



Press release

## **Allarity Therapeutics Submits Premarket Approval Application to U.S. FDA for DRP® Companion Diagnostic for Dovitinib**

- Submission precedes expected NDA filing for dovitinib in 2021
- Premarket Approval will allow U.S. marketing of DRP-Dovitinib as companion diagnostic to dovitinib

**Hørsholm, Denmark (2 April 2021)** Allarity Therapeutics A/S (“Allarity” or the “Company”) today announced the submission of a premarket approval application (PMA) to the U.S. Food and Drug Administration (FDA) for DRP®-Dovitinib, the Company’s validated companion diagnostic for the drug dovitinib. Dovitinib is a small molecule, pan-tyrosine kinase inhibitor licensed from Novartis, and is Allarity’s most advanced clinical asset. This milestone marks the first time that Allarity has sought regulatory approval for one of its drug-specific DRP®s used to guide patient therapy.

Allarity’s unique DRP® biomarker technology makes it possible to predict whether a particular cancer patient is likely to benefit from treatment with dovitinib, in addition to a broad range of anti-cancer drugs. DRP® drug response assessments of the individual patients are done based on a biopsy from the patients’ tumors. The DRP®-Dovitinib is intended to be used to identify patients, suffering from renal cell carcinoma (RCC), who by the gene expression signature of their tumor are found to have a high likelihood of responding to dovitinib.

Allarity plans to file a New Drug Application (“NDA”) with the FDA for the approval of dovitinib for the treatment of renal cell carcinoma (kidney cancer) during 2021. If the FDA provides the anticipated premarket approval of the dovitinib DRP® as a companion diagnostic, as well as an NDA approval for dovitinib, Allarity will be able to market dovitinib to DRP®-selected RCC patients as an effective new therapy to treat their disease. The DRP® for dovitinib, if approved, will be the first complex, gene expression signature approved by the U.S. FDA as a companion diagnostic to guide patient selection for cancer therapy.

Allarity’s CEO, Steve Carchedi, noted “*Our current goal for dovitinib is to make it available to the group of RCC patients for whom a treatment with this particular therapeutic will be the most efficacious treatment for their disease. Today, marks a milestone for the advancement of our unique DRP® biomarker technology for dovitinib, and approval of our PMA will enable oncologists to select those patients who are high likelihood responders to this drug.*” Mr. Carchedi further stated: “*Later this year, I look forward to announcing our expected filing of a New Drug Application for dovitinib itself. Ultimately, if both of these filings are approved by the FDA, our Company will be positioned to significantly change how treatment of RCC will be conducted in the future, and help realize the promise of personalized medicine for these patients.*”

Steen Knudsen, Ph.D., CSO and Co-Founder of the Company, further stated, “*I am extremely pleased to reach the milestone event of our first regulatory approval application for a DRP® companion diagnostic, following our extensive work, over the past 15 years, developing, validating, and perfecting our DRP® technology. I look forward to our Company advancing dovitinib, in combination with the*

*Dovitinib-DRP®, through approval and to market, and to similarly advancing the rest of our oncology therapeutics pipeline with DRP® companion diagnostics in a true personalized medicine approach.”*

In October 2020 Allarity announced that the United States Patent and Trademark Office (USPTO) had issued a notice of allowance to the Company on its patent application no 16/444,881 titled “METHODS FOR PREDICTING DRUG RESPONSIVENESS IN CANCER PATIENTS” – directed to a DRP® biomarker for dovitinib.

### **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, the response rate can be significantly increased. The DRP® 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® is based on messenger RNA from the patient’s biopsies. DRP® 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® platform can be used in all cancer types and is patented for more than 70 anti-cancer drugs.

### **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® 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 U.S. NDA filing for renal cell carcinoma; IXEMPRA® (Ixabepilone), a microtubulin inhibitor approved in the U.S. for the treatment of breast cancer; LiPlaCis®, 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.

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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. Allarity’s clinical programs may be delayed or impacted by the ongoing global COVID-19 pandemic.

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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 2 April 2021**.