profile relative to 1st generation PARP inhibitors. It also inhibits the Tankyrase 1 and 2 enzymes, which helps block the activity of the WNT/Beta-catenin pathway, a pathway often overactive in ovarian and many other solid cancers. The safety and unique, dual inhibitory activities of stenoparib make it a differentiated and compelling potential therapeutic product.

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, all but two 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, the impact of recent clinical and operational achievements on future trial designs, potential commercial partnerships, planning and carrying out registrational intent clinical trials, the anticipated regulatory progress of stenoparib following the early conclusion of our Phase 2 clinical trial, and the possibility that there may not be any presentation at a scientific event. 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, the risks associated with maintaining compliance with Nasdaq’s continued listing requirements, the trading price of Allarity’s shares of common stock may be volatile and other risks inherent in Allarity’s business, including, the risk that the Company is not able 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, and 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 April 17, 2024, 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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