

30 May 2017



**SalvaRx Group PLC**  
**("SalvaRx" or "the Company")**  
**Intensity Therapeutics Treats First Patient**

SalvaRx is pleased to notify that Intensity Therapeutics Inc. ("Intensity"), in which the Company has an 8.5 per cent interest, has announced that the first patient has been dosed with INT230-6 as part of a Phase 1/2 international clinical study. Dr Ian B. Walters, Chief Executive of SalvaRx, has helped design the study and oversaw the medical aspects of INT230-6 as Chief Medical Officer of Intensity. Initiation of the study followed acceptance of an investigational new drug (IND) submission made by Intensity to the U.S. Food and Drug Administration's Division of Oncology Products 1 (DOP1) and receipt from Health Canada of a No Objection Letter. The clinical trial, IT-01 (NCT#03058289), entitled *A Phase 1/2 Safety Study of Intratumorally Administered INT230-6 in Adult Subjects with Advanced Refractory Cancers* aims to enroll approximately 60 patients with several different types of advanced solid tumors.

"Bringing our novel product into human testing is a major milestone for Intensity Therapeutics," commented Lewis H. Bender, President and CEO of Intensity, "Over the past few years Intensity has demonstrated impressive tumor shrinkage in several murine models of cancers. Our product, INT230-6, eradicated large tumors, activated a systemic immune response and improved survival. Some animals having a complete response show no evidence of regrowth for the remainder of their lives. In fact, many acquired the capability to spontaneously clear additional challenges of the same cancer (suggesting a protection effect similar to that of a vaccine). We are therefore excited to have initiated human testing of INT230-6. Our staff, investigators, and clinical centers are enthusiastic about bringing patients our potentially life-saving product."

Intensity's Phase 1/2 study will first assess the safety of INT230-6. Initial tumor types treated will be those at the skin surface (e.g. breast, melanoma, head-and-neck and lymphoma). Subsequent

patients receiving INT230-6 will include those with deep tumors (e.g. liver, pancreatic, colon, lung cancers, and others). Investigators will utilize image guidance to inject the tumors. A cohort is planned to study INT230-6 in combination with anti-PD1 agents. The study's primary goal is to demonstrate the safety of INT230-6. Secondary analyses will examine the efficacy of INT230-6 treatment via multiple parameters. The trial includes several adaptive components that will allow for adjustments in patient groups, dosing schedule and dose volumes administered.

“Our studies with INT230-6 have shown the ability to stimulate a strong T-cell response as a monotherapy, and there is considerably enhanced activity using INT230-6 in combination with checkpoint inhibitors such as anti-PD-1 antibodies, while maintaining a favorable safety profile,” said Intensity’s Chief Medical Officer Ian B. Walters, MD, “We are optimistic that our novel trial design can quickly detect evidence of direct tumor killing and immune system activation. Physicians desperately need improved treatments for patients with advanced cancers that are not responding to approved immunotherapies. Intensity is grateful to the volunteers participating in our study and looks forward to collecting data on INT230-6 in different cancer types.”

## **Enquiries**

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## **Notes**

## **About INT230-6**

INT230-6 is a novel, anti-cancer drug for direct intratumoral injection. The product contains potent anti-cancer agents that disperse throughout tumors and diffuse into cancer cells. INT230-6 was identified from Intensity's DfuseRx<sup>SM</sup> platform and is being evaluated in a clinical trial; IT-01. In preclinical studies INT230-6 administration eradicated tumors by a combination of direct tumor kill coupled with recruitment of dendritic cells to the tumor micro-environment that stimulated anti-cancer T-cell activation. Treatment with INT230-6 in in vivo models of severe cancer resulted in substantial improvement in overall survival compared to standard therapies. Further, INT230-6 provided complete responder animals with long-term, durable protection from multiple re-inoculations of the initial cancer and resistance to other cancers.

## **About Study IT-01**

IT-01 is entitled *A Phase 1/2 Safety Study of Intratumorally Administered INT230-6 in Adult Subjects with Advanced Refractory Cancers*. The trial aims to enroll approximately 60 patients with different types advanced solid tumor malignancies in a multicycle dosing regimen. The study will be conducted in multiple countries and includes a cohort combining INT230-6 with an anti-PD-1 antibody. Currently the study is recruiting in the U.S. at two hospitals associated with the University of Southern California (USC) and in Canada at the University Health Network (UHN) in Toronto. The principal investigator at USC is Dr. Anthony El-Khoueiry; the principal investigator at UHN is Dr. Lillian Siu.

The study's primary objective is to assess the safety and tolerability of multiple intratumoral doses of INT230-6. Secondary assessments are to understand preliminary efficacy of INT230-6 by measuring the injected and bystander tumor responses. The study will characterize the systemic pharmacokinetic profile of multiple doses of INT230-6's drug substances after single and then multiple intratumoral injections. Exploratory analysis will characterize patient outcome, as well as evaluate various tumor and anti-tumor immune response biomarkers that may correlate with response. Data will be used to assess the progression free and overall survival in subjects receiving INT230-6. Further information including estimated completion date can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT#03058289).

## **About SalvaRx**

SalvaRx Limited was founded in 2014 to develop therapies within the rapidly growing immuno-

oncology market, which uses treatments designed to boost the body's natural defences to fight the cancer. Immuno-oncology therapy is a fast growing and new therapeutic area, a market expected to grow to \$80 billion worldwide by 2020 (Global & USA Cancer Immunotherapy Market Analysis 2020). SalvaRx Limited is majority owned by SalvaRx Group PLC.

In addition to Intensity Therapeutics, SalvaRx manages a portfolio of cancer immunotherapy companies which includes iOx Therapeutics, a University of Oxford spin-out company developing products that stimulate Natural Killer T-Cells, RIFT Therapeutics a San Diego company focused on developing novel antibody targets to the tumor micro-environment, and Nekonal Oncology, a BVI company developing novel immune-oncology antibodies.

SalvaRx's strategy is to invest in and acquire a portfolio of companies involved in novel cancer immunotherapies and develop them up to clinical proof of concept. SalvaRx provides portfolio companies with operational support in addition to capital, either by managing its portfolio companies directly or augmenting an existing team. SalvaRx's management team have a proven track record of discovering and commercialising drugs in the area of cancer immunotherapy with Bristol-Myers Squibb and Johnson & Johnson. The team is supported by an extended network of senior academic and industry executives to promote commercial and scientific outcomes, including licensing and partnering discussions.

**For more information please visit: [www.salvarx.io](http://www.salvarx.io)**

**Ends**