

## US patent issued for DEP cabazitaxel nanoparticle

**Melbourne, Australia; 15 September 2021: Starpharma** (ASX: SPL, OTCQX: SPHRY) today announced that the US Patent and Trademark Office has granted a new patent in relation to DEP<sup>®</sup> cabazitaxel. The *composition of matter* patent builds on Starpharma's suite of existing international DEP<sup>®</sup> patents for the product. It specifically covers a DEP<sup>®</sup> dendrimer conjugated to multiple cabazitaxel drug molecules via a particular releasable linker, with a patent term to 2039 and the potential for a further 5 year extension. The [DEP<sup>®</sup> cabazitaxel](#) nanoparticle is currently in late phase 2 clinical development, recruiting patients with solid tissue tumours, including prostate, ovarian and gastro-oesophageal cancers.

[DEP<sup>®</sup> cabazitaxel](#) is a proprietary nanoparticle version of leading prostate cancer drug cabazitaxel (Jevtana<sup>®</sup>), which had global sales of US\$536 million in 2020.

DEP<sup>®</sup> cabazitaxel is an aqueous nanoparticle formulation which has a number of advantages compared to the original formulation of cabazitaxel. DEP<sup>®</sup> cabazitaxel is a water soluble, polysorbate-80 (detergent)-free formulation, with no requirement for pre-treatment with steroids nor G-CSF to reduce the risk of severe bone marrow toxicity. In both preclinical and clinical studies, DEP<sup>®</sup> cabazitaxel has shown an improved side effect profile, notably markedly reduced bone marrow toxicity demonstrated by lower rates of severe neutropenia, thrombocytopenia and severe anaemia, which are all experienced by a significant proportion of patients treated with Jevtana<sup>®</sup>.

Starpharma has completed a phase 1 trial of DEP<sup>®</sup> cabazitaxel in patients with solid tissue tumours where efficacy signals were observed including in patients with prostate, gastro-oesophageal, breast, ovarian, cholangiocarcinoma and pancreatic cancer. Patients in the phase 1 trial were treated with up to 15 cycles of DEP<sup>®</sup> cabazitaxel with no steroid, antihistamine or anti-emetic pre-treatment. Patients experienced significantly lower levels of side effects commonly associated with Jevtana<sup>®</sup> such as bone marrow toxicity (neutropenia, anaemia, thrombocytopenia) anorexia and vomiting. There were no cases of hypersensitivity; no cases of hair-loss; no need for anti-nausea medications.

Starpharma's phase 2 trial of DEP<sup>®</sup> cabazitaxel is well advanced with more than 40 patients treated with multiple cycles of DEP<sup>®</sup> cabazitaxel in which the markedly reduced rates of severe / life-threatening bone marrow toxicity and a lack of severe hypersensitivity continues to be demonstrated. In the trial, encouraging efficacy signals have been observed in multiple tumour types, including in prostate cancer where radiological responses, significant reductions in prostate-specific antigen (PSA) and no new bone metastases were observed. These encouraging efficacy signals were observed despite patients having been heavily pre-treated - with an average of 30 prior cycles of treatment, and in some cases with more than 100 cycles and up to 10 different treatment regimens. In addition to the responses described above in prostate cancer, patients treated with DEP<sup>®</sup> cabazitaxel have also exhibited encouraging

efficacy signals in gastro-oesophageal, ovarian, cholangiocarcinoma, lung, and head and neck cancers.

Starpharma Chief Executive, Dr Jackie Fairley, commented: “The grant of this new US patent illustrates the unique and compelling benefits of Starpharma’s DEP<sup>®</sup> drug delivery technology and DEP<sup>®</sup> cabazitaxel. We look forward to completing the phase 2 clinical program for DEP<sup>®</sup> cabazitaxel, in parallel with commercial discussions with potential licensing partners.”

