ASX Announcement

FDA Authorisation of First-in-Human Clinical Trial with AstraZeneca's DEP® product AZD0466

- **AZD0466 is a highly optimised nanomedicine formulation of a novel dual Bcl2/xL inhibitor using Starpharma's DEP® delivery technology**
- **This important milestone precedes initiation of the clinical trial program for AZD0466, expected to start later this year**

Melbourne, Australia; 26 September 2019: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that that the U.S. Food and Drug Administration (FDA) has authorised the use of AstraZeneca's DEP® Bcl2/xL conjugate AZD0466 in clinical trials under an investigational new drug (IND) application. This is the first DEP® candidate to reach this milestone from Starpharma's multiproduct license with AstraZeneca.

Authorisation by the FDA precedes the commencement of US clinical trials, with the AZD0466 clinical program expected to commence later this year following site set-up and ethics committee/IRB approvals.

AZD0466 is a highly optimised nanomedicine formulation of a novel dual Bcl2/xL inhibitor which utilises Starpharma's DEP® delivery technology to improve the therapeutic margin[1].

AstraZeneca describes AZD0466 as having the potential to be a best-in-class agent in this field with a broad combination opportunity in solid and haematological tumours (blood cancers)[2] due to its ability to target *both* Bcl2 and BclxL.

The Bcl family of proteins are important in the regulation of cell death, known as apoptosis. Bcl2 is a clinically validated oncology target with venetoclax (Venclexta™ - AbbVie/Genentech) being approved by the US FDA in 2016 with estimated peak global sales projected to be between US$2-3 billion[3].

Starpharma CEO, Dr Jackie Fairley commented: "This first partnered DEP® product to receive IND clearance is a really exciting and significant milestone, not only for our collaboration with AstraZeneca, but also for Starpharma's DEP® platform more broadly. This milestone, together with the recent announcement of the granting of a US patent for DEP® Bcl2/xL inhibitor conjugates, demonstrates both the therapeutic and commercial benefits of the DEP® platform and provides further validation for DEP®. We look forward to AstraZeneca commencing clinical trials for AZD0466 in the near future and are excited to be involved with such a ground-breaking therapy".

AZD0466 is the first DEP® product under Starpharma's previously announced multiproduct DEP® license with AstraZeneca, with Starpharma eligible to receive development, launch and sales milestones of up to US$124 million, plus tiered royalties on net sales. Starpharma has previously received US$4 million in milestones under this license. AstraZeneca funds the development costs of DEP® AstraZeneca products under the license, including AZD0466.

[1] https://www.astrazeneca.com/content/dam/az/events_files/asco-2019/20190601%20Prsn%20bos3.pdf
[2] 3rd AstraZeneca-MedImmune-CRUK Cambridge Centre Symposium 2017 presentation
[3] https://www.fiercepharma.com/pharma/abbvie-roche-snag-another-cll-nod-time-for-venclexta-gazyva; https://www.fiercepharma.com/pharma/abbvie-roche-drive-venclexta-toward-3b-rituxan-combo-nod-cll

Starpharma also has three other clinical-stage products (DEP® docetaxel, DEP® cabazitaxel and DEP® irinotecan) which utilise its novel, patented DEP® technology, therefore AZD0466 will be the fourth DEP® product to enter the clinic.

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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Media
WE Buchan Consulting
Rebecca Wilson
Mob: +61 417 382 391
rwilson@buchanwe.com.au

Arthur Chan
+61 2 9237 2805
achan@buchanwe.com.au

Starpharma
Dr Jackie Fairley, Chief Executive Officer
Nigel Baade, CFO and Company Secretary
+61 3 8532 2704
investor.relations@starpharma.com

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.