ASX Announcement

DEP® SN38 Results Showcased at GI Cancer Conference

- *Results from patients with metastatic colorectal cancer (mCRC) deemed exceptional responders in the DEP® SN38 Phase 1/2 clinical trial were presented at a specialist gastrointestinal cancer conference in Brisbane, Australia.*
- *DEP® SN38 demonstrated promising efficacy, with sustained and durable disease control for up to 72 weeks in patients previously treated with irinotecan.*
- *DEP® SN38 exhibited a favourable toxicity profile compared with standard irinotecan, contributing to improved quality of life experiences for these patients.*
- *One patient with platinum-resistant ovarian cancer continues to receive DEP® SN38 treatment, having achieved prolonged disease control for more than 1.7 years.*

Melbourne, Australia; 21 November 2024: Starpharma (ASX: SPL, US OTC: SPHRY), an innovative biotechnology company with two decades of experience in advancing dendrimer technology from the lab to the patient, today shares a copy of a DEP® SN38 scientific poster that was presented at the Australasian Gastro-Intestinal Trials Group (AGITG) Annual Scientific Meeting in Brisbane this week.

The poster presentation highlights the outcomes for five selected patients with advanced metastatic colorectal cancer (mCRC) who participated in the Phase 1/2 clinical trial of DEP® SN38 at The Kinghorn Cancer Centre at St Vincent's Hospital and Garvan Institute of Medical Research in Sydney. These patients were deemed exceptional responders by the study site investigators based on their impressive responses to DEP® SN38 treatment, particularly given their advanced disease and extensive prior treatment.

These heavily pre-treated patients' disease had progressed following prior irinotecan exposure and, in some cases, they had experienced intolerance to irinotecan. Despite these challenges, treatment with DEP® SN38 achieved sustained and durable disease control for up to 72 weeks in this group of patients. One of the patients, treated with DEP® SN38 in combination with 5-fluorouracil (5-FU) and leucovorin (LV), achieved a partial response, with a reduction in the size of their target tumour of more than 30%. Importantly, DEP® SN38 also exhibited an excellent toxicity profile with manageable side effects, leading to improved quality of life experiences for these patients.

The development and presentation of the poster was led by Dr Jordan Cohen, MBBS MMed, Medical Oncology Fellow in the team of Dr Jia (Jenny) Liu, MD PhD FRACP, Medical Oncologist and Principal Investigator of the DEP® SN38 Phase 1/2 clinical study at The Kinghorn Cancer Centre.

Dr Liu commented: "The DEP® SN38 trial results are very exciting. DEP® SN38 in heavily pre-treated, advanced cancer patients demonstrated highly encouraging efficacy results in a range of tumour types, including in colorectal cancer where there is a high unmet need for more efficacious and tolerable treatments. These responses include significant and sustained tumour shrinkage and disease control in patients who have previously been treated with irinotecan.

"DEP® SN38 exhibits excellent tolerability, with a distinct lack of severe gastrointestinal toxicity that is a common and problematic feature of irinotecan treatment. The treatment tolerability demonstrated by Starpharma's DEP® SN38, combined with sustained disease control, has meant that many of our patients, including those who are quite young with advanced colorectal cancer, have been able to

receive long-term treatment and continue to work and engage socially with their peers, which is very important for their quality of life."

DEP® SN38 is a novel, water-soluble dendrimer conjugated to SN38, the topoisomerase I (TOP1) inhibitor and active metabolite of irinotecan. DEP® delivery of SN38 avoids liver metabolism normally required for activation, which helps reduce off-target toxicity that is a feature of standard irinotecan. The DEP® dendrimer nanoparticles are retained in the tumour microenvironment via enhanced permeability and retention, enabling prolonged, targeted delivery of the cytotoxic drug to tumours.

The multicentre, global, Phase 1/2 clinical trial of DEP® SN38 (N=114) has shown promising efficacy in several tumour types, including mCRC and platinum-resistant ovarian cancer, along with highly favourable safety and tolerability, particularly low rates of severe gastrointestinal events and a lack of cholinergic symptoms compared to published data on conventional irinotecan. One patient with platinum-resistant ovarian cancer remains on treatment, having received 45 dose cycles of DEP® SN38 with achievement of prolonged disease control for now more than 1.7 years.

Summary of the DEP® SN38 Efficacy and Safety Results in these Exceptional Responders

- One patient treated with DEP® SN38 + 5-FU/LV combination therapy achieved a partial response, with a reduction in size of their target tumour of more than 30%, and four patients exhibited stable disease, with durable disease control lasting up to 72 weeks.
- Four patients showed a concomitant reduction in the levels of the CEA cancer biomarker of up to 74%.
- Dose-limiting toxicities were observed in one patient, who experienced grade 3 febrile neutropenia that required a dose reduction.
- Neutropenia in other patients was managed effectively with G-CSF[1], and gastrointestinal events were mostly mild to moderate, with only one instance of grade 3 nausea reported, and no cases of severe diarrhoea in any patients.
- Two patients continued treatment beyond progression of their disease due to clinical benefit.

Summary of the Patient Characteristics

- Five patients (2 male, 3 female) with mCRC and median age of 38 years.
- Treatment included either monotherapy with DEP® SN38 or a combination of DEP® SN38 with 5-FU/LV (equivalent to the "FOLFIRI" regimen).
- For these patients, the median number of DEP® SN38 treatment cycles administered was 24.
- The median duration of treatment with DEP® SN38 was 59 weeks.

Colorectal cancer is the second leading cause of cancer-related deaths globally. It is often diagnosed at advanced stages, making treatment options limited. The incidence of CRC is increasing among adults younger than 50, as reflected by the ages of the patients in this study. According to the American Cancer Society (ACS), 20% of colorectal cancer diagnoses in 2019 were in patients under the age of 55. This figure is approximately twice the rate seen in 1995[2] and continues to rise.

Starpharma's DEP® SN38 is a priority candidate for licensing, showing promising Phase 1/2 results in mCRC and platinum-resistant ovarian cancer. Starpharma will meet with key regulators in the coming weeks to discuss potential clinical development pathways for DEP® SN38 aimed at achieving commercialisation.

[1] G-CSF, granulocyte-colony stimulating factor, is a growth factor that stimulates the bone marrow to make more blood cells, and increases the number of some types of white blood cells in the blood

[2] https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2023.pdf

About Starpharma

Starpharma ASX: SPL, OTCQX: SPHRY) is an innovative biotechnology company with two decades of experience in advancing dendrimer technology from the lab to the patient. Our mission is to help patients with significant illnesses, such as cancer, achieve improved health outcomes and quality of life through the application of our unique dendrimer technology.

Dendrimers are precise, synthetically manufactured, nanoscale molecules. Their unique properties—including their size, structure, high degree of branching, polyvalency, and water solubility—are advantageous in medical and pharmaceutical applications.

Starpharma's portfolio of dendrimer-based products includes three clinical-stage DEP® (dendrimer enhanced product) assets, preclinical radiopharmaceutical assets, research collaborations, and three commercially marketed over-the-counter (OTC) products.

For more information about Starpharma, visit www.starpharma.com or connect with Starpharma on LinkedIn.

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Disclosure
This ASX Announcement was authorised for release by the Chair, Mr Rob Thomas.

Forward-Looking Statements

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