



Press release

## Allarity Therapeutics and Oncoheroes Biosciences Sign Agreements to Advance Pediatric Cancer Development of Dovitinib and Stenoparib

*Oncoheroes will fund and advance the clinical development of both dovitinib and stenoparib in pediatric cancers, utilizing Allarity's DRP® companion diagnostics*

*Allarity has submitted a new drug application (NDA) for the U.S. approval of dovitinib in renal cell carcinoma (RCC) together with the Dovitinib-DRP® companion diagnostic*

**Cambridge, MA U.S.A. (January 3, 2022)** — Allarity Therapeutics, Inc. (Nasdaq: ALLR) ("Allarity" or the "Company"), a clinical-stage biopharmaceutical company developing novel oncology therapeutics together with drug-specific DRP® companion diagnostics for personalized cancer care, and Oncoheroes Biosciences, Inc. ("Oncoheroes"), a clinical-stage biotechnology company advancing new therapies for childhood cancers, today announced that they have entered into licensing agreements under which Oncoheroes will acquire exclusive, global development rights to Allarity's therapeutic candidates dovitinib, a pan-targeted kinase inhibitor (pan-TKI), and stenoparib, a PARP inhibitor, and assume responsibility for their further clinical development in pediatric cancers.

Under the terms of the licensing agreements, Oncoheroes acquires global, exclusive rights to fund and conduct further clinical development of both dovitinib and stenoparib in pediatric cancers. Oncoheroes will take responsibility for pediatric cancer clinical development activities for both clinical-stage therapeutics. Allarity will support Oncoheroes' pediatric clinical trials by providing clinical-grade drug inventory at cost and by facilitating DRP® companion diagnostic screening of pediatric patients for each drug. Under the licenses, Oncoheroes will receive commercialization rights for pediatric cancers, subject to Allarity's first buy-back option for each program, and Allarity will receive an undisclosed upfront license fee and regulatory milestones for each program. If Allarity does not re-acquire the pediatric field rights, it will further receive certain clinical/regulatory milestone payments and royalties on sales of stenoparib and dovitinib in the pediatric cancer market from Oncoheroes. Further financial terms of the licenses were not disclosed.

**Steve R. Carchedi, CEO of Allarity Therapeutics**, commented, *"We are very pleased to partner with Oncoheroes Biosciences to advance both dovitinib and stenoparib as potential new therapeutic options for the personalized treatment of children and adolescents with cancer. Oncoheroes is a leader in advancing new therapeutics to help address historically underserved, rare childhood cancers, and an ideal partner for Allarity in the pediatric cancer market. Our out-licensing of these pediatric development programs enables Allarity to remain focused on our top priority programs in adult cancers, while at the same time leveraging Oncoheroes' resources, capabilities, and commitment to clinically advancing dovitinib and stenoparib in childhood cancers, together with our DRP® companion diagnostics, in a true personalized cancer care approach."*

In December 2021, Allarity submitted an NDA, to the U.S. Food and Drug Administration (FDA), for marketing approval for dovitinib for the treatment of third line RCC. In April 2021, the Company submitted a premarket approval (PMA) application for use of its Dovitinib-DRP® companion diagnostic to select and treat patients most likely to respond to dovitinib. In support of its NDA filing, and in accordance with FDA requirements, the Company is also planning a clinical trial of dovitinib in pediatric patients with osteosarcoma, in partnership with Oncoheroes, where the patients will be selected with the Dovitinib-DRP® companion diagnostic. Allarity's focus on pediatric osteosarcoma development is based on the results of two previously reported preclinical studies in which treatment with dovitinib, compared to control treatment (sucrose solution lacking dovitinib), increased the median survival time of mouse models of osteosarcoma by 50% and antitumor growth activity was observed for dovitinib as a single agent.

**Ricardo Garcia, CEO & Founder of Oncoheroes Biosciences**, further commented, *“Oncoheroes is a mission-driven company committed to deliver more effective and safer treatments for children and adolescents with cancer. We are excited to partner with Allarity on these co-development programs. These fit perfectly with our goal of becoming the partner of choice for life sciences companies with drug candidates that have the potential to treat pediatric cancers. We are confident that this collaborative model will create powerful synergies to accelerate pediatric drug development and bring tangible benefits to younger cancer patients.”*

Allarity is currently evaluating stenoparib for the treatment of advanced ovarian cancer in a Phase 2 clinical trial at the Dana-Farber Cancer Institute (Boston, MA U.S.A.), and additional U.S. and European trial sites, using the Stenoparib-DRP® companion diagnostic to guide patient enrollment and improve therapeutic outcome. In prior clinical testing of more than 60 patients, stenoparib was well tolerated with a demonstrated acceptable safety profile. Through use of DRP® patient selection, Allarity aims to provide a superior clinical benefit to ovarian cancer patients receiving stenoparib as compared to other approved PARP inhibitors. Moreover, there is increasing evidence pointing to the potential use of PARP inhibitors in the treatment of various pediatric cancers.

