ASX Announcement

Promising efficacy signals observed in ongoing DEP® trials, including DEP® cabazitaxel escalation phase

- **DEP® cabazitaxel and DEP® docetaxel continue to show promising efficacy signals and a notable lack of bone marrow toxicity and other common side effects**
- **Several patients dosed with DEP® cabazitaxel in the phase 1 / 2 dose escalation phase have exhibited efficacy signals in tumours including prostate, ovarian and pancreatic cancer**
- **Efficacy signals for DEP® cabazitaxel include patients with stable disease of more than 30 weeks (treatment ongoing) and significant reductions in specific tumour biomarkers, such as Prostate Specific Antigen (PSA)**
- **Encouraging efficacy signals observed for both DEP® cabazitaxel and DEP® docetaxel patients, despite them typically having been previously treated with multiple cycles of other anti-cancer agents, including taxanes (i.e. conventional docetaxel, cabazitaxel, or Abraxane®)**

Melbourne, Australia; 28 August 2019: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that promising efficacy signals have been observed in its ongoing clinical trials for both DEP® cabazitaxel and DEP® docetaxel.

DEP® cabazitaxel and DEP® docetaxel are two of three clinical stage products from Starpharma's DEP® platform, alongside DEP® irinotecan.

DEP® cabazitaxel

Efficacy signals in the phase 1 / 2 DEP® cabazitaxel trial have been seen in several patients with a variety of tumour types where stable disease of more than 30 weeks, and a decrease in specific tumour biomarkers such as PSA, have been observed.

These early efficacy signals have been seen in a range of cancer types, including prostate for which Jevtana® is approved, and also others such as pancreatic and ovarian cancers, which are not currently approved indications for Jevtana®. These efficacy signals are particularly exciting as most patients in the trial have been previously treated with multiple cycles of a variety of cancer therapies, including chemotherapies such as taxanes (docetaxel, cabazitaxel, Abraxane®), hormone therapies and immuno-oncology (IO) agents.

In addition, patients that were treated with DEP® cabazitaxel exhibited a notable lack of bone marrow toxicity, e.g. neutropenia, leukopenia and anaemia, compared to Jevtana® for which greater than 90% of patients experience these potentially life-threatening bone marrow toxicities. No dose-limiting or other significant toxicities have been observed to date.

Currently, two UK sites are recruiting patients for the dose escalation phase, which is moving to its seventh dose escalation level, with the majority of patients having been dosed with multiple cycles of DEP® cabazitaxel. New sites are being qualified and will be added to the trial once it progresses to the dose expansion phase on reaching the recommended phase 2 dose.

DEP® cabazitaxel is Starpharma's detergent-free version of the cancer drug, Jevtana®, which is marketed by Sanofi Aventis to treat advanced prostate cancer, and which is also under clinical development for a range of other cancer types, including testicular, ovarian, breast and head and neck. Jevtana® sales are forecast to exceed US$500 million this year[1].

[1] Medtrack database – accessed 26 August 2019

DEP® docetaxel

The ongoing phase 2 DEP® docetaxel trial is also delivering promising interim results in a variety of tumour types, including prostate cancer and non-small cell lung cancer (NSCLC). The DEP® docetaxel phase 2 program includes both a monotherapy arm and the use of the product in combination with Nintedanib. Both arms also continue to show a notable lack of bone marrow toxicity (e.g. neutropenia) and other common side effects including hair-loss, anaphylaxis and oedema.

In the DEP® docetaxel trial, efficacy signals have been observed in tumour types typically treated with docetaxel (prostate cancer and NSCLC) and in tumour types not typically treated with docetaxel. Based on efficacy signals observed and investigator interest, cohorts have been expanded to allow additional tumour types to be explored, including pancreatic cancer.

Further potential combinations are also being explored following interest from specialist oncologists. This interest stems from DEP® docetaxel's lack of bone marrow toxicity and impressive performance when combined with other chemotherapeutic agents in preclinical human cancer models. In addition, given the lack of need for steroid pre-treatment, combinations with IO agents are also under discussion.

