

Press Release

## Allarity Therapeutics to test activity of its PARP inhibitor, stenoparib, as a potential therapy for new highly infectious Strain B.1.1.7 of Coronavirus

**Hørsholm, Denmark (26 January 2021)** – Allarity Therapeutics A/S (“Allarity” or the “Company”) today announced plans to further test the antiviral activity of stenoparib, its PARP inhibitor, against SARS-CoV-2 lineage B.1.1.7, also known as Coronavirus Variant B117 (the “British variant”), at the Pathogen and Microbiome Institute at Northern Arizona University (NAU).

The virus variant was labelled “Variant of Concern 202012/01” by Public Health England (PHE), an agency of the UK Department of Health & Social Care, in a publication on 21 December 2020, after it was found to have spread rapidly within the UK, and the PHE assessed that this variant has a substantially increased transmissibility compared with other Coronavirus variants. This variant has also been identified in the U.S. in several states.

Based on the previous positive pre-clinical test results with stenoparib as a treatment of SARS-CoV-2, announced on 26 August 2020, Allarity Therapeutics will now test the similar ability of stenoparib to block the infection and replication of SARS-CoV-2 lineage B.1.1.7. The tests will be conducted at the Pathogen and Microbiome Institute, a leading U.S. infectious disease test center.

The previous series of pre-clinical studies, for SARS-CoV-2, with results first announced on 26 August 2020, have since been published in the peer-review journal mBio ([mbio.asm.org](https://www.mbio.org)) on 19 January 2021. The data show that stenoparib inhibits SARS-CoV-2 as a single agent. In addition, stenoparib in combination with remdesivir was active in inhibiting coronavirus *in vitro*. The concentration of stenoparib required for virus inhibition was lower in the combination study than in the single agent study. The two drugs target the virus through unique but different mechanisms of action.

Stenoparib (formerly 2X-121, E7449) is a small molecule, targeted inhibitor of Poly ADP-Ribose Polymerase (PARP), a key DNA damage repair enzyme active in tumors, which was originally developed by the pharmaceutical company Eisai. Besides investigating whether stenoparib has therapeutic potential as a possible treatment of SARS-CoV-2 and the British variant (lineage B.1.1.7), Allarity Therapeutics is also currently evaluating stenoparib for the treatment of advanced ovarian cancer in a Phase 2 clinical trial at the Dana-Farber Cancer Institute (Boston, MA U.S.A.) using a DRP® companion diagnostic to guide patient enrollment and improve therapeutic outcome.

“We are excited to be one of the first few companies to be working on a possible treatment for the new variant by further testing, pre-clinically, the therapeutic potential of stenoparib against the British variant of Coronavirus, given the positive results of our prior pre-clinical tests of the drug as an anti-viral treatment for SARS-Cov-2,” said Steve R. Carchedi, CEO of Allarity Therapeutics. “We intend to work with FDA and NIH, as well as other funding sources, to advance stenoparib as soon as possible into clinical trials for the treatment of COVID-19 and/or the British variant. Exploring our novel drug as a promising new treatment for COVID-19 underscores our company commitment to develop new therapies for the improvement of patient care, and we are pleased to do whatever we can to provide a meaningful impact on solutions to this global pandemic.”

Paul Keim, NAU Regents’ Professor and PMI executive director, said “The emergence of SARS-CoV-2 variants is a challenge to our current approaches to COVID-19. They necessitate the validation of our diagnostics,

vaccines, and therapeutics against a panel of these new and dangerous strains. B.1.1.7, in particular, has to be included in order for us to choose the right approaches and drugs for this disease.”

Allarity Therapeutics has applied for stenoparib to become a part of what is popularly known as Operation Warp Speed, a partnership among components of the US government, including the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), as mentioned in a company announcement published on 14 December 2020. Specifically, Allarity Therapeutics has submitted a phase 2/3 protocol through the BARDA portal, and if this proposal is successful it may lead to a fully or partially government funded development process of stenoparib as a treatment of SARS-Cov-2.

### **About Allarity Therapeutics**

Allarity Therapeutics (Nasdaq First North Growth Market Stockholm: ALLR.ST) develops drugs for personalized treatment of cancer guided by its proprietary drug response predictor technology, the DRP<sup>®</sup> platform. The company has a mature portfolio of six drug candidates, including compounds in the pre-registration stage. The product portfolio includes: stenoparib (2X-121), a PARP inhibitor in Phase 2 for ovarian cancer; dovitinib, a pan-TKI advancing towards a new drug approval (NDA) for renal cell carcinoma; IXEMPRA<sup>®</sup> (Ixabepilone), a microtubulin inhibitor approved in the U.S. for the treatment of breast cancer; LiPlaCis<sup>®</sup>, a liposomal formulation of cisplatin in Phase 2 trials for breast and prostate cancer; 2X-111, a liposomal formulation of doxorubicin under manufacturing for Phase 2 in breast cancer; and Irofulven, a DNA damaging agent in Phase 2 for prostate cancer.

### **About Northern Arizona University**

Northern Arizona University is a higher-research institution providing exceptional educational opportunities in Arizona and beyond. NAU delivers a student-centered experience to its nearly 30,000 students in Flagstaff, statewide and online through rigorous academic programs in a supportive, inclusive and diverse environment. Dedicated, world-renowned faculty help ensure students achieve academic excellence, experience personal growth, have meaningful research opportunities and are positioned for personal and professional success.

### **About the Drug Response Predictor – DRP<sup>®</sup> Companion Diagnostic**

Allarity uses its drug specific DRP<sup>®</sup> 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, the response rate can be significantly increased. The DRP<sup>®</sup> method builds on the comparison of sensitive vs. resistant human cancer cell lines, including genomic information from cell lines combined with clinical tumor biology and prior clinical trial outcomes. DRP<sup>®</sup> is based on messenger RNA from the patient's biopsies. DRP<sup>®</sup> has proven its ability to provide a statistically significant prediction of the clinical outcome from drug treatment in cancer patients in nearly 40 clinical studies that were examined, including an ongoing, prospective Phase 2 trial. The DRP<sup>®</sup> platform can be used in all cancer types and is patented for more than 70 anti-cancer drugs.

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### **Forward-looking statements**

This announcement includes forward-looking statements that involve risks, uncertainties and other factors, many of which are outside of Allarity's control and which could cause actual results to differ materially from the results discussed in the forward-looking statements. Forward-looking statements include statements concerning Allarity's plans, objectives, goals, future events, performance and/or other information that is not historical information. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany the forward-looking statements. Allarity undertakes no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.

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This information is information that Allarity A/S is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for **publication on 26 January 2021**.