Press release

Allarity Therapeutics Receives Acceptance & Review Notification from U.S. FDA for Pre-Market Approval Application for Dovitinib-DRP®

- *Administrative acceptance review notification of pre-market approval (PMA) application is first step in multi-step process conducted by the FDA*
- *The PMA is submitted in support of an imminent new drug application (NDA) for dovitinib*

Hørsholm, Denmark (5 July 2021) — Allarity Therapeutics A/S ("Allarity" or the "Company") today announced that the U.S. Food and Drug Administration (FDA) has provided a positive administrative acceptance and review notification for the Company's PMA application for its Dovitinib-DRP®, the Company's validated companion diagnostic for the drug dovitinib. Dovitinib is a small molecule, pan-tyrosine kinase inhibitor in-licensed from Novartis, and is Allarity's most advanced clinical asset.

On 2 April, 2021, Allarity announced the filing of the PMA application. The FDA's acceptance of the Company's PMA application means that the FDA has made a threshold determination that the application is sufficiently complete to begin an in-depth review. Allarity's PMA application, to gain FDA approval to use the Dovitinib-DRP® as a companion diagnostic to select and treat patients likely to respond to dovitinib, supports the Company's imminent NDA filing for the drug, and is the Company's first PMA filing for a drug-specific DRP® companion diagnostic.

Allarity's CEO, Steve Carchedi, noted, "*The FDA's acceptance of our PMA filing for the Dovitinib-DRP® companion diagnostic is an important milestone for our Company. This marks a turning point for our DRP® technology, as it represents the first time in our Company's history that we have advanced towards regulatory approval for one of our drug-specific DRP® companion diagnostics.*"

Allarity's unique and clinically validated 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 for individual patients are done based on a biopsy from the patients' tumor. The Dovitinib-DRP® companion diagnostic 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 an NDA with the FDA for the approval of dovitinib for the treatment of renal cell carcinoma (kidney cancer) during 2021. If the FDA, following the agency's complete review process, provides the anticipated PMA approval of the Dovitinib-DRP® as a companion diagnostic for dovitinib, as well as an NDA approval for dovitinib, Allarity will be able to market dovitinib in the U.S. to DRP®-selected RCC patients as an effective new therapy to treat their disease.

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. For more information, please visit the company's website at www.Allarity.com

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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Investor Contact:

Jens Knudsen, CFO
+45 8874 2415
Email inquiries: InvestorRelations@allarity.com

U.S. Media Contact:

Mike Beyer
Sam Brown, Inc.
+1 312-961-2502
mikebeyer@sambrown.com

EU Media Contact:

Thomas Pedersen
Carrotize PR & Communications
+45 6062 9390
tsp@carrotize.com

Certified Adviser:
Svensk Kapitalmarknadsgranskning AB, Email: ca@skmg.se. Tel: +46 11 32 30 732

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 5 July 2021.**