

## **Allarity Therapeutics Makes Strategic Pivot to Focus Solely on Accelerating Stenoparib Toward Regulatory Approval in Advanced Recurrent Ovarian Cancer**

- *The stenoparib Phase 2 monotherapy trial in advanced, recurrent ovarian cancer continues to show promise, prompting shift in resources to accelerate stenoparib development*
- *Further development of IXEMPRA® and dovitinib is de-prioritized*
- *The Company has been able to reduce costs materially*

**Boston** (March 27, 2024) — Allarity Therapeutics, Inc. (“Allarity” or the “Company”) (NASDAQ: ALLR), a clinical-stage pharmaceutical company dedicated to developing personalized cancer treatments, today announced a strategic pivot aimed at advancing its clinical-stage candidate stenoparib, a novel PARP/Tankyrase dual inhibitor, toward registration in advanced recurrent ovarian cancer, leveraging its DRP® platform to identify and enroll only the patients most likely to derive clinical benefit.

This decision is the outcome of an extensive analysis of the Company’s strategic opportunities, initiated immediately after Thomas Jensen stepped into his role as Interim CEO in early December 2023. In partnership with Executive Advisor Jeremy R. Graff, PhD and in agreement with the Board of Directors, this analysis was meticulously carried out with a dual objective: to rapidly channel the Company’s proprietary DRP® technology towards benefiting a patient population with an unmet medical need while at the same time taking the clinical risk/reward balance as well as commercial and regulatory probabilities of success into consideration.

This decisive shift in priorities is driven by the compelling initial data from the Phase 2 monotherapy trial evaluating stenoparib in advanced, recurrent ovarian cancer patients, as announced on December 5, 2023.

For this trial, 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.

Emerging and maturing data continue to show that the clinical benefit and duration on stenoparib are substantially exceeding expectations:

- Clinical benefit has now exceeded 20 weeks for each of the five patients originally mentioned in the December release, with the first patient on trial remaining on treatment for more than ten months.
- The Complete Responder, referenced in the December release, has confirmed continued response through multiple additional scans and remains on therapy.
- Durable clinical benefit is evident in patients with:
  - Platinum-sensitive or resistant disease.
  - Homologous repair proficient or deficient tumors; and
  - both BRCA-wt or mutant cancers.
- These points highlight the differentiated mechanism of therapeutic action for stenoparib and accentuate the benefit of pre-selecting patients with DRP®.

These data have prompted the Company to funnel its finances and internal resources to accelerate stenoparib development for this advanced patient population.

Interim CEO of Allarity Thomas Jensen stated, “There remains a clear unmet medical need in patients with advanced ovarian cancer whose treatment options are limited to standard, older chemotherapies that provide limited benefit and come with significant toxicity. Based on the favorable tolerability with stenoparib and the emerging clinical benefit evident in our patients so far, we have decided to focus on re-tooling our company to accelerate development of stenoparib toward registration as quickly as possible for these desperately ill patients.”

As part of this strategic shift, the Company will deprioritize the other clinical trials for dovitinib and IXEMPRA®.

An additional outcome of the strategic review is that Allarity Therapeutics has been able to materially reduce its ongoing costs and cash burn and still prioritize stenoparib to better align with its new strategic priorities.

Several factors outside the Company have been included in the above-mentioned analysis of the Company’s strategic opportunities. This includes that the PARP inhibitor market, expected to reach \$22 billion in revenue by 2028, has historically seen significant partnerships and acquisitions. A recent notable example occurred earlier this year with Merck KGaA’s agreement with Jiangsu Hengrui Pharmaceuticals, involving an upfront payment of approx. \$176 million for a PARP inhibitor (HRS-1167) and an antibody-drug conjugate, potentially altogether totaling around \$1.5 billion. In terms of availability of treatments, 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. Extensive clinical experience with stenoparib has continuously shown a favorable toxicity profile. In addition, stenoparib is unique in its mechanism of action, inhibiting PARP as well as the novel cancer target, tankyrase. Tankyrase inhibition would restrain the WNT pathway, which is commonly upregulated not only in ovarian cancers but in many other solid cancers. Given the unique, dual mechanism of action for stenoparib—coupled with its favorable safety profile—stenoparib may represent the next-generation alternative in the evolving market for advanced ovarian cancer patients.

### **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/ $\beta$ -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 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 in 37 out of 47 clinical studies that were examined (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](http://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 related to any statements related to the de-prioritization of the other clinical trials for dovitinib and IXEMPRA®, and any statements concerning an acceleration of the stenoparib development. 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 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 (the “SEC”), available at the SEC’s website at [www.sec.gov](http://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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