



PLOS ONE Publishes Data on Allarity Therapeutics' DRP[®] Companion Diagnostic for Dovitinib

- *The DRP[®]-Dovitinib companion diagnostic demonstrated an ability to identify advanced renal cell carcinoma patients that have improved clinical benefit from dovitinib treatment, as compared to unselected patients*

BOSTON (August 30, 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, announced today the publication of its clinical validation of a novel drug-specific DRP[®]-companion diagnostic (CDx) for dovitinib in the peer-reviewed journal PLOS ONE. Data showed that the DRP[®]-Dovitinib CDx was able to identify a subgroup of advanced renal cell carcinoma (RCC) patients that have improved clinical benefit from treatment with dovitinib, as compared to unselected patients. PLOS ONE published the paper online today titled, "[A novel drug-specific mRNA biomarker predictor for selection of patients responding to dovitinib treatment of advanced renal cell carcinoma and other solid tumors.](#)"

"Having our work published in PLOS ONE underscores the importance and potential impact of our DRP[®]-Dovitinib CDx in oncology," said Allarity's Chief Scientific Officer and Study Author Dr. Steen Knudsen. "This is the first validated predictive biomarker in renal cell carcinoma, a long-standing goal in potentially improving the treatment of these patients. An additional prospective trial would be required before RCC patients that are candidates for dovitinib can benefit from this diagnostic breakthrough. This DRP[®] publication marks yet another important step forward in Allarity's mission to redefine cancer treatment paradigms and realize true personalized cancer care."

Dovitinib is a pan-targeted kinase inhibitor (pan-TKI) formerly [developed through Phase 3 clinical studies](#). The DRP[®]-Dovitinib CDx is a complex transcriptomic signature comprising 58 mRNA biomarkers that are collectively predictive of tumor response to the drug. In the study evaluating pre-treatment biopsies of 135 advanced RCC patients, the

DRP[®] positive subgroup (indicating that the patient was likely to respond) (N=49) had a median overall survival of 15 months (96% CI 12.94-26.25), whereas the DRP[®] negative subgroup (N=86) had a median overall survival of 9.13 months (95% CI 7.49-13.2). The hazard ratio was 0.60 (95% CI 0.39-0.91).

In addition to the 135 RCC biopsies, the DRP[®]-Dovitinib showed equally promising data in a number of other solid tumors, such as hepatocellular carcinoma (HCC), thereby demonstrating that it is independent of tumor type and has applicability beyond RCC.

The PLOS ONE article is Allarity's 14th peer-reviewed publication of data from clinical validations of DRP[®] companion diagnostics for a range of different cancer therapeutics, further establishing the robustness of the DRP[®] platform.

Dovitinib has been the focus of numerous clinical studies, showing promising properties as an anti-cancer agent, but is not yet approved for the treatment of any cancer type. It is currently being advanced by Allarity [in an ongoing Phase 1b clinical study](#) exploring the potential synergy of dovitinib and stenoparib (a PARP inhibitor) for the treatment of advanced solid tumors, including ovarian cancer. In addition, [in partnership with Allarity](#), Oncoheroes Biosciences has an ongoing program to develop dovitinib, together with the DRP[®]-dovitinib CDx, as a treatment for pediatric osteosarcoma.

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,” “towards,” “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 maintain

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, 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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