

New Australian site opening for DEP® trials

Melbourne, Australia; 9 July 2020: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced the opening of a new trial site for the phase 2 DEP® irinotecan trial, at the Kinghorn Cancer Centre in Sydney. The DEP® irinotecan trial is also being conducted at multiple leading UK cancer centres including The Christie, The Royal Marsden, Newcastle Freeman Hospital, and The Beatson West of Scotland Cancer Centre. The Kinghorn Cancer Centre will also be opened shortly as an additional site for the phase 2 DEP® cabazitaxel trial.

The phase 2 study for DEP® irinotecan is an open-label trial, with the objective of establishing anti-tumour activity (efficacy) and safety of the product. The trial has already enrolled several colorectal cancer (CRC) patients, and will enrol a total of approximately 20-30 patients with CRC and other cancers. As part of this clinical program, Starpharma is currently also evaluating a number of potential value-adding clinical combinations, including with immuno-oncology (IO) agents following impressive data from a [recent combination study](#) with DEP® irinotecan plus an IO agent (anti PD-1 antibody) in multiple preclinical CRC models.

Dr Jackie Fairley, Starpharma CEO, commented: “The Kinghorn Cancer Centre is a world-class facility and we’re very pleased that Australian patients will be able to access Starpharma’s innovative DEP® products in these trials.”

About DEP® irinotecan & colorectal cancer

DEP® irinotecan is a novel, patented dendrimer nanoparticle of SN-38, the active metabolite of irinotecan.

DEP® irinotecan recently progressed to phase 2 following positive human clinical results in phase 1 announced on [7 May 2020](#). In the phase 1 trial conducted in major cancer centres in the UK, DEP® irinotecan was well-tolerated and patients generally experienced fewer severe side effects than are reported with conventional irinotecan, including no cases of the problematic severe diarrhoea, for which conventional irinotecan has an FDA black box warning. Encouraging efficacy signals with DEP® irinotecan were also observed in 50% of evaluable patients - not only in patients with CRC but also in patients with breast and pancreatic cancer.

These encouraging clinical results follow an extensive body of preclinical data in which DEP® irinotecan has shown multiple benefits compared to the original form of irinotecan, including significant improvements in anti-cancer efficacy and improved survival in multiple human cancer models (colorectal, pancreatic and breast). It has also shown benefit in combination in a range of current therapies including [5-FU](#), [Eribitux®](#) and [Lynparza®](#) in a variety of 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.

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, astodimer sodium, a proprietary dendrimer. VivaGel® BV for bacterial vaginosis (BV), is available for sale under the brand names Betafem® BV Gel (UK), Betadine BV™ (Europe), Betadine™ BV Gel (Asia) and Fleurstat BVgel (Australia and New Zealand) 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. The VivaGel® condom is approved in Europe.

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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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.