This exciting clinical data for both DEP® cabazitaxel and DEP® docetaxel continues to be fed into partnering discussions and has been positively received by potential partners.

Dr Jackie Fairley, Starpharma CEO, commented: "We are very pleased with these early observations for DEP® cabazitaxel, particularly for those patients who have had long-standing stable disease and reduced bone marrow toxicity which often results in significant side-effects (neutropenia, anaemia etc) with Jevtana® therapy. In addition, the fact that we are seeing efficacy in a variety of tumours such as prostate, pancreatic and ovarian is extremely promising. The growing body of clinical data from our DEP® docetaxel and DEP® cabazitaxel products demonstrates the compelling advantages for patients and for our commercial partners. The commercial utility of the DEP® platform is also evidenced by our partnerships, including with AstraZeneca, and we look forward to them taking their first DEP® candidate, AZD0466, into the clinic later this year", concluded Dr Fairley.

About DEP® docetaxel

DEP® docetaxel is a patented, detergent-free, enhanced version of the widely used anti-cancer drug, docetaxel (Taxotere®), and is currently in a phase 2 trial. Docetaxel is one of the most widely used cancer drugs for treatment of a wide range of solid tumours including breast, lung and prostate. It is marketed by Sanofi Aventis as Taxotere® and generated peak global sales in excess of US$3 billion. These sales are despite the current (non-dendrimer) formulation of docetaxel having US Food and Drug Administration (FDA)-mandated 'black box' warnings.

About DEP® cabazitaxel

DEP® cabazitaxel is a patented, detergent free version of the cancer drug, Jevtana®, and is currently in a phase 1 / 2 trial. Jevtana® is a leading oncology agent used to treat advanced prostate cancer and is also under development for other cancers including testicular, ovarian, breast, and head and neck. The current (non-dendrimer) formulation of the product has US Food and Drug Administration (FDA)-mandated 'black box' warnings in relation to neutropenia, which is a major dose limiting side effect, and severe hypersensitivity (e.g. anaphylaxis) resulting from the polysorbate-80 detergent excipient used in its formulation.

About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX:SPHRY), located in Melbourne Australia, is an ASX 300 company and is a world leader in the development of dendrimer products for pharmaceutical, life science and other applications.

Starpharma's underlying technology is built around dendrimers – a type of synthetic nanoscale polymer that is highly regular in size and structure and well suited to pharmaceutical and medical uses. Starpharma has two core development programs: VivaGel® portfolio and DEP® drug delivery with the Company developing several products internally and others via commercial partnerships.

VivaGel®: Starpharma's women's health product - VivaGel® BV is based on SPL7013, astodrimer sodium, a proprietary dendrimer. VivaGel® BV for bacterial vaginosis (BV), is available for sale under the brand name Betadine BV™ (Europe) and Fleurstat BVgel (Australia) and a new drug application has been submitted to the US FDA. Starpharma has licensed the sales and marketing of VivaGel® BV to ITF Pharma for the US; Mundipharma for Europe, Russia, CIS, Asia, the Middle East, Africa and Latin America; and to Aspen Pharmacare for Australia and New Zealand. Starpharma also has licence agreements to market the VivaGel® condom (an antiviral condom which includes VivaGel® in the lubricant) in several regions, including Australia, Europe, Canada, China and Japan (Okamoto). The VivaGel® condom has been launched in Japan under Okamoto's 003 brand, and in Australia and Canada under the Lifestyles® Dual Protect™ brand.

DEP® - Dendrimer Enhanced Product®: Starpharma's DEP® drug delivery platform has demonstrated reproducible preclinical benefits across multiple internal and partnered DEP® programs, including improved efficacy, safety and survival. Starpharma has three internal DEP® products – DEP® docetaxel, DEP® cabazitaxel and DEP® irinotecan - in clinical development in patients with solid tumours. Starpharma's partnered DEP® programs include a multiproduct DEP® licence with AstraZeneca, which involves the development and commercialisation of two novel oncology compounds, with potential to add more. In June 2019 Starpharma signed a Development and Option agreement with AstraZeneca for a DEP® version of one of AstraZeneca's major marketed oncology medicines.

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Forward Looking Statements

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