**Press release**

# Allarity Therapeutics Submits New Drug Application (NDA) to the U.S. FDA for Dovitinib for Third-Line Treatment of Renal Cell Carcinoma (RCC)

*Marks Allarity's first regulatory application for marketing approval for one of its prioritized oncology pipeline programs*

*NDA is supported by Allarity's previously-filed pre-market approval (PMA) submission to the FDA for the Dovitinib-DRP® companion diagnostic to select RCC patients most likely to respond to the drug*

**Cambridge, MA U.S.A. (December 22, 2021)** — Allarity Therapeutics, Inc. ("Allarity" or the "Company") (Nasdaq: ALLR) today announced the submission of a new drug application (NDA) with the U.S. Food and Drug Administration (FDA) seeking marketing approval for dovitinib for the third-line treatment of renal cell carcinoma (RCC) patients.

The Company's NDA filing is supported by its prior PMA submission with the FDA for use of Dovitinib-DRP®, the Company's validated companion diagnostic for the drug, to select and treat RCC patients most likely to respond to dovitinib.

Allarity's CEO Steve Carchedi noted, "*This NDA submission for dovitinib, in connection with the Dovitinib-DRP® companion diagnostic, is a historic milestone for our Company and an important step for late-stage renal cell carcinoma patients awaiting new treatment options. Over the past decade, we have worked diligently to advance our novel oncology therapeutics pipeline together with our unique DRP® diagnostic technology to realize the promise of personalized cancer care for patients. We greatly look forward to the approval of dovitinib and to introducing the clinical value of DRP® companion diagnostics to oncologists and their patients."*

Dovitinib is a small molecule, pan-tyrosine kinase inhibitor in-licensed from Novartis, and is Allarity's most advanced clinical therapeutic candidate. The drug has previously shown clinical activity in a number of cancer indications, including RCC, gastrointestinal stromal tumors (GIST), endometrial cancer, metastatic breast cancer, and hepatocellular carcinoma (HCC). The Company expects to further evaluate the therapeutic benefit of dovitinib in one or more of these additional indications, either as a monotherapy or in combination with other oncology therapeutics.

*"As a clinical oncologist looking for new therapies for my RCC patients, I am enthusiastic about Allarity's NDA filing together with its Dovitinib-DRP(R) companion diagnostic,"* stated Professor Roberto Pili, M.D., Associate Dean for Cancer Research and Integrative Oncology at the University at Buffalo Jacobs School of Medicine and Biomedical Sciences. *"These patients, and their treating oncologists, are greatly in need of new precision medicines, coupled with validated companion diagnostics, to help select and treat the most likely responders. I look forward to working with Allarity to advance this new personalized cancer care approach for RCC patients."*

Allarity's unique and clinically-validated DRP® companion diagnostics platform enables the prediction of whether a particular cancer patient is likely to respond to treatment with dovitinib, in addition to a broad range of anti-cancer drugs. DRP® drug response assessments for an individual patient are made based on a biopsy from the patient's tumor. The Dovitinib-DRP® companion diagnostic is intended to be used to identify patients with later-stage renal cell carcinoma (RCC) who, by the gene expression signature of their tumor, are identified as having a high likelihood of responding to dovitinib. By identifying and treating only those RCC patients most likely to respond to dovitinib, and avoiding treatment of those RCC patients likely to not respond to the drug, Allarity aims to improve treatment options for patients and their treating oncologist to improve therapeutic benefit.

## 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 five drug candidates, including: Stenoparib, a PARP inhibitor in Phase 2 development for ovarian cancer; Dovitinib, a pan-TKI submitted for NDA review by the FDA for 3rd line treatment of renal cell carcinoma; IXEMPRA® (Ixabepilone), a microtubule inhibitor approved in the U.S. for the treatment of 2nd line metastatic breast cancer and in Phase 2 development, in Europe, for the treatment of the same indication; LiPlaCis®, a liposomal formulation of cisplatin in Phase 2 development for metastatic breast cancer; and 2X-111, a liposomal formulation of doxorubicin in Phase 2 development for metastatic breast cancer and/or glioblastoma multiforme (GBM). The LiPlaCis® and 2X-111 programs are partnered, via out-license, to Smerud Medical Research International AS. In 2021, Allarity sold the global rights to Irofulven, a DNA-damaging agent in Phase 2 for prostate cancer, back to Lantern Pharma, Inc. The Company 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 relating to the Company's NDA submission for dovitinib and its PMA submission for the drug-specific DRP® companion diagnostic for dovitinib, any statements related to ongoing clinical trials for stenoparib for the treatment of advanced ovarian cancer, or ongoing clinical trials (in Europe) for IXEMPRA® for the treatment of metastatic breast cancer, and 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. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of 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 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 S-1 registration statement 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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*Company Contact:*

Jens Knudsen
Chief Financial Officer
investorrelations@allarity.com

*Investor Relations:*

Chuck Padala
LifeSci Advisors
+1 (646) 627-8390
chuck@lifesciadvisors.com

*U.S. Media Contact:*

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

*EU Media Contact:*

Thomas Pedersen
Carrotize PR & Communications
+45 6062 9390
tsp@carrotize.com