



## **Initial Data from Allarity’s Phase 2 Trial of IXEMPRA® Indicate Potential for Improved Clinical Benefit in DRP®-Selected Metastatic Breast Cancer Patients**

**Boston, MA** (July 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 initial results from its European Phase 2 clinical trial evaluating the efficacy of IXEMPRA® in metastatic breast cancer (mBC) patients selected with the DRP®-IXEMPRA® companion diagnostic (CDx) candidate. Researchers prescreened mBC patients using Allarity’s DRP®-IXEMPRA® CDx, a complex transcriptomic signature comprising multiple mRNA biomarkers of drug response/resistance. Patients were assigned a DRP®-score, and those with scores above 67% were selected for treatment with IXEMPRA®.

Of the 36 patients screened with the DRP®-IXEMPRA® CDx, investigators identified five DRP® positive patients. Among the evaluable patients assessed up to the data evaluation cut-off, there were promising signs of clinical benefit in four out of four evaluable cases:

- One partial responder (PR) (tumor shrinkage of 66%).
- One partial responder (PR) (tumor shrinkage of 59%).
- One patient experienced 24 weeks of stable disease.
- One patient experienced 19 weeks of stable disease.

*“We are enthusiastic about these promising very early trial results since the observed clinical benefit rate exceeds what has been historically observed for IXEMPRA® treatment without the DRP®-IXEMPRA® CDx patient selection. While still early, these data suggest that the use of the DRP®-IXEMPRA® CDx for patient selection and treatment may help identify mBC patients most able to benefit from this course of treatment. Accordingly, the DRP®-IXEMPRA® CDx, if approved, may provide clinicians with an important diagnostic to guide patient treatment in this hard-to-treat population,”* said Marie Foegh, M.D., Chief Medical Officer of Allarity.

The study is in a very early stage of an ongoing open-label, single-arm trial, at multiple sites in Europe, evaluating the anti-tumor effect of IXEMPRA<sup>®</sup> in patients with locally recurrent or metastatic breast cancer after previous chemotherapies, including a taxane and an anthracycline. The included patients received a maximum of three prior lines of chemotherapies in the metastatic setting. Allarity recently amended the clinical trial protocol, lowering the DRP<sup>®</sup> cut-off score in order to include more likely responder patients while still excluding those unlikely to respond to the drug. The ultimate objective is to further refine the DRP<sup>®</sup>-IXEMPRA<sup>®</sup> CDx criteria and broaden the enrollment of mBC patients who may substantially benefit from this treatment. The Company anticipates an additional interim data readout before the end of this year.

The DRP<sup>®</sup>-IXEMPRA<sup>®</sup> CDx is a transcriptomic signature comprising 191 mRNA biomarkers that are collectively predictive of tumor sensitivity or resistance to IXEMPRA<sup>®</sup>. Using the DRP<sup>®</sup> CDx to select likely responder patients while excluding likely resistant ones, Allarity aims to improve the benefit-risk ratio of IXEMPRA<sup>®</sup> in metastatic or locally advanced breast cancer. The U.S. FDA-approved IXEMPRA<sup>®</sup> label currently indicates a monotherapy efficacy with an objective response rate (ORR) of 12.4% and a clinical benefit rate (CBR) of 24.8% in metastatic or locally advanced breast cancer. However, the initial data from the ongoing DRP<sup>®</sup>-guided Phase 2 study of IXEMPRA<sup>®</sup> suggest that the DRP<sup>®</sup>-IXEMPRA<sup>®</sup> CDx may identify a subset of patients who potentially have an improved ORR and CBR as compared to monotherapy efficacy indicated by the U.S. FDA-approved label for the drug. The DRP<sup>®</sup>-IXEMPRA<sup>®</sup> CDx is a clinical stage companion diagnostic candidate and has not yet been approved by the U.S. FDA or the EMEA. Early trial results are insufficient to show statistical significance and may not be a reliable indicator of subsequent trial results based on a larger patient population.

IXEMPRA<sup>®</sup> was originally developed by Bristol Myers Squibb and is approved for metastatic breast cancer patients in the U.S., where it is marketed by R-PHARM U.S., LLC. Allarity has the exclusive option rights for the development and commercialization of IXEMPRA<sup>®</sup> in Europe.

Allarity's Chief Executive Officer, James G. Cullem, further stated, *"We are encouraged by these promising, early clinical data suggesting that mBC patients selected for treatment with IXEMPRA<sup>®</sup> using our DRP<sup>®</sup> companion diagnostic candidate for the drug may have substantially improved clinical benefit versus unselected patients. Allarity looks forward to fully enrolling and completing our ongoing Phase 2 trial for IXEMPRA<sup>®</sup>, and remains enthusiastic about advancing this program towards market approval in Europe and, if approved, providing European mBC patients with first-time access to this beneficial drug."*

## **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 clinical-stage pipeline 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<sup>®</sup> 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<sup>®</sup> score, the therapeutic response rate can be significantly increased. The DRP<sup>®</sup> 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<sup>®</sup> is based on messenger RNA from patient biopsies. The DRP<sup>®</sup> 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<sup>®</sup>. The DRP<sup>®</sup> 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 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.*

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