**Press release**

# Allarity Therapeutics Receives Refusal to File Letters from U.S. FDA

- *Refusal to File letters concern the new drug application for dovitinib and the DRP®-Dovitinib companion diagnostic pre-market approval application*

- *Allarity intends to seek guidance from the FDA on how to further advance dovitinib and its accompanying DRP®-Dovitinib companion diagnostic towards approval*

**Cambridge, MA U.S.A. (February 18, 2022)** — Allarity Therapeutics, Inc. ("Allarity" or the "Company"), a clinical-stage pharmaceutical company developing novel oncology therapeutics together with drug-specific DRP® companion diagnostics for personalized cancer care, today announced that the U.S. Food and Drug Administration ("FDA") has provided the Company with Refusal to File ("RTF") letters regarding the new drug application ("NDA") for dovitinib, and its accompanying pre-market approval ("PMA") application for the DRP®-Dovitinib companion diagnostic, for the third-line treatment of metastatic renal cell carcinoma ("mRCC").

Upon preliminary review, the FDA determined that the NDA, submitted on December 22, 2021, and the PMA application, submitted on April 2, 2021, were not sufficiently complete to permit substantive reviews. In the letter regarding the NDA, the FDA's cited reasons for the RTF decision primarily include, but are not limited to, that submitted clinical trial data do not enable a conclusion of efficacy based on non-inferiority data set. Given that the PMA and NDA were filed as related applications, the RTFs also apply to the DRP®-Dovitinib companion diagnostic.

Allarity intends to seek immediate guidance from the FDA, which potentially includes requesting a Type A meeting with the agency to clarify and respond to the issues identified in the RTF letters and seek additional guidance concerning information, data, and specific deliverables that the agency would require for a resubmitted NDA and PMA to be deemed complete. The Company anticipates that a new prospective clinical trial will be required to overcome the FDA's outstanding objections.

"We remain highly confident in the clinical profile of dovitinib, together with the DRP®-Dovitinib companion diagnostic, and remain committed to advancing this product candidate as a potential new treatment option for individuals with mRCC," said Allarity's CEO Steve Carchedi. "We are fully determined to work with the FDA staff as quickly as possible to address the open issues and clarify the path to successfully re-filing our applications."

## 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 being prepared for regulatory

advancement for the 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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