ASX Announcement

Starpharma to commence DEP® cabazitaxel phase 1/2 trial

Melbourne, Australia; 31 January 2018: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that it has received regulatory and ethics approvals to commence its phase 1/2 clinical trial for DEP® cabazitaxel. The objectives of the trial are to evaluate the safety, tolerability and pharmacokinetics of DEP® cabazitaxel, to define a recommended phase 2 dose (RP2D), and then to determine anti-tumour efficacy of the product in select tumour types.

The trial will be conducted at multiple sites, with Guy's Hospital London and University College London Hospital (UCLH) in the UK being the first sites to open for recruitment. Further sites will open and commence recruitment as dose escalation progresses and the phase 2 part of the trial gets underway. Approximately 35 patients will be enrolled across the phase 1/2 trial.

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

DEP® cabazitaxel is the second product from Starpharma's DEP® platform to enter the clinic, and follows DEP® docetaxel, which delivered positive phase 1 clinical results in 2017 and recently progressed to phase 2. The reproducible benefits observed for DEP® docetaxel and DEP® cabazitaxel in preclinical models include decreased bone marrow toxicity and enhanced efficacy, and in both cases DEP® has also allowed for a detergent-free formulation resulting in significant additional benefits for patients.

In parallel, AstraZeneca's first DEP® product, AZD0466, has been developed under licence with Starpharma and has also demonstrated preclinical improvements consistent with findings for DEP® docetaxel and DEP® cabazitaxel.

The phase 1/2 study for DEP® cabazitaxel will enrol patients with advanced solid tumours and is an open-label study. In phase 1, DEP® cabazitaxel will be administered once every three weeks at escalating doses to determine if there are any Dose Limiting Toxicities (DLTs) and to establish the Maximum Tolerated Dose (MTD). The characterisation of the safety, tolerability and PK profile of DEP® cabazitaxel will help establish and characterise the RP2D.

In phase 2, the study will initially enrol up to 20 patients at the RP2D to determine the anti-tumour efficacy of DEP® cabazitaxel in specific tumour types, and to further characterise the safety, tolerability and PK of the product.

The adaptive trial design employed enables 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 any additional patients required to further characterise efficacy in specific tumour types.

Dr Jackie Fairley, Starpharma CEO, commented: "We are delighted to advance DEP® cabazitaxel – our second DEP® product from our internal portfolio to the clinic. DEP® cabazitaxel has already delivered exciting preclinical results showing sustained efficacy and survival benefits, as well as eliminating neutropenia, which is a significant dose-limiting side effect of many anti-cancer drugs, including Jevtana®.

"These benefits for DEP® cabazitaxel are consistent with the recent positive phase 1 results for our lead internal DEP® product, DEP® docetaxel and findings in partnered DEP® programs. The growing body of data from our DEP® products illustrates the broad applicability of the DEP® platform and the compelling commercial advantages of enhancing drug performance and reducing toxicity for patients, while extending patent life", concluded Dr Fairley.

About DEP® cabazitaxel

Starpharma's DEP® platform was utilised to create DEP® cabazitaxel, a detergent free version of cancer drug Jevtana®. Jevtana® is a leading oncology agency which is used to treat advanced prostate cancer and also under development for other cancers including breast cancer, bladder cancer and head and neck cancer. The current (non-dendrimer) formulation 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 sever hypersensitivity (e.g. anaphylaxis) resulting from the polysorbate 80 detergent used in its formulation.

DEP® cabazitaxel significantly outperformed Jevtana® in a human breast cancer model with respect to both level and duration of anti-cancer activity and survival, whilst protecting against the development of neutropenia, which is a serious side effect for Jevtana®.

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 a number of products internally and others via commercial partnerships.

VivaGel®: Starpharma's portfolio includes women's health products based on VivaGel® (SPL7013, astodrimer sodium), a proprietary dendrimer. VivaGel® BV is approved for marketing in the EU and Australia for bacterial vaginosis (BV). Starpharma has a license agreement with Aspen Pharmacare Australia Pty Ltd for the sales and marketing of VivaGel® BV in Australia and New Zealand. Starpharma has also developed an antiviral condom which uses VivaGel® in the lubricant, which is available in Australia and Canada under the Lifestyles® Dual Protect™ brand. Starpharma has a number of license agreements to market the VivaGel® condom in other regions, including China and Japan (Okamoto).

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 two internal DEP® products – DEP® docetaxel and DEP® cabazitaxel - in clinical development in patients with solid tumours, and further DEP® products approaching clinical development. 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.

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