Allarity Therapeutics' Stenoparib Shows Clear Clinical Benefit and Achieves Significant Milestone with Early Conclusion of Phase 2 Trial in Advanced Ovarian Cancer

Boston (May 2, 2024)—Allarity Therapeutics, Inc. ("Allarity" or the "Company") (NASDAQ: ALLR), a clinical-stage pharmaceutical company dedicated to developing personalized cancer treatments, today announced the early discontinuation of its Phase 2 clinical trial of stenoparib, a novel PARP inhibitor, for the treatment of advanced recurrent ovarian cancer. The patients enrolled in the trial had been pre-screened by Allarity's unique Drug Response predictor (DRP®) companion diagnostic (CDx) in order to treat only patients with the highest likelihood of deriving clinical benefit.

The trial, evaluating stenoparib given twice daily, has shown clear clinical benefit, including tumor shrinkage and long-term disease stability, in heavily pre-treated ovarian cancer patients who otherwise have limited life expectancy. These results have provided sufficient clinical proof of concept for stenoparib as monotherapy, prompting Allarity to halt further enrollment in this trial to enable and accelerate the development of a follow-on trial with FDA regulatory intent.

"Based on the substantial clinical benefit observed in the early stages of the trial, we have achieved proof of concept results that surpassed our initial expectations and provided the critical insights we were seeking," stated Thomas Jensen, CEO of Allarity Therapeutics. "Concluding the trial now is the most effective way to re-allocate our financial resources to develop a follow-on trial with the fastest route to regulatory submission for stenoparib. The patients enrolled in this trial are heavily pretreated, having undergone multiple prior treatments, often including PARP inhibitors. It is highly noteworthy that stenoparib, used in patients selected with the DRP® CDx, has delivered sustained clinical benefit for such very heavily pre-treated patients in the trial."

This Company's decision will not affect the ongoing treatment of current patients, as described in greater detail in Allarity's March 27, 2024, press release.

Allarity is committed to rapidly analyzing the trial data and plans to present more comprehensive data as early as possible in a clinical update. This early trial conclusion marks a significant milestone in developing stenoparib, reflecting Allarity's dedication to advancing stenoparib to address the urgent needs of advanced ovarian cancer patients.

About Advanced, Recurrent Ovarian Cancer

Advanced, recurrent ovarian cancer refers to the return of ovarian cancer after it has been treated. This condition typically occurs in the later stages of the disease, which are classified as stage III or IV at diagnosis. It is characterized by the cancer's resistance to treatment, making its management particularly challenging. The initial symptoms of ovarian cancer can be very subtle, leading to a late diagnosis in many cases.

The recurrence of ovarian cancer is not uncommon, and it significantly complicates the therapeutic landscape. The current main goals of treating advanced, recurrent ovarian cancer are to extend the patient's life while maintaining or improving their quality of life, as curative options are limited. Treatment strategies may involve a combination of surgery, chemotherapy, targeted therapy, and, in some cases, radiation therapy. However, the effectiveness of these treatments diminishes with each recurrence, highlighting the need for innovative approaches to manage the disease.

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.

Follow Allarity on Social Media
LinkedIn: https://www.linkedin.com/company/allaritytx/
X: https://twitter.com/allaritytx

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 potential benefits of stenoparib for patients with advanced ovarian cancer, the DRP®, the Company's plans to rapidly advance towards a registration-focused clinical trial, and the expected timing of the release of comprehensive trial data. 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 regain compliance with the minimum bid price requirement and maintain its listing on Nasdaq, 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, the risk that the results of previously conducted studies will not be repeated or observed in ongoing or future studies involving our therapeutic candidates, and the risk that the current COVID-19 pandemic will impact the Company's current and future clinical trials and the timing of the Company's preclinical studies and other operations. 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 8, 2024, 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.

###

Company Contact:
investorrelations@allarity.com

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