ASX Announcement

Starpharma receives positive feedback from FDA on DEP® SN38 clinical pathway for platinum-resistant ovarian cancer

- *Starpharma has met with the US FDA to discuss the clinical pathway options for DEP® SN38 in Platinum-Resistant Ovarian Cancer (PROC), which the FDA recognises as a patient group with significant unmet need.*
- *During the meeting, the FDA provided positive feedback on Starpharma's proposed clinical development plan for DEP® SN38, confirming the applicability of the "505(b)(2)" registration pathway and the potential for Fast Track designation and accelerated approval.*
- *The FDA's feedback provides confidence for an Investigational New Drug (IND) application for DEP® SN38, supporting our ultimate goal of licensing the product.*

Melbourne, Australia; 19 December 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 announces a positive development regarding its DEP® SN38 (DEP® irinotecan) program following a meeting with the US Food and Drug Administration (FDA).

The purpose of the meeting was to confirm the regulatory approval pathways and seek regulatory guidance on the design of a Phase 2/3 clinical program aimed at obtaining registration for DEP® SN38 in patients with platinum-resistant ovarian cancer in the US.

Key Outcomes from the Meeting with the US FDA

The FDA agreed with Starpharma's proposal that DEP® SN38 could be considered for FDA Fast Track designation, acknowledging that platinum-resistant ovarian cancer is a serious condition with significant unmet medical need.

The FDA also agreed that a "505(b)(2)" regulatory approval pathway is appropriate for DEP® SN38, as the product delivers the active moiety of the FDA-approved drug, irinotecan (Camptosar®). The 505(b)(2) pathway allows Starpharma to utilise existing FDA findings of safety and efficacy for an already approved drug, potentially streamlining the approval process by removing the need for some additional studies.

The FDA indicated that DEP® SN38 may qualify for accelerated approval based on an interim analysis of early surrogate endpoints from the proposed Phase 2/3 clinical trial program. Final outcomes will depend on the results of these studies and the overall data package; however, this accelerated approval could provide early access to DEP® SN38 for patients with platinum-resistant ovarian cancer.

The proposed clinical program for achieving both accelerated and full approval of DEP® SN38 involves comparing the safety and efficacy of DEP® SN38—whether alone or in combination with

other anticancer agents—against single-agent chemotherapies, such as paclitaxel, topotecan and pegylated liposomal doxorubicin, either as monotherapy or in combination with other agents.

During the meeting, the FDA offered valuable guidance on the study design, particularly in defining the target patient population, study endpoints, and biostatistical aspects. The agency emphasised the importance of ensuring that DEP® SN38 is applicable to a broad range of patients with platinum-resistant ovarian cancer.

Overall, the feedback and collaborative discussions with the FDA reflect a positive and constructive interaction for Starpharma, clarifying the pathways for clinical development and regulatory approval of DEP® SN38. The FDA's feedback provides confidence for an Investigational New Drug (IND) application for DEP® SN38, which could be advanced by a commercial partner.

Starpharma was supported in the meeting by a team of external clinical, regulatory and biostatistics advisers. Robert L. Coleman, MD FACOG FACS, one of the world's leading gynaecologic oncologists and experts in the treatment of, and development of new agents for, ovarian cancer, advised Starpharma on its DEP® SN38 development program and attended the FDA meeting as a representative of Starpharma. Dr Coleman provided real-world expertise on the clinical management of ovarian cancer and the design of registrational clinical trials for this indication.

Following the meeting with the FDA, Dr Coleman commented:

"Starpharma's meeting with the FDA provided clear guidance on the most efficient path forward for the development and eventual registration of DEP® SN38 as a promising new treatment for patients with platinum-resistant ovarian cancer. This disease represents a significant unmet medical need, and the FDA demonstrated a clear, positive intention to work constructively with the company on the DEP® SN38 program, with the goal of bringing a much-needed new therapy to patients with platinum-resistant ovarian cancer as rapidly as possible."

Cheryl Maley, Starpharma's Chief Executive Officer, commented:

"While we focus on maximising the value of our DEP® clinical assets, it is important to ensure we have the best asset package for a potential partner. We have worked hard to create a highly attractive opportunity for prospective partners.

"This feedback from the US FDA marks an important milestone, supporting the IND submission, which a partner can advance through further development, registration, and commercialisation. We are encouraged by the FDA's guidance, which validates our approach and allows us to proceed confidently with the proposed clinical pathways for DEP® SN38."

DEP® SN38 | Starpharma's Priority DEP® Candidate for Out-Licensing

DEP® SN38 is Starpharma's priority clinical-stage DEP® asset for licensing. It is a novel dendrimer-drug conjugate of the topoisomerase I (TOP1) inhibitor, SN38, which is the active metabolite of irinotecan (Camptosar®). DEP® SN38 has demonstrated highly encouraging anticancer results in a Phase 1/2 study in patients with a range of advanced cancers, including colorectal and platinum-resistant ovarian cancer (PROC). These results were presented at the American Society of Oncology (ASCO) 2024 Annual Meeting in June 2024. Following a strategic review of the program, Starpharma has prioritised PROC as a key indication, given its significant unmet patient need, commercial opportunities, and regulatory considerations.

Platinum-Resistant Ovarian Cancer | A Patient Group with Significant Unmet Need

In 2022, there were an estimated 325,000 new cases of ovarian cancer worldwide, and 207,000 deaths[1]. Platinum-resistant and platinum-refractory ovarian cancer are the largest unmet needs within the ovarian cancer indication. Nearly all patients who have recurrent ovarian cancer become resistant to platinum-based therapies, which are the mainstay of initial cancer treatment. Effective treatment options for patients who are platinum-resistant/refractory are limited, and the prognosis is poor.

About Starpharma

Starpharma ASX: SPL, US OTC: 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

This document contains certain forward-looking statements, relating to Starpharma's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other authorities' requirements regarding any one or more product candidates, nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated, or expected. Starpharma is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise. Clinical case studies and other clinical information given in this document are given for illustrative purposes only and are not necessarily a guide to product performance and no representation or warranty is made by any person as to the likelihood of achievement or reasonableness of future results. Nothing contained in this document, nor any information made available to you is, or shall be relied upon as, a promise, representation, warranty or guarantee as to the past, present or the future performance of any Starpharma product.

[1] https://gco.iarc.who.int/media/globocan/factsheets/populations/900-world-fact-sheet.pdf