

Press release

## Allarity Therapeutics Gains Allowance from U.S. Patent and Trademark Office for New DRP® Biomarker Patents

**Hørsholm, Denmark (26 October 2020)** – Allarity Therapeutics A/S (“Allarity” or the “Company”) today announced that the United States Patent and Trademark Office (USPTO) has issued Notices of Allowance to the Company for three new DRP® biomarker patents in conjunction with use of several of its clinical pipeline drugs.

The USPTO has issued Notices of Allowance to the Company on the following three patent applications:

- U.S. Patent Application No.: 16/444,881, “METHODS FOR PREDICTING DRUG RESPONSIVENESS IN CANCER PATIENTS” – Directed to a DRP® biomarker for the Company’s cancer drug Dovitinib, which biomarker is in development by Company as a companion diagnostic to select high likely responders for Dovitinib.
- U.S. Patent Application No.: 15/858,703, “METHODS FOR PREDICTING DRUG RESPONSIVENESS IN CANCER PATIENTS” – Directed to a DRP® biomarker for Cisplatin, including the Company’s cancer drug LiPlaCis®, which biomarker is in development by Company as a companion diagnostic to select high likely responders for LiPlaCis®.
- U.S. Patent Application No.: 15/978,655, “METHODS FOR PREDICTING DRUG RESPONSIVENESS IN CANCER PATIENTS” – Directed to DRP® biomarkers for anthracyclines, including doxorubicin, epirubicin, and the Company’s cancer drug 2X-111, which biomarker is in partnered development by Smerud Medical Research International as a companion diagnostic to select high likely responders for 2X-111.

The allowance and imminent issuance of these three new DRP® biomarker patents further expands Allarity’s patent portfolio on unique, drug-specific DRP® biomarkers developed with its best-in-class and highly validated DRP® platform technology. The Company has now gained allowance and/or issuance of patents on more than 60 different DRP® biomarkers.

Dovitinib, originally developed by Novartis, addresses a significant unmet need for improved therapies for the treatment of renal cell carcinoma and is a potential therapeutic alternative to sorafenib. Allarity is currently preparing to file its first new drug application (NDA) with the U.S. Food and Drug Administration (FDA) for approval of dovitinib as a treatment for renal cell carcinoma (RCC), using its Dovitinib DRP® as a companion diagnostic to select and treat high likely responder patients. Dovitinib also has promising potential as a monotherapy in a number of other indications, including metastatic estrogen receptor (ER) positive breast cancer, hepatocellular cancer, endometrial cancer and gastrointestinal stromal tumors, as well as in combination therapy with other approved drugs, including immune checkpoint inhibitors.

LiPlaCis® is an advanced, targeted liposomal formulation of cisplatin, one of the world’s most widely used chemotherapies, being developed in partnership with Smerud Medical Research International AS for the treatment of metastatic breast cancer, using the Cisplatin DRP® as a companion diagnostic to select and treat high likely responder patients. The specific LiPlaCis® formulation allows delivery of the drug directly at tumor site, thereby increasing drug targeting at the tumor and reducing negative, off-target drug effects. LiPlaCis® has previously shown promising results in a Phase 2 study in DRP®-selected patients with late-stage metastatic breast

cancer (mBC). In August 2019, the U.S. FDA approved an investigational device exemption (IDE) application for use of the Company's LiPlaCis® DRP® companion diagnostic in a planned pivotal Phase 3 study in mBC.

2X-111 is an advanced, targeted liposomal formulation of doxorubicin, one of the world's most widely used chemotherapies, being developed in partnership with Smerud Medical Research International AS for the treatment of glioblastoma multiforme (GBM), using the Doxorubicin DRP® as a companion diagnostic to select and treat high likely responder patients. The specific 2X-111 formulation allows delivery of the drug across the blood-brain barrier (BBB) directly at the brain tumor site, thereby increasing drug targeting at the tumor and reducing negative, off-target drug effects. 2X-111 has previously shown promising results in a Phase 2 study in both GBM patients and patients with brain metastases of breast cancer.

**Steve Carchedi, CEO of the Company**, noted *"We see the allowance of these patents from the USPTO as further validation of the inventive importance of our core DRP® platform and its resulting, drug-specific companion diagnostics, which we believe will help bring the promise of personalized medicine to cancer patients. The issuance of these new patents on our dovitinib, LiPlaCis®, and 2X-111 programs solidifies our competitive advantage as we advance these promising cancer therapeutics to the market and to patients, and underscores our global leadership in the development and use of best-in-class companion diagnostics that are designed to match the right cancer patient to the right drug."*

**Steen Knudsen, Ph.D., CSO and Co-Founder of the Company**, further stated, *"I am pleased to see the USPTO's recognition of these three novel and valuable DRP® biomarkers, through allowance of these patents, as Allarity continues to develop and utilize such DRP® biomarkers as companion diagnostics to advance our therapeutic pipeline, including dovitinib, LiPlaCis®, and 2X-111 towards approval and to improve treatment options for cancer patients."*

#### **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 in post-Phase 3 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.

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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 October 2020**.