ASX Announcement

Starpharma commences phase 1/2 DEP® irinotecan trial

Melbourne, Australia; 8 August 2019: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that it has received the necessary regulatory and ethics approvals and will commence its phase 1/2 clinical trial for DEP® irinotecan. The objectives of the trial are to evaluate the safety, tolerability and pharmacokinetics of DEP® irinotecan to define a recommended phase 2 dose (RP2D), and to determine anti-tumour efficacy of the product in select tumour types. DEP® irinotecan is the third DEP® product to enter the clinic from Starpharma's internal portfolio with a fourth, partnered DEP® candidate, AZD0466, also set to enter the clinic later this year.

The DEP® irinotecan trial will be conducted at multiple leading UK cancer centres including The Christie, The Royal Marsden and Newcastle Freeman Hospital as the initial trial sites. Additional sites in the UK and Australia will open and commence recruitment as the trial progresses and for the phase 2 part of the trial. Approximately 40-45 patients will be enrolled across the combined phase 1/2 trial.

Irinotecan, a widely used cancer drug marketed by Pfizer as Camptosar® or Campto®, is used alone or in combination with other drugs for the treatment of colorectal cancer (CRC). Despite US FDA "Black Box" warnings for both neutropenia and severe diarrhoea, Camptosar® achieved peak annual sales of US$1.1 billion. The clinical use of irinotecan is limited by these toxicities.

DEP® irinotecan is a novel, patented nanoparticle formulation of SN-38, the active metabolite of irinotecan, delivered using Starpharma's proprietary DEP® technology. DEP® irinotecan has shown a number of benefits compared to the original form of irinotecan, including significant improvements in anti-cancer efficacy and improved survival in multiple human cancer models.

CRC is one of the most common cancers in the world, affecting more than 1 million individuals annually, and is the fourth-leading cause of cancer-related death. The efficacy of Camptosar® in the treatment of cancer is dependent on the conversion of irinotecan in the liver to the active metabolite, SN-38, and this process can be highly variable within and between patients. The variability can lead to difficulties in patient management and dosing.

Starpharma's phase 1/2 study for DEP® irinotecan will enrol patients with advanced solid tumours, including CRC, and is an open-label study. In the phase 1 part of the study, DEP® irinotecan will be administered once every three weeks at escalating doses to characterise the safety, tolerability and pharmacokinetic (PK) profile of DEP® irinotecan and to establish the RP2D. In the phase 2 part of the study, patients will be enrolled at the RP2D to generate information on the anti-tumour efficacy of DEP® irinotecan in specific tumour types while further characterising the safety, tolerability and pharmacokinetics of the product.

The adaptive trial design employed will enable Starpharma to move seamlessly from phase 1 to phase 2 and to explore efficacy as early as possible. As the trial progresses, decisions will be made as to which tumour types to focus on, and the tumour types need not necessarily be limited to current indications approved for irinotecan. Already, DEP® irinotecan has demonstrated exciting preclinical results in both colorectal and pancreatic cancer. Combination therapy regimens with DEP® irinotecan may also be investigated.

Dr Jackie Fairley, Starpharma CEO, commented: "We are delighted to be advancing DEP® irinotecan into the clinic. This is the third internal DEP® product developed using Starpharma's delivery platform to commence human trials. There are currently limited options available for colorectal cancer patients who do not respond to conventional therapy, and clinicians are keen to get this trial underway."

"In addition to our three internal DEP® products, we are also looking forward to AstraZeneca's first DEP® product, AZD0466, commencing clinical trials later this year. The growing DEP® clinical portfolio illustrates the optionality and commercial value created by Starpharma's DEP® platform," concluded Dr Fairley.

Additional background:

DEP® irinotecan has already been extensively investigated in preclinical human colon and pancreatic cancer models:

- DEP® irinotecan showed significant efficacy and survival benefits over leading colorectal cancer drugs, irinotecan (Camptosar®) and cetuximab (Erbitux®), in the irinotecan-refractory, HT-29 human colon cancer model – announced on 24 May 2019.

- DEP® irinotecan also showed impressive efficacy and survival benefits over standard irinotecan in combination with 5-FU in a human pancreatic cancer model – announced on 5 September 2018.

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

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.