



NEWS RELEASE

# Allarity Therapeutics Refocuses Oncology Pipeline Strategy Towards Combination Therapies

8/2/2022

New strategy aligns with ongoing shift in oncology standard-of-care towards combination therapies

Combination therapy focus expected to improve the Company's future funding and commercial prospects

New pipeline strategy follows Type C meeting held with FDA regarding dicitinib clinical development path for third-line mRCC

Press release

Cambridge, MA, U.S.A. (August 2, 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 its Board of Directors has mandated a refocus of the Company's oncology pipeline strategy away from development of monotherapies towards development of more promising and clinically relevant combination therapies.

Following a lengthy and in-depth analysis of current pipeline opportunities, clinical/commercial/ regulatory risks, development costs and timelines, expected availability of funding, and in consultation with Allarity's senior management, its Scientific Advisory Board (SAB), and external experts, Allarity's Board of Directors has concluded that refocusing the Company's pipeline to development of combination therapies will accomplish the following:

- Align with the ongoing shift in cancer therapy standard-of-care away from monotherapies toward combination therapies, which are increasingly driving market opportunities and which have shown dramatic increases in patient benefit.
- Strengthen the Company's ability to attract additional funding from institutional life science investors, which is necessary to support the Company's clinical development activities and future success.
- Significantly broaden the Company's possibilities for future commercial partnering with larger pharmaceutical companies to maximize the value of its pipeline assets and DRP® platform technology.
- Improve the likelihood of clinical and commercial success of the Company's pipeline assets.

The Board's decision also takes into account feedback that the Company recently received from the U.S. Food and Drug Administration (FDA) from a Type C advisory meeting held in Q2 2022, regarding a potential Phase 3 clinical development path for dovitinib as a monotherapy third-line treatment for metastatic renal cell carcinoma (mRCC). As part of that feedback, the FDA has indicated, under its recent Project Optimus guidelines relating to new optimization of therapeutic dosing, that the Company will likely need to conduct a new dosing study for dovitinib prior to Company conducting any future Phase 3 studies that could enable the submission of a new NDA. Conducting a new dosing study for dovitinib, if required, would further delay the initiation and completion of a future Phase 3 study, and increase the cost, time, and market risks of advancing dovitinib as a monotherapy in the increasingly competitive indication of third-line mRCC. In view of those delays and increased costs/risks, the Company has determined that advancing dovitinib as a monotherapy in adults is no longer commercially viable or in the best interests of its shareholders. However, the drug will continue to be externally developed, via the partnership with OncoHeroes Biosciences, as a potential monotherapy for pediatric cancers.

As part of its new strategic pipeline focus, the Company has announced it expects to initiate enrollment in a Phase 1b/2 study of its PARP inhibitor, stenoparib, in combination with its pan-TKI, dovitinib, for the second-line or later treatment of metastatic ovarian cancer by or before Q4 2022. The Company plans to have trial sites in both the U.S. and Europe. The Company is currently evaluating other potential Phase 1b/2 studies for either stenoparib or dovitinib combined with another oncology therapeutic, including the mRCC space. Allarity's ongoing Phase 2 studies of stenoparib, as monotherapy for ovarian cancer, and IXEMPRA®, as monotherapy for metastatic breast cancer, will continue through their interim data readouts, now anticipated in Q4 2022 and Q1 2023, respectively. All pipeline development activities will continue to utilize drug-specific DRP® companion diagnostics to guide patient selection and treatment.

"We are grateful for the clear guidance from our Board on the best path our Company can take to advance our mission to improve cancer patient care by realizing the promise of truly personalized medicine," said James G.

Cullem, J.D., Interim Chief Executive Officer of Allarity. "New therapeutic development is recognized as a very challenging endeavor, with constantly shifting regulatory requirements, standard-of-care improvements as new drugs come to market, and financial and market challenges. It has therefore become increasingly difficult to advance development of monotherapies in increasingly competitive therapeutic spaces. I am confident that our strategic shift of focus and resources is the correct path forward for Allarity given the current regulatory and market realities, and will best leverage our DRP® companion diagnostics to match the right patients to the cancer therapeutic from which they will most likely benefit."

Dr. Duncan Moore, Ph.D., Allarity's Board Chairman, stated: "It is clear to our Board, following lengthy discussions with our management team, SAB, and additional key opinion leaders, that the current, and future, standard of care in cancer treatment is combination therapies, and that, increasingly, the field and market opportunities are shifting away from monotherapy approaches. In view of that key shift, and in consideration of many other market and financial factors, as well as the FDA's new Project Optimus drug dose optimization requirements, we have determined that Allarity's future pipeline must focus on the development of promising combination therapy approaches utilizing its current assets together with DRP® companion diagnostics. I remain very enthusiastic about the Company's vision, mission, and strategy, and this strategic refocus towards combination therapies, together with our core DRP® technology, will give Allarity the best chance of success as well as best optimize shareholder return on investment."

#### 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; dovitinib, a post-Phase 3 pan-tyrosine kinase inhibitor; and IXEMPRA® (Ixabepilone), a microtubule inhibitor approved in the U.S. for the treatment of second-line metastatic breast cancer and 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 in Phase 2 development 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 ApS, an affiliate of Smerud Medical Research International, 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 ® 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 related to the expected availability capital to fund its anticipated clinical trials, statements related to advancing dovitinib in combination with 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, 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](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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Attachment

- **Allarity Press Release Pipeline Strategy Change August 2022**

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