### **About Allarity Therapeutics**

Allarity Therapeutics, Inc. (Nasdaq: ALLR) develops drugs for personalized treatment of cancer guided by its proprietary and highly validated companion diagnostic technology, the DRP® platform. The Company has a mature portfolio of five drug candidates, including: Stenoparib, a PARP inhibitor in Phase 2 development for ovarian cancer; Dovitinib, a pan-TKI submitted for NDA review by the FDA for the 3<sup>rd</sup> line treatment of renal cell carcinoma; IXEMPRA® (Ixabepilone), a microtubule inhibitor approved in the U.S. for the 2<sup>nd</sup> line treatment of metastatic breast cancer and in Phase 2 development, in Europe, for the treatment of the same indication; LiPlaCis®, a liposomal formulation of cisplatin in Phase 2 development for metastatic breast cancer; and 2X-111, a liposomal formulation of doxorubicin in Phase 2 development for metastatic breast cancer and/or glioblastoma multiforme (GBM). The LiPlaCis® and 2X-111 programs are partnered, via out-license, to Smerud Medical Research International AS. In 2021, Allarity sold the global rights to Irofulven, a DNA-damaging agent in Phase 2 for prostate cancer, back to Lantern Pharma, Inc. The Company maintains an R&D facility in Hoersholm, Denmark. For more information, please visit the company's website at [www.Allarity.com](http://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, and only treating those patients with a sufficiently high DRP® score, the therapeutic

response rate can be significantly increased. The DRP<sup>®</sup> method builds on the comparison of sensitive vs. resistant human cancer cell lines, including transcriptomic information from cell lines combined with clinical tumor biology filters and prior clinical trial outcomes. DRP<sup>®</sup> is based on messenger RNA from patient biopsies. The DRP<sup>®</sup> platform has proven its ability to provide a statistically significant prediction of the clinical outcome from drug treatment in cancer patients in 37 out of 47 clinical studies that were examined (both retrospective and prospective), including ongoing, prospective Phase 2 trials of Stenoparib and IXEMPRA<sup>®</sup>. The DRP<sup>®</sup> platform, which can be used in all cancer types and is patented for more than 70 anti-cancer drugs, has been extensively published in peer reviewed literature.

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### **About Oncoheroes Biosciences**

Oncoheroes is a ground-breaking biotech company exclusively focused on the discovery and development of better drugs for children and adolescents with cancer. Our vision is to deliver benefits to young cancer patients and create value in the process. The company is headquartered in Boston, US, with a discovery lab in Barcelona, Spain. Oncoheroes is actively looking for in-licensing opportunities in the pediatric oncology space while working to generate new proprietary assets for a number of pediatric cancer indications with high unmet medical needs. For more information please visit: [oncoheroes.com](http://oncoheroes.com)

### **Follow Oncoheroes on social media**

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### **Forward-looking statements**

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements provide Allarity’s current expectations or forecasts of future events. The words “anticipates,” “believe,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predicts,” “project,” “should,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements include, but are not limited to, statements relating to the submitted NDA for dovitinib and PMA for the drug-specific DRP<sup>®</sup> companion diagnostic for dovitinib, future clinical trials for dovitinib in pediatric cancers, development of dovitinib with an indication for osteosarcoma based on preclinical studies, ongoing clinical trials for stenoparib for the treatment of advanced ovarian cancer, and statements relating to the effectiveness of the Company’s DRP<sup>®</sup> companion diagnostics platform in predicting whether a particular patient is likely to respond to a specific drug. Any forward-looking statements in this press release are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that results of a clinical study do not necessarily predict final results and that one or more of the clinical outcomes may materially change following more comprehensive reviews of the data, and as more patient data become available, the risk that results of a clinical study are subject to interpretation and additional analyses may be needed and/or may contradict such results, the receipt

of regulatory approval for dovitinib, the drug-specific DRP<sup>®</sup> companion diagnostic for dovitinib, or any of our other therapeutic candidates or, if approved, the successful commercialization of such products, the risk of cessation or delay of any of the ongoing or planned clinical trials and/or our development of our product candidates, the risk that the results of previously conducted studies will not be repeated or observed in ongoing or future studies involving our therapeutic candidates, and the risk that the current COVID-19 pandemic will impact the Company's current and future clinical trials and the timing of the Company's preclinical studies and other operations. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our Form S-1 registration statement on file with the Securities and Exchange Commission, available at the Securities and Exchange Commission's website at [www.sec.gov](http://www.sec.gov), and as well as discussions of potential risks, uncertainties and other important factors in the Company's subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and the Company undertakes no duty to update this information unless required by law.

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