



Press release

Allarity Therapeutics Doses First Patient in Phase 1b Clinical Trial Evaluating Dovitinib and Stenoparib Combination in Advanced Solid Tumors

Company anticipates that the combination of pan-TKI dovitinib and PARP inhibitor stenoparib may generate synergistic anti-cancer activity

Program initiation marks key milestone in Allarity's clinical strategy shift towards combination therapies

BOSTON, Mass - March 20, 2023 — Allarity Therapeutics, Inc. (Nasdaq: ALLR) (“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 it has dosed the first patient in a Phase 1b clinical study evaluating the combination of stenoparib and dovitinib for the treatment of advanced solid tumors, including ovarian cancer.

Currently, approximately 70 percent of patients diagnosed with ovarian cancer will experience recurrences.¹ However, PARP inhibitors have improved the treatment outlook for many patients who have completed initial treatment with surgery and platinum-based chemotherapy. The strategy underscoring Allarity’s combination of dovitinib and stenoparib is to address the unmet need of ovarian cancer patients, as well as those with other solid tumors, who currently do not benefit from the existing PARP inhibitor treatments.

“Having investigated novel combinations of anticancer agents, including a PARP inhibitor and an anti-angiogenic therapeutic, we have seen improved efficacy. Combining a PARP inhibitor with a pan-tyrosine kinase (PTK) inhibitor, we are also anticipating efficacy in homologous recombination proficient tumors” stated [Kathleen N. Moore](#), MD, MS, Associate Director of Clinical Research, Director of the Oklahoma TSET/Sarah Cannon Phase I Drug Development Unit, Professor of the Section of Gynecologic Oncology at the Stephenson Cancer Center, and the Principal Investigator for Allarity’s Phase 1b study. *“I look forward to working with patients and the clinical team at Allarity to determine if the particular combination of dovitinib and stenoparib can provide synergistic therapeutic benefits and improve outcomes for patients, including those with ovarian cancer.”*

¹ [Source: Ovarian Cancer Research Alliance](#)



Study Design

The two-part, open label multicenter Phase 1b program will first evaluate the safety and anti-cancer activity, and determine the maximum tolerated dose (MTD), of stenoparib administered twice a day in participants with advanced solid tumors. The second portion of the study will evaluate safety and anti-cancer activity and determine the MTD of dovitinib when given in combination with the MTD of stenoparib determined in the first cohort.

The Phase 1b trial is designed with a target enrollment of up to 36 patients with advanced solid tumors, focusing on specific tumor types that Allarity anticipates will be most responsive to the drug combination. Researchers will analyze patient tumor samples retrospectively using Allarity's DRP[®] companion diagnostics for stenoparib and dovitinib. The purpose of this analysis is to further validate the DRP[®] companion diagnostics in advance of an anticipated DRP[®]-guided Phase 2 trial of the dovitinib and stenoparib combination in second line or later metastatic ovarian cancer, targeted for H2 2024.

Study Rationale

Stenoparib is a small molecule, dual-targeted inhibitor of Poly ADP-Ribose Polymerases (PARP 1 and 2) and tankyrase 1 and 2. It works by limiting cancer's ability to repair single stranded DNA breaks within tumors, which in turn makes tumor cells more vulnerable to death (apoptosis). Dovitinib is a pan-tyrosine kinase inhibitor (pan-TKI), and its mechanisms of action (MOA) works in part to block the formation of new blood vessels that supply a tumor with nutrients and oxygen (anti-angiogenesis), as well as to alter homologous recombination (HR) proficient to HR deficient tumors by down-regulation of HR. As these combined MOAs serve to promote cancer cell vulnerability and restrict blood flow necessary to fuel cancer growth and repair, Allarity believes the combination may cause synthetic lethality, thereby increasing the chances of cancer cell death and providing synergistic, enhanced anti-tumor activity.

"I am very pleased that we have initiated our first combination therapy trial, an important milestone in our pipeline strategy focused on identifying unmet needs in which combination therapies may benefit patients with hard-to-treat cancers," said James G. Cullem, Allarity's Chief Executive Officer. *"Given that we own both of these assets, the development of this combination benefits from our existing drug supply and manufacturing pathways, and, subject to our ability to raise additional capital to support the study, should enable us to efficiently conduct the Phase 1b dosing portion of the study with an anticipated data readout in the first half of 2024."* Mr. Cullem further noted, *"Our clinical team, together with Dr. Moore and our Scientific Advisory Board, have smartly designed this Phase 1b study to both identify early signs of therapeutic benefit in likely-to-respond tumor types, as well as to assess the ability of Allarity's DRP[®] companion diagnostics for stenoparib and dovitinib to identify responder patients."*



The initiation of a new combination trial marks a previously-announced shift in the Company's clinical-stage activities toward development of combination therapies (that are dependent upon the Company's ability to raise sufficient capital to support these new trials), and reflects the Company's commitment to delivering innovative treatments that address unmet medical needs and improve patient outcomes.

Allarity holds exclusive, global commercial rights to both dovitinib and stenoparib.

About the Drug Response Predictor – DRP[®] Companion Diagnostic

Allarity uses its drug-specific DRP[®] companion diagnostic to select those patients who, by the genetic signature of their cancer, are found to have a high likelihood of responding to a specific drug. By screening patients before treatment, and only treating those patients with a sufficiently high DRP[®] score, Allarity believes that the therapeutic response rate can be significantly increased. The DRP[®] method builds on the comparison of sensitive versus 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 demonstrated 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 anticancer drugs, has been extensively published in peer reviewed literature.

About Allarity Therapeutics

Allarity Therapeutics, Inc. (Nasdaq: ALLR) develops drugs for personalized treatment of cancer guided by its proprietary and highly developed 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 pan-tyrosine kinase inhibitor previously developed in renal cancer through Phase 3; 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, which is 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.

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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 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 regain 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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