



FOR IMMEDIATE RELEASE

Allarity Therapeutics Provides Update on Dovitinib Program

- *Allarity has requested a Type C meeting with the FDA to discuss potential clinical paths to support approval of dovitinib in view of the regulatory agency's recent Refusal to File letters for the Company's NDA and related PMA*
- *Allarity intends to announce the results of the Type C meeting and its plans for further advancing dovitinib and its DRP[®]-Dovitinib companion diagnostic before end of Q3 2022*

Cambridge, MA U.S.A. (March 15, 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 provided an update on its lead dovitinib program.

On February 18, 2022, the Company announced that the U.S. Food and Drug Administration ("FDA") had 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"). In its announcement, Allarity stated that it intends to seek guidance concerning information, data, and specific deliverables that the agency would require for a resubmitted NDA and PMA to be deemed complete. The Company also stated that it anticipates that a new prospective clinical trial will be required to overcome the FDA's outstanding objections.

Following several weeks of analysis by Company leadership together with clinical and regulatory experts, Allarity has now filed a formal request with the FDA for a "Type C" meeting to further discuss potential clinical paths to support approval of dovitinib, together with its DRP[®]-Dovitinib companion diagnostic, in view of the FDA's recent RTFs. According to FDA guidelines, "A *Type C meeting is any meeting other than a Type A or Type B meeting between CBER or CDER and a sponsor or applicant regarding the development and review of a product.*" The Type C meeting is typically scheduled within 75 days of FDA receipt of the written meeting request. The Company anticipates providing a further update on the outcome of its FDA meeting and the future of the dovitinib program before the end of the third quarter of this year.

"We look forward to working closely with the FDA and we remain highly confident in the clinical profile of dovitinib, together with the DRP[®]-Dovitinib companion diagnostic. We are determined to further advance this product candidate as a potential new treatment option for cancer patients," said Allarity's CEO **Steve Carchedi**. *"With clarification from the FDA following our requested Type C meeting, we hope to have a clinical path forward with the goal of refiling our NDA and PMA once additional clinical data are in hand."*

“I remain enthusiastic about dovitinib, together with its DRP[®]-Dovitinib companion diagnostic, as a promising new treatment option for mRCC patients,” 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. Although the landscape of treatment options for later-stage mRCC is evolving to include combination therapies, I continue to see a potential place for dovitinib with its DRP[®] companion diagnostic in the treatment of these patients.”*

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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