

## Positive AZD0466 clinical data presented by AstraZeneca

- AZD0466 shown to be well tolerated in patients with advanced haematological malignancies, with no dose-limiting toxicities (DLTs) reported to date
- AstraZeneca presents preliminary AZD0466 clinical trial results from an ongoing Phase 1/2 multi-centre trial at the 64<sup>th</sup> American Society of Hematology (ASH) Annual Meeting 2022
- AZD0466 is a highly optimised dendrimer nanoparticle formulation of an AstraZeneca drug which utilises Starpharma's DEP<sup>®</sup> technology and is being developed by AstraZeneca under its multi-product license with Starpharma. Under this agreement, Starpharma stands to receive milestones of up to US\$124M, plus royalties
- Patient recruitment is ongoing for the Phase 1/2 multi-centre trial in patients with advanced relapsed/refractory leukemia at escalating doses of AZD0466 as a precursor to the Phase 2 component of the trial

**Melbourne, Australia; 13 December 2022: Starpharma** (ASX: SPL, OTCQX: SPHRY) today announces preliminary AZD0466 clinical trial results from the ongoing Phase 1/2 trial in patients with advanced relapsed/refractory leukemia (NCT04865419), presented by Starpharma's partner AstraZeneca at the 2022 [American Society of Hematology](#) (ASH) Annual Meeting today.

The clinical data reported show that AZD0466 has been well tolerated, with no DLTs reported to date and no discontinuations due to treatment-related adverse events. Five dose escalations have already been successfully completed, with further dose escalations underway. This Phase 1/2 trial in relapsed/refractory leukemia patients continues to enroll at 17 sites across the United States, Europe, Asia and Australia, with more than 30 additional sites planned.

Starpharma's dendrimer drug delivery technology, known as DEP<sup>®</sup>, is used to enhance the therapeutic properties of drugs to improve solubility, efficacy, pharmacokinetics, targeting, and reduce certain toxicities. Starpharma has developed three clinical stage products using the DEP<sup>®</sup> technology, which is also the subject of multiple partnerships with leading pharmaceutical companies, including AstraZeneca, Merck & Co., Inc., Genentech, and Chase Sun.

These AZD0466 clinical results were presented in a poster presentation by AstraZeneca at the ASH Annual Meeting today. The poster is available on Starpharma's website. AZD0466 was also highlighted in a session titled 'Emerging AstraZeneca Hematology Pipeline'. Starpharma is also participating in the ASH conference and meeting with partners while in the US.

**Dr Jackie Fairley, Starpharma CEO, commented:** "We are delighted to see these AZD0466 clinical trial results presented for the first time at the ASH meeting in New Orleans. AZD0466 is the result of a highly successful collaboration between AstraZeneca and Starpharma and the presentation of this trial data marks an important milestone in the development of AZD0466. This positive clinical data further validates the potential of Starpharma's DEP<sup>®</sup> technology in a fourth clinical-stage oncology product."

AZD0466 is a highly optimised dendrimer nanoparticle formulation of AstraZeneca's dual Bcl-2/xL inhibitor, AZD4320, which utilises Starpharma's DEP<sup>®</sup> technology, and is being

developed by AstraZeneca under their multi-product DEP<sup>®</sup> license with Starpharma. AZD0466 is in a novel class of oncology drugs called dual Bcl-2/xL inhibitors which seek to overcome drug resistance which occurs in treatment with Bcl-2-specific inhibitors including venetoclax. AZD0466 allows for efficient delivery of AstraZeneca's dual Bcl-2/xL inhibitor, with an optimised release profile also designed to reduce the potential for toxicities associated with dual Bcl-2/xL inhibition. Dual Bcl-2/xL inhibition with AZD0466 also has the potential for broader activity than the marketed Bcl-2-specific inhibitor, venetoclax (Venclexta<sup>®1</sup>).

In addition to this clinical trial in patients with advanced relapsed/refractory leukemias, AZD0466 is also being trialed in patients with non-Hodgkin lymphoma, with other indications under consideration. AZD0466 has shown efficacy in both solid and haematological tumours in preclinical models, including resistant/refractory leukemia models.

AZD0466 is the first candidate under Starpharma's multi-product license with AstraZeneca. Starpharma is eligible to receive development, launch and sales milestones, in addition to royalties. To date, Starpharma has received US\$7M in milestones for AZD0466, with the potential to receive milestones of up to US\$124M, plus royalties.

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#### About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) 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 DEP<sup>®</sup> drug delivery, respiratory viruses and VivaGel<sup>®</sup>.

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 MSD in the area of Antibody Drug Conjugates (ADCs), with Chase Syn in the area of anti-infectives, and with other world leading pharmaceutical companies. Partnered DEP<sup>®</sup> programs have the potential to generate significant future milestones and royalties.

Starpharma has developed VIRALEZE<sup>™</sup>, an antiviral nasal spray that is registered in a number of countries, including in Europe and the UK. VIRALEZE<sup>™</sup> is not approved for use or supply in Australia. SPL7013 is also utilised in the following products: VivaGel<sup>®</sup> condom and VivaGel<sup>®</sup> BV. VivaGel<sup>®</sup> products have been licensed in >160 countries and are registered in >45 countries, including the in UK, in Europe, Japan, in Southeast Asia, South Africa, Australia, and New Zealand.

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#### Disclosure

This ASX Announcement was authorised for release by the Chairman, Mr Rob Thomas.

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<sup>1</sup> In 2021, Venclexta<sup>®</sup>, marketed by AbbVie and Roche, had sales of ~US\$1.82 billion, growing at 36% per annum (AbbVie, Press Releases, [AbbVie Reports Full-Year and Fourth Quarter 2021 Financial Results](#), published on 2 February 2022)

### **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.