ASX Announcement

DEP® cabazitaxel Phase 2 clinical trial completes enrolment and treatment

Melbourne, Australia; 17 April 2023: Starpharma (ASX: SPL, OTCQX: SPHRY) today announces that it has completed enrolment and treatment of patients for the Phase 2 clinical trial of its investigational anticancer product DEP® cabazitaxel. Encouraging efficacy signals, including significant tumour shrinkage and substantial tumour biomarker reductions, have been observed in multiple cancer types, including prostate cancer, ovarian cancer, gastro-oesophageal cancer, cholangiocarcinoma and head and neck cancer, following treatment with DEP® cabazitaxel.

Developed by Starpharma, DEP® cabazitaxel is a patented, dendrimer nanoparticle version of the chemotherapy drug, cabazitaxel, which is marketed as Jevtana® and widely used in the treatment of prostate cancer. Unlike standard cabazitaxel, DEP® cabazitaxel is highly water soluble, does not contain toxic detergent-like excipients associated with anaphylaxis, and avoids the need for patients to pre-medicate with steroids. DEP® cabazitaxel is one of three clinical-stage anticancer products developed by Starpharma, with a fourth being clinically developed by Starpharma's partner, AstraZeneca, and others in preclinical development.

In the Phase 2 trial of DEP® cabazitaxel, a total of 76 patients were enrolled across sites in the United Kingdom and Australia, with the final patient having now completed treatment. In the latter part of the trial, patient enrolment was focused on certain hard-to-treat cancers, including platinum-resistant ovarian and gastro-oesophageal cancers where encouraging efficacy signals have been observed. Given the challenges faced by patients with these tumours and the advanced nature of their disease, multiple patients who were recruited into the trial subsequently failed clinical, laboratory or radiological screening, which impacted recruitment rates in the latter stage of the trial.

Starpharma previously reported preliminary results from the prostate cancer cohort of the Phase 2 trial of DEP® cabazitaxel and presented these at the European Society of Medical Oncology Congress in September 2022. As previously announced[1], DEP® cabazitaxel showed multiple potential benefits for patients with metastatic Castration-Resistant Prostate Cancer (mCRPC), including longer progression-free survival (PFS) and a lower incidence of key side effects than conventional cabazitaxel (Jevtana®). The median PFS for DEP® cabazitaxel in this cohort was 3.9 months[2], which is more than 30% longer than the 2.9 months[3] reported for standard cabazitaxel. mCRPC patients treated with DEP® cabazitaxel also experienced a lower incidence of severe (Grade 3 or 4) treatment-related adverse events (7.5%[2]), compared to published data on standard cabazitaxel (39.7%)[3]. No mCRPC patients experienced severe hypersensitivity reactions and patients were not required to have steroid pre-medication, in contrast to standard cabazitaxel. In addition, only two mCRPC patients required prophylactic G-CSF[4], which is commonly required in prostate cancer patients treated with Jevtana®.

Having now completed dosing of patients in the DEP® cabazitaxel trial, Starpharma and its specialist clinical research organisation are now focused on follow-up and finalising the patient data set and quality control processes. At this stage, Starpharma expects to report top-line

[1] ASX Announcement, dated 12 September 2022, '*Starpharma presents promising additional clinical data for DEP® cabazitaxel in prostate cancer*'.
[2] Jones, RH, et al. Efficacy and Safety of Dendrimer-Enhanced (DEP®) Cabazitaxel (CTX-SPL9111) in Men with Metastatic Castration-Resistant Prostate Cancer (mCRPC) in a Phase 1/2 Trial, ESMO 2022 Congress, FPN 1403P.
[3] Eisenberger, M, et al. *J Clin Oncol*, 2017;35(28):3198-206.
[4] G-CSF: granulocyte-colony stimulating factor, is used as a therapy for myelosuppression. Myelosuppression is a condition in which bone marrow function is adversely impacted, resulting in fewer red blood cells, white blood cells, and platelets. It is a side effect of some cancer treatments.

results from the Phase 2 clinical trial of DEP® cabazitaxel during Q3 CY23, following the final requisite data verification and review. In parallel, licensing activities and discussions for DEP® cabazitaxel are ongoing as part of the Company's DEP® commercialisation strategy.

Dr Jackie Fairley, CEO of Starpharma, commented: "We are pleased to have completed enrolment and treatment of patients in Starpharma's Phase 2 clinical trial of DEP® cabazitaxel. DEP® cabazitaxel demonstrated longer progression-free survival in the prostate cancer cohort as well as a lower incidence of key side effects in patients[5] in comparison with published data on standard cabazitaxel treatment. We look forward to reporting data from other patient cohorts.

"We would like to express our gratitude to the patients who participated in this trial, as well as our appreciation for the contributions made by our clinical investigators and the clinical teams. Thank you to all involved for your dedication to developing improved oncology medicines for patients."

In addition to this DEP® cabazitaxel trial completing enrolment and treatment of patients, Starpharma's Phase 2 monotherapy trials of DEP® docetaxel and DEP® irinotecan are in the final stages, with commercial discussions for these products also underway.

About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a biopharmaceutical company, focussed on the development of pharmaceutical and medical products for unmet patient needs, including in the areas of oncology and infectious diseases.

Starpharma's innovative technology is based on proprietary polymers called dendrimers, which are precise, synthetically manufactured, nanoscale molecules. The unique properties of dendrimers – including their size, structure, high degree of branching, polyvalency, and water solubility – are advantageous in medical and pharmaceutical applications.

Starpharma uses its dendrimer technology to develop novel therapeutics and to improve the performance of existing pharmaceuticals. Starpharma's portfolio includes multiple clinical stage oncology products, which utilise its Dendrimer Enhanced Product ('DEP®') drug delivery technology; and marketed products, including VIRALEZE™ and VivaGel® BV, which utilise SPL7013, a proprietary dendrimer with antimicrobial properties.

Starpharma's DEP® drug delivery platform is being used to enhance the effectiveness of existing and novel therapies and to reduce drug-related toxicities through controlled and specified drug delivery.

In addition to Starpharma's internal DEP® programs, Starpharma has multiple DEP® partnerships with international biopharmaceutical companies including AstraZeneca (oncology); MSD (antibody drug conjugates); Chase Sun (anti-infectives); and other world leading pharmaceutical companies. Due to the broad applicability and optionality of Starpharma's DEP® platform, partnered DEP® programs have the potential to generate significant future milestones and royalties.

Starpharma's topical antiviral nasal spray, VIRALEZE™, is now registered in more than 30 countries*, including in Europe, in the UK, and in Southeast Asia. Starpharma's novel non-antibiotic vaginal gel, VivaGel® BV, for treatment of bacterial vaginosis (BV) and prevention of recurrent BV, is registered in more than 45 countries, including in the UK, in Europe, in Southeast Asia, South Africa, Australia and New Zealand.

* Note: VIRALEZE™ is not approved for use or supply in Australia.

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[5] ASX Announcement, dated 12 September 2022, '*Starpharma presents promising additional clinical data for DEP® cabazitaxel in prostate cancer*'.

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Disclosure
This ASX Announcement was authorised for release by the Chairman, 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.