Press release

Allarity Therapeutics Announces Positive Data from Preclinical Study of Dovitinib in Osteosarcoma

- Treatment of animal osteosarcoma models with dovitinib increased the median survival time by 50 % as compared to control animals.

Hørsholm, Denmark (9 March 2021) – Allarity Therapeutics A/S ("Allarity" or the "Company") today announced positive data from its preclinical assessment of dovitinib's antitumor activity in osteosarcoma, the most common primary malignant bone tumor in children and young adults. The purpose of the study was to investigate the capacity of dovitinib alone, and in combination with a specific checkpoint inhibition strategy (anti-PD-1), for slowing the progression of experimental pulmonary metastases in animal models of osteosarcoma.

Two separate studies, performed contemporaneously in a syngeneic, mouse model of experimental pulmonary osteosarcoma metastases in mice using the K7M2 cell line, generated the following key results:

- Treatment with dovitinib, compared to control treatment (sucrose solution lacking dovitinib), increased the median survival time by 50 %.
- Antitumor growth activity was also observed for dovitinib as a single agent in this model.

In addition, it was found that no significant antitumor activity was observed in mice treated with single-agent anti-PD-1 antibody at the investigated dosage and dosing schedule. Furthermore, the combination of dovitinib and anti-PD-1 antibody did not generate additive or synergistic antitumor activities equal or greater than observed by dovitinib alone in the mouse osteosarcoma model.

Allarity is preparing for the submission of a new drug application (NDA) for marketing approval, by the U.S. FDA, for dovitinib as a treatment for renal cell carcinoma (RCC). In support of its NDA filing, and in accordance with FDA requirements, the company is also planning a clinical trial in pediatric patients with osteosarcoma, where the patients will be selected with the DRP® companion diagnostic for Dovitinib. The FDA defines pediatric patients as persons aged 21 or younger.

Allarity Therapeutics has chosen osteosarcoma as the pediatric indication in which to evaluate the efficacy and safety of dovitinib on the basis of the reported preclinical study. A positive preclinical assessment, as announced today, is a part of the normal prerequisites for initiating a clinical trial in pediatric patients with osteosarcoma.

Allarity's CEO, Steve Carchedi, noted "These data further demonstrates that dovitinib is a therapy that has a potential beyond RCC. We look forward to continuing our work towards regulatory approval of dovitinib, and ultimately realize its potential as a personalized cancer treatment by applying our unique DRP® technology."

M.D., D.Sc., Marie Foegh, CMO of Allarity Therapeutics, further stated. “We are now ready to move forward towards initiating a pediatric clinical trial for dovitinib after receiving these excellent preclinical results. If we can show that dovitinib is also a potential treatment for patients with osteosarcoma, it will further strengthen the case for bringing this new therapy to the market.”

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 9 March 2021.**