DEP<sup>®</sup> cabazitaxel was developed using the Company’s proprietary DEP<sup>®</sup> drug delivery platform, which is being used by Starpharma and a number of partners to create novel nanoparticle formulations of existing and new drugs to enhance both their therapeutic and commercial value. DEP<sup>®</sup> drug delivery is applicable to a wide range of drugs, in oncology (including radiopharmaceuticals and ADCs) and other therapeutic areas. In addition to developing its own internal pipeline of DEP<sup>®</sup> assets, Starpharma has several DEP<sup>®</sup> commercial partnerships with companies, including AstraZeneca, Chase Sun and Merck & Co., Inc., to develop DEP<sup>®</sup> versions of their products or ADCs, including AstraZeneca’s DEP<sup>®</sup> AZD0466, a Bcl2/xL inhibitor that is currently in clinical development with a global trial in haematological tumours commencing earlier this year.

### **About DEP<sup>®</sup>**

Starpharma’s proprietary dendrimer-based DEP<sup>®</sup> platform has broad commercial applicability in drug delivery by enhancing the therapeutic utility of drugs through improved solubility, efficacy and pharmacokinetic control, reductions in certain toxicities (e.g. bone marrow toxicity) and creating a unique intellectual property position. The novel DEP<sup>®</sup> platform has shown reproducible advantages across a wide range of drug classes and can be utilised with both small molecule drugs, peptides and proteins, and in the development of unique DEP<sup>®</sup> based ADCs, radiotherapies and radiodiagnostics.

Benefits of DEP<sup>®</sup> dendrimer drug delivery include:

- Improving efficacy
- Improving therapeutic index
- Reducing toxic side effects of drugs
- Enhanced and controllable pharmacokinetics
- Tumour targeting
- Increased aqueous solubility, avoiding the need for toxic excipients (e.g. polysorbate-80) thus reducing the need for steroid pre-treatment
- Delivering a variety of payloads (small molecules, proteins, radio-isotopes)
- Creation of new intellectual property

Starpharma has three phase 2 clinical stage DEP<sup>®</sup> assets, multiple preclinical DEP<sup>®</sup> programs, and has applied its DEP<sup>®</sup> technology in partnership with pharmaceutical companies for many different applications (passive and targeted ADC and radiotheranostics) and diseases (oncology and non-oncology applications).

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## About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHY) is a global biopharmaceutical company and a world leader in the development of new pharmaceutical and medical products based on proprietary polymers called dendrimers, with programs for respiratory viruses, DEP<sup>®</sup> drug delivery and VivaGel<sup>®</sup>. Starpharma has developed VIRALEZE<sup>™</sup>, an antiviral nasal spray that is registered for sale in the UK/Europe and India, and available in certain markets via [www.viraleze.co](http://www.viraleze.co). VIRALEZE<sup>™</sup> is not approved for sale or supply in Australia. SPL7013 is utilised in approved products - the VivaGel<sup>®</sup> condom and VivaGel<sup>®</sup> BV. VivaGel<sup>®</sup> BV has been licensed in >160 countries, is approved in >45 countries and available for sale in the UK, Europe, Japan, South East Asia, South Africa, Australia and New Zealand.

As a leading company in dendrimer-based drug delivery, Starpharma's proprietary drug delivery platform technology, DEP<sup>®</sup>, is being used to improve pharmaceuticals, to reduce toxicities and enhance their performance. There are numerous internal and partnered programs underway to develop DEP<sup>®</sup> versions of existing drugs, particularly in the area of anti-cancer therapies. DEP<sup>®</sup> partnerships include oncology programs with AstraZeneca, with Merck in the area of Antibody Drug Conjugates (ADCs), with Chase Sun in the area of anti-infectives and other world leading pharmaceutical companies. Starpharma's partnered DEP<sup>®</sup> programs have the potential to generate significant future milestones and royalties.

[Starpharma.com](http://Starpharma.com) | [Twitter](https://twitter.com/Starpharma) | [LinkedIn](https://www.linkedin.com/company/starpharma)

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### Media: Sumit Media

Grant Titmus  
Mob: +61 419 388 161  
[grant@sumitmedia.com.au](mailto:grant@sumitmedia.com.au)

### Starpharma Holdings Limited

Dr Jackie Fairley, Chief Executive Officer  
Nigel Baade, CFO and Company Secretary  
+61 3 8532 2704  
[investor.relations@starpharma.com](mailto:investor.relations@starpharma.com)  
4-6 Southampton Crescent  
Abbotsford Vic 3067

### 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.