



Press release

## Allarity Therapeutics Provides Updates for IXEMPRA and Stenoparib Phase 2 Monotherapy Clinical Studies

*Efforts underway to accelerate patient recruitment and amend protocols to improve patient outcomes.*

*Interim data readouts for both studies anticipated in H2 2023.*

**BOSTON — March 28, 2023 –** Allarity Therapeutics, Inc. (NASDAQ: ALLR) (“Allarity” or “the Company”), a clinical-stage pharmaceutical company developing novel oncology therapeutics together with drug-specific DRP<sup>®</sup> companion diagnostics for personalized cancer care, today announced updates to its ongoing phase 2 clinical programs evaluating IXEMPRA<sup>®</sup> and stenoparib as monotherapies.

For both IXEMPRA and stenoparib monotherapy trials, Allarity is taking steps to accelerate patient recruitment to support the goals for interim data readouts by the end of 2023. Due to slower than anticipated patient enrollment in both studies, owing in part to impacts of the COVID pandemic on trial site staffing, Allarity has expanded its collaboration with multiple contract research organizations (CROs) to substantially increase the number of active trial sites. The Company has also made changes to the clinical trial protocols to increase the availability of eligible participants for both monotherapy studies.

*“Patient recruitment in oncology clinical trials is an ongoing challenge and has delayed target date readouts across our sector. I am optimistic that our ongoing efforts to address this challenge will make a positive impact on our goal of providing interim data readouts in our ongoing Phase 2 studies by year’s end,”* said James G. Cullem, Chief Executive Officer of Allarity Therapeutics. *“Similarly, our trial protocol amendments reflect Allarity’s adaptability and commitment to seek optimal patient benefit in our clinical studies, guided by our unique DRP companion diagnostics, to select and treat most likely-to-respond patients.”*

Allarity is sponsoring an ongoing DRP-guided Phase 2 clinical trial evaluating IXEMPRA as a monotherapy in metastatic breast cancer in Europe. In addition to expanding its CRO partnerships, Allarity has implemented a trial protocol amendment that will lower the IXEMPRA-DRP companion diagnostic cut-off score, for enrollment, from 67% to 33%. As a result, Allarity anticipates that it will have sufficient DRP-positive patient enrollment to support an interim data readout from this study in late 2023.



The Company is also evaluating stenoparib as a monotherapy in ovarian cancer in an ongoing DRP-guided Phase 2 clinical trial. Based on early data (unpublished) from this study and in consultation with trial investigators and the Company's Scientific Advisory Board (SAB), Allarity has implemented a trial protocol amendment to change patient dosing from once daily dose to a BID regimen (twice daily). The aim is to improve therapeutic benefit by providing a consistent level of the drug in the patient throughout the treatment period. As a result of these efforts, Allarity anticipates that it will have sufficient DRP-positive patient enrollment to support an interim data readout from this study in late 2023.

The dosing-related protocol amendment in the Phase 2 stenoparib monotherapy trial also aligns with the BID dosing strategy for Allarity's [recently initiated Phase 1b combination study](#) of stenoparib and dovitinib for the treatment of advanced solid tumors.

## **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<sup>®</sup> 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<sup>®</sup> (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<sup>®</sup>, a liposomal formulation of cisplatin and its accompanying DRP<sup>®</sup>, 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](http://www.Allarity.com).

## **About the Drug Response Predictor – DRP<sup>®</sup> 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.

## Follow Allarity on Social Media

Facebook: <https://www.facebook.com/AllarityTx>

LinkedIn: <https://www.linkedin.com/company/allaritytx/>

Twitter: <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 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 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 dovitinib or any of our*



*other therapeutic candidates 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 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](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 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.*

###

Company Contact:

Thomas Jensen  
Senior V.P. of Investor Relations  
[investorrelations@allarity.com](mailto:investorrelations@allarity.com)

U.S. Media Contact:

Mike Beyer  
Sam Brown, Inc.  
+1 (312) 961-2502  
[mikebeyer@sambrown.com](mailto:mikebeyer@sambrown.com)

EU Media Contact:

Thomas Pedersen  
Carrotize PR & Communications  
+45 6062 9390  
[tsp@carrotize.com](mailto:tsp@carrotize.com)