



Allarity Therapeutics and FivepHusion Announce Collaboration to Support Clinical Development of Deflexifol™ with DRP® Companion Diagnostics

BOSTON and SYDNEY (July 31, 2023) — Allarity Therapeutics, Inc. (Nasdaq: ALLR) (“Allarity”), a clinical-stage pharmaceutical company developing novel oncology therapeutics together with drug-specific DRP® companion diagnostics for personalized cancer care, and Detsamma Investments Pty. Ltd. trading as “FivepHusion,” an advanced clinical-stage biotechnology company developing Deflexifol™, an optimized all-in-one formulation of the chemotherapeutic agent 5-fluorouracil (5FU) and its biomodulator leucovorin (LV), announced today that the two companies have entered into a Clinical Collaboration Agreement. Under this agreement, Allarity will support FivepHusion’s future clinical development of Deflexifol™ for the treatment of solid tumors by using certain of Allarity’s drug-specific DRP® companion diagnostics, including its validated DRP®-5FU companion diagnostic, to potentially select patients for enrollment and treatment in clinical trials of Deflexifol™ as a monotherapy and in combination with other drugs.

Deflexifol™ is a novel anti-cancer drug reformulation designed to address the safety and efficacy limitations of standard-of-care 5FU chemotherapy. It combines, in a single infusion, 5FU and LV, a drug that potentiates 5FU anti-tumor activity, to improve the therapeutic activity of 5FU. FivepHusion expects to start a phase 1b/2a study investigating Deflexifol™ in combination with oxaliplatin (“DEFLOX”) and bevacizumab in the 1st line treatment of unresectable metastatic colorectal cancer (mCRC) patients in H2 2023. This ~50 patient trial is designed to evaluate the safety, tolerability and pharmacokinetics of Deflexifol™ in the DEFLOX plus bevacizumab regimen, to enable selection of the optimal Deflexifol™ dose to be utilized in a Phase 3 pivotal trial in 1st line treatment of unresectable mCRC. A secondary endpoint is the assessment of objective response (eight-week scan) and overall survival of patients treated with DEFLOX plus bevacizumab.

Allarity’s DRP®-5FU is a companion diagnostic (CDx) that has been retrospectively validated and shown to predict patient response to 5FU treatment in late-stage colorectal cancer. Clinical data showing the predictive ability of the DRP®-5FU CDx in colorectal cancer were presented at the annual congress of the European Society for Medical Oncology (ESMO) in Barcelona on September 29, 2019, and were later the same year published in the [scientific journal Annals of Oncology](#).



Dr. Christian Toouli, CEO and Managing Director of FivepHusion, said, “We are excited to collaborate with Allarity Therapeutics to evaluate the drug-specific DRP[®] companion diagnostic technology as part of our upcoming Deflexifol[™] phase 1b/2a trial in 1st line unresectable metastatic colorectal cancer. This collaboration has the potential to develop an exciting precision medicine companion diagnostic for oncologists, facilitating administration of Deflexifol[™] to likely patient responders as a superior treatment for a range of solid tumours with significant unmet medical need.”

James G. Cullem, CEO of Allarity Therapeutics, added, “Allarity is thrilled to work together with FivepHusion to support the clinical advancement of their lead Deflexifol[™] program by evaluating the potential of DRP[®] companion diagnostics to select cancer patients most likely to respond to this novel and improved formulation of the widely-used chemotherapeutic 5FU. Together with the FivepHusion team, we look forward to advancing true personalized cancer care by using DRP[®] companion diagnostics to help provide Deflexifol[™] to patients that will most likely benefit from this promising therapeutic candidate.”

The Clinical Collaboration Agreement

Under the terms of the Clinical Collaboration Agreement, Allarity will initially support FivepHusion’s planned Phase 1b/2a trial of DEFLOX plus bevacizumab in 1st line treatment of unresectable mCRC, which will be conducted at trial sites in Australia. Allarity will receive patient biopsies from the trial and analyze them using the DRP[®] companion diagnostics technology to identify patients most likely to respond or not respond to the DEFLOX plus bevacizumab regimen. This analysis will be conducted blindly (without knowledge of any patient data and/or actual clinical response to the drug), so as to enable the retrospective analysis of the DRP[®] companion diagnostics predictive power following the completion of the Phase 1b/2a trial. FivepHusion will receive a first option to negotiate and obtain from Allarity a global, exclusive license to use and commercialize the DRP[®]-5FU CDx (together with other DRP[®] CDx relevant to drug combinations including Deflexifol[™]) through Phase 3 registration trials, regulatory approval, and to market.

Following conclusion of the Phase 1b/2a study, FivepHusion will determine whether the ability of the DRP[®] companion diagnostics technology to select patients responsive to DEFLOX plus bevacizumab and/or Deflexifol[™] monotherapy warrants prospective use of the companion diagnostic(s), to select and enroll mCRC patients, in an international, Phase 3 registration study for the drug. Allarity will receive patient biopsies from the trial and analyze them using



the DRP[®] companion diagnostics technology to prospectively identify patients most likely to respond or not respond to Deflexifol[™]. Allarity will further assist FivepHusion in the preparation and submission of any regulatory approvals, including Investigational Device Exemptions (IDEs) and Pre-Market Approvals (PMAs), required to use the DRP[®] companion diagnostics technology in such a Phase 3 trial and to use and market the CDx following any regulatory approval of Deflexifol[™].

