



Allarity's Early Phase 2 Stenoparib Data Indicates Clinical Benefit in Women with Advanced Ovarian Cancer Selected with DRP[®] Companion Diagnostic

- *All evaluable participants, with prior PARP inhibitor therapy and chemotherapy, showed significant tumor shrinkage including one complete response*
- *Early data follows Phase 2 dose optimization change from once-daily to twice-daily*

Boston (December 5, 2023) — Allarity Therapeutics, Inc. (“Allarity” or the “Company”) (Nasdaq: ALLR), a clinical-stage pharmaceutical company developing novel oncology therapeutics together with drug-specific DRP[®] companion diagnostics for personalized cancer care, today announced encouraging initial results from its ongoing Phase 2 clinical trial evaluating the efficacy of its PARP inhibitor, stenoparib, in women with advanced ovarian cancer (AOC). Of the five evaluable patients included in the initial data analysis, one patient experienced a complete response and the other four demonstrated stable disease.

Investigators prescreened women with AOC using Allarity's DRP[®]-Stenoparib CDx, a complex transcriptomic signature comprising 414 mRNA biomarkers indicative of response/resistance to the drug. Each woman was assigned a DRP[®]-score, and those with scores above 50%, which suggested a higher likelihood of benefiting from treatment with stenoparib, were selected for treatment. Selected patients received stenoparib in a twice daily (BID) dosing regimen (200 mg morning, 400 mg evening) under a change in protocol, implemented earlier in the year, from prior once-daily dosing of 600 mg. Allarity implemented the protocol change to optimize the drug exposure taking into account the half-life of stenoparib in patients.

Of the 22 patients screened with the DRP[®]-Stenoparib CDx, 17 DRP[®] positive patients were identified. Eleven women have entered treatment, and among the five evaluable participants assessed up to the data evaluation cut-off, there were early signs of clinical benefit in all cases:

- One patient experienced a complete response (CR) by scan (to be confirmed by second scan) and by decreased levels of CA125 (a biomarker of AOC).
- One patient experienced stable disease with tumor shrinkage of 19%.
- One patient experienced stable disease for more than 24 weeks with tumor shrinkage of 11%.
- Two patients experienced stable disease with tumor shrinkage of 8%.

All five patients had previously been treated with another PARP inhibitor. All five patients remain in treatment with stenoparib and the four that did not have complete responses are showing stable disease at this time.

"We are enthusiastic about these early, promising data since the observed clinical benefit indicates that stenoparib is active in advanced ovarian cancer patients selected with the DRP[®]-Stenoparib CDx, even though these women had prior PARP inhibitor therapy and chemotherapy. While still early, these data suggest that BID dosing of this drug, and the use of the DRP[®]-Stenoparib CDx for patient selection and treatment, may provide advanced ovarian cancer patients meaningful benefit. The DRP[®]-Stenoparib CDx, if approved, may provide clinicians with an important diagnostic to guide patient treatment in this hard-to-treat patient population," said Marie Foegh, M.D., Chief Medical Officer of Allarity.

The initial data readout is from an ongoing Phase 2 open-label, single-arm trial that Allarity is conducting at multiple sites in the U.S. and Europe. The goal of the study is to evaluate the anti-tumor effect of stenoparib as monotherapy in DRP[®]-selected patients with locally recurrent or metastatic ovarian cancer after previous PARP inhibitor and chemotherapy treatments. The primary endpoint is objective response rate (ORR). Allarity anticipates an interim data readout in Q1 2024.

The DRP[®]-Stenoparib CDx is a transcriptomic signature comprising 414 mRNA biomarkers that are collectively predictive of tumor sensitivity or resistance to stenoparib. Using the DRP[®] CDx to select likely responder patients while excluding likely resistant ones, Allarity aims to improve the benefit-risk ratio of stenoparib in metastatic or locally advanced ovarian cancer. The initial data from Allarity's ongoing DRP[®]-guided Phase 2 study of stenoparib suggests that the DRP[®]-Stenoparib CDx may identify a subset of AOC patients previously treated with a PARP inhibitor who may benefit from treatment with stenoparib. The DRP[®]-Stenoparib CDx is a clinical-stage companion diagnostic candidate and has not yet been approved by the U.S. FDA or the EU's EMA.

All preliminary data are subject to change until the final study data readout. Early trial results may not be a reliable indicator of subsequent trial results based on a larger patient population.

