

Press release

Allarity Therapeutics Provides Update on Dovitinib Program

Hørsholm, Denmark (23 October 2020) – Allarity Therapeutics A/S (“Allarity” or the “Company”) today announced several updates related to its planned filing of a new drug application (NDA) with the U.S. Food and Drug Administration (FDA) for dovitinib, a pan-tyrosine kinase inhibitor (TKI) that is one of Allarity’s priority programs.

The Company is announcing an update on timing for its originally planned first NDA filing for dovitinib as a treatment for renal cell carcinoma (RCC). This NDA is based on non-inferiority to the approved drug sorafenib. The Company’s preparation of the application itself is progressing as scheduled, however the third-party contract manufacturer of the registration batch of the drug is experiencing delays, in part as a result of the ongoing coronavirus pandemic. A registration batch is a mandatory component of the NDA filing. Due to this reported delay, Allarity is now expecting to file the NDA in 2021.

Separately, the Company remains on track to file its first pre-market approval (PMA) application with the U.S. FDA for the use of the dovitinib DRP® companion diagnostic to select and treat likely responders to the drug. If regulatory authorities provide the expected PMA approval of the Dovitinib DRP® and an NDA approval of dovitinib, the Company believes it can make the drug available to DRP®-selected RCC patients as an effective new therapy to treat their disease.

Dovitinib, originally developed by Novartis, addresses a significant unmet need for improved therapies for the treatment of RCC, and is a potential therapeutic alternative to sorafenib. Annual sales of sorafenib, under the trade name Nexavar®, were approximately USD \$715 million in 2018. The global RCC market is projected to grow to USD \$6.3 billion by 2022. In addition to the RCC market, dovitinib has promising potential as a monotherapy in a number of other indications, including estrogen receptor (ER) positive metastatic breast cancer, hepatocellular cancer, endometrial cancer and gastrointestinal stromal tumors, as well as in combination therapy with other approved drugs, including immune checkpoint inhibitors.

Steve Carchedi, CEO of the Company, noted *“Although we are disappointed with the unanticipated contract manufacturing delay for our priority dovitinib program, and the resulting setback of our planned first NDA filing for this promising cancer therapeutic, we recognize the delays are a result of the ongoing coronavirus pandemic that is affecting many facets of our industry. We remain fully committed to advancing the near-term filing of our first dovitinib NDA towards hopeful U.S. approval and to bringing this beneficial cancer therapeutic to RCC patients. Moreover, we are enthusiastic about remaining on track with our planned PMA filing for the Dovitinib DRP® companion diagnostic this year.”*

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 irifolven, a DNA damaging agent in Phase 2 for prostate cancer.

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.

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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 23 October 2020**.