Financial terms of the clinical collaboration, option and potential license are not disclosed. If FivepHusion exercises its option right and receives a license to the Allarity DRP[®] companion diagnostic technology related to Deflexifol[™], Allarity will receive certain milestone payments triggered by regulatory approvals of Deflexifol[™] and attainment of drug sales benchmarks.

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 three drug candidates: stenoparib, a PARP inhibitor in Phase 2 development for ovarian cancer; dovitinib, a pan-tyrosine kinase inhibitor previously developed through Phase 3 in renal cancer; and IXEMPRA[®] (Ixabepilone), a microtubule inhibitor approved in the U.S. and marketed by R-PHARM U.S. for the treatment of second-line metastatic breast cancer, and is currently in Phase 2 development in Europe for the same indication. Additionally, the Company has rights in two secondary assets: 2X-111, a liposomal formulation of doxorubicin for metastatic breast cancer and/or glioblastoma multiforme (GBM), which is the subject of discussions for a restructured out-license to Smerud Medical Research International AS; and LiPlaCis[™], a liposomal formulation of cisplatin and its accompanying DRP[®], being developed via a partnership with Chosa Oncology AB for late-stage metastatic breast cancer. The Company is headquartered in the United States and maintains an R&D facility in Hoersholm, Denmark. 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, and only treating those patients with a sufficiently high DRP[®] score, the therapeutic response rate can be significantly increased. The DRP[®] 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[®] is based on messenger RNA from patient biopsies. The DRP[®] 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[®]. The DRP[®] 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.

About FivepHusion and Deflexifol™

FivepHusion (www.fivephusion.com) is an advanced clinical-stage, globally focused biotechnology company whose purpose is to optimise chemotherapy to improve patient treatment and quality of life. Its lead program, Deflexifol™, is a proprietary, novel, and optimized physiological pH formulation of the chemotherapeutic agent 5-fluorouracil (5FU) and its biomodulator leucovorin (LV) for the treatment of solid tumours. Current formulations of 5FU and LV are the standard of care for modern treatment of metastatic colorectal cancer (mCRC) and are also frequently utilized to treat a range of other highly incident tumors, including colorectal, breast, gastric, head & neck and pancreatic cancers. However, current formulations of 5FU and LV suffer from limitations in their safety, tolerability, effectiveness and pharmacological compatibility. These disadvantages contribute to limited treatment response rates, unpleasant side effects and toxicities, and a reduced quality of life experienced by cancer patients. Deflexifol™ has been designed to address these limitations, with clinically demonstrated improvements in safety and tolerability and the potential to offer superior anti-tumor efficacy, better quality of life, and overall enhanced clinical benefit for cancer patients.

FivepHusion is developing Deflexifol™ as a bioequivalent, chemotherapy replacement of sub-optimal standard of care formulations of 5FU and LV for the treatment of mCRC, and other tumors with a projected global incidence of greater than 6 million patients. Deflexifol™ is also being developed as a new therapy for cancers with high unmet medical need, such as pediatric ependymoma; a rare and deadly brain cancer which afflicts very young children.

Deflexifol™ is a trademark of FivepHusion.

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Follow FivepHusion on Social Media

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Allarity 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,” “toward,” “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 related to the Company’s ability to maintain compliance with the Nasdaq Listing Rule, use of proceeds from the offering, that the closing of offering will occur or will occur on the anticipated closing date, ability to raise capital, statements related to the expected availability capital to fund its anticipated clinical trials, statements related to advancing dovitinib in combination with another therapeutic candidate or other approved drug, any statements related to ongoing clinical trials for stenoparib as a monotherapy or in combination with another therapeutic candidate for the treatment of advanced ovarian cancer, or ongoing clinical trials (in Europe) for IXEMPRA® for the treatment of metastatic breast cancer, and statements relating to the effectiveness of the Company’s DRP® companion diagnostics platform in predicting whether a particular patient is likely to respond to a specific drug, including, but not limited to, DeflexifoI™. Any forward-looking statements in this press release are based on management’s current expectations of future events and are subject to multiple 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 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, 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.

FivepHusion Forward-Looking Statements

This announcement (and any attachments) may contain certain forward-looking statements that are based on any number of assumptions and estimates which may prove incorrect and relate to circumstances and events that may not take place. Forward-looking statements involve known and unknown risks, uncertainties, and other factors (such as significant business, economic and competitive uncertainties and contingencies, and regulatory and clinical development risks and uncertainties) which may cause the actual future plans, results or the performance of FivepHusion and its drug Deflexifol™ to differ materially from the plans, results or performance expressed or implied by such forward-looking statements. Past performance is not a reliable indicator of future performance. There can be no assurance that any forward-looking statements will be realised. FivepHusion does not make any representation or give any warranty as to the likelihood of achievement or reasonableness of any forward-looking statements.

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