About Stenoparib

Stenoparib is an orally-available, small molecule dual-targeted inhibitor of PARP1/2 and telomerase maintenance enzymes (Tankyrase 1 and 2). At present, tankyrases are attracting significant attention as emerging therapeutic targets for cancer, principally due to their role in the *Wnt* signaling pathway. Aberrant *Wnt*/β-catenin signaling has been implicated in the development and progression of multiple cancers, potentially giving stenoparib a unique, dual tumor inhibitory action. Stenoparib was originally developed by Eisai Co. Ltd. and was

formerly known under the names E7449 and 2X-121. Allarity has the exclusive, global rights for the development and commercialization of stenoparib.

Some approved PARP inhibitors have recently been shown to be associated with less favorable survival outcomes than initially established. Allarity's Phase 2 trial data for stenoparib to date shows that the drug has much less myelotoxicity than the FDA approved PARP inhibitors. Specifically, in 42 evaluable women in Phase 2 studies with stenoparib, anemia (21%), neutropenia (2%) and thrombocytopenia (0%) was lower than the approved PARP inhibitor niraparib with anemia 51%, neutropenia in 20% and thrombocytopenia observed in 52% of 463 patients. Allarity anticipates that this lower myelotoxicity may make stenoparib a better candidate for combination with other drugs. Allarity is studying the therapeutic potential of stenoparib in combination with dovitinib (a pan-targeted kinase inhibitor) in an ongoing Phase 1b trial, with an anticipated data readout near early Q2 2024. The Company believes that stenoparib may have broad therapeutic potential in combination with other anti-tumor agents.

About Allarity Therapeutics

Allarity Therapeutics, Inc. (Nasdaq: ALLR) develops drugs for personalized treatment of cancer guided by its proprietary and highly validated companion diagnostic technology, the DRP[®] platform. The Company has a mature portfolio of three drug candidates: stenoparib, a PARP inhibitor in Phase 2 development for ovarian cancer, and in Phase 1 development for advanced solid tumors in a combination treatment with dovitinib, a pan-tyrosine kinase inhibitor (pan-TKI) that has previously been developed through Phase 3 in renal cancer; and IXEMPRA[®] (Ixabepilone), a microtubule inhibitor approved in the U.S. and marketed by R-PHARM U.S. for the treatment of second-line metastatic breast cancer, currently in Phase 2 development in Europe for the same indication. Additionally, the Company has rights in two secondary assets: 2X-111, a liposomal formulation of doxorubicin for metastatic breast cancer and/or glioblastoma multiforme (GBM), which is the subject of discussions for a restructured out-license to Smerud Medical Research International AS; and LiPlacis[®], a liposomal formulation of cisplatin and its accompanying DRP[®], being developed via a partnership with CHOSA Oncology AB for late-stage metastatic breast cancer. The Company is headquartered in the United States and maintains an R&D facility in Hoersholm, Denmark. For more information, please visit the Company's website at www.Allarity.com.

About the Drug Response Predictor – DRP[®] Companion Diagnostic

Allarity uses its drug-specific DRP[®] to select those patients who, by the genetic signature of their cancer, are found to have a high likelihood of responding to the specific drug. By

screening patients before treatment, and only treating those patients with a sufficiently high DRP[®] score, the therapeutic response rate can 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 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 in 37 out of 47 clinical studies that were examined (both retrospective and prospective), including ongoing, prospective Phase 2 trials of Stenoparib and IXEMPRA[®]. 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 peer-reviewed literature.

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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 Allarity’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 related to the expected availability of capital to fund its anticipated clinical trials, statements related to advancing dovitinib in combination with stenoparib or another therapeutic candidate or other approved drug, any statements related to ongoing clinical trials for stenoparib as a monotherapy or in combination with another therapeutic candidate for the treatment of advanced ovarian cancer, or ongoing clinical trials (in Europe) for IXEMPRA[®] for the treatment of metastatic breast cancer, statements relating to the effectiveness of the Company’s DRP[®] companion diagnostics platform in predicting whether a particular patient is likely to respond to a specific drug, and statements related to the Company’s ability to regain compliance with the Nasdaq Listing Rule. 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 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, dovitinib 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 October 30, 2023, as amended and our Form 10-K annual report on file with the Securities and Exchange Commission, available at the Securities and Exchange Commission'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 Securities and Exchange Commission. 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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