ASX Announcement

# FDA confirms path to DEP® HER2 first-in-human study

**Melbourne, Australia; 21 April 2026: Starpharma** (ASX: SPL, US OTC: SPHRY), an innovative biotechnology company with two decades of experience in advancing dendrimer technology from the lab to the patient, today announces that the company has met with the United States Food and Drug Administration (US FDA) in a Type C guidance meeting and received positive feedback on the proposed clinical development strategy and design of the first-in-human (FIH) phase 1 clinical study for its DEP® HER2 radiotherapy candidate ("DEP® HER2[1]").

DEP® HER2 is a HER2 receptor-targeting dendrimer conjugate with a lutetium-177 radionuclide payload. Starpharma is developing DEP® HER2 for the treatment of locally advanced or metastatic HER2-overexpressing gastric/gastro-oesophageal junction cancers and other HER2 expressing advanced cancers in patients who have received prior HER2-targeted therapy.

**Key highlights for investors**

- FDA alignment on FIH phase 1 study design and overall clinical development approach for DEP® HER2
- FDA feedback supports plans to initiate the FIH phase 1 study
- FDA confirms that patients with advanced HER2-expressing cancers who have exhausted available HER2-directed therapies represent a population with significant unmet medical need
- FIH phase 1 study remains on track to enter the clinic in H2 CY 2026

**Unmet need**

Overexpression of HER2 is a key driver in aggressive breast and gastric cancers, and there are limited treatment options available to patients after progression, resistance, or toxicity from current HER2-directed therapies. Starpharma is developing DEP® HER2 to address these clinical challenges.

The FDA confirmed that patients with advanced HER2-expressing cancers who have exhausted available HER2-directed therapies represent a population with significant unmet medical need, meaning that there is potential to pursue Fast Track designation and other accelerated development pathways for DEP® HER2 in the future.

**Clinical pathway**

Starpharma plans to conduct a FIH phase 1 study in Europe initially in up to 15 patients to evaluate safety and tolerability, and to characterise pharmacokinetics, biodistribution and organ radiation dosimetry of DEP® HER2 in patients with advanced HER2-positive cancers.

[1] Human Epidermal growth factor Receptor 2

The FDA confirmed that the clinical data generated outside of the US, together with the currently available DEP® HER2 preclinical data package, including a recently completed formal toxicology study, should be adequate to support future US-based clinical studies under an Investigational New Drug (IND) application.

The FDA provided clear guidance on chemistry, manufacturing and controls (CMC) expectations for DEP® HER2, and agreed with Starpharma's current approach to the manufacture and characterisation of Starpharma's novel dendrimer-based radioligand therapy.

Professor Tony Lahoutte, MD, PhD, a physician and Head of the Department of Nuclear Medicine at University Hospital (UZ) Brussel, and Head of Molecular Imaging and Therapy Research (MITH) at the Vrije Universiteit Brussel (VUB) in Belgium, advised Starpharma on the DEP® HER2 radiotherapy clinical development strategy. He attended the FDA meeting as a representative of Starpharma, contributing expert clinical nuclear medicine input to the discussion of our radiopharmaceutical study design.

Following the meeting with the FDA, Prof. Lahoutte commented:

"The FDA's feedback provides important confirmation that Starpharma's first-in-human phase 1 design and overall clinical strategy for DEP® HER2 are in line with regulatory expectations. From a nuclear medicine and radiopharmaceutical perspective, the proposed approach to patient selection, dosimetry and safety evaluation is appropriate. DEP® HER2 combines a HER2-targeting moiety with Starpharma's novel, dendrimer-based delivery platform. The planned clinical study is well positioned to demonstrate the benefit of the dendrimer technology in targeted radioligand therapy, and to support further clinical development of the product for this high unmet-need population with HER2-expressing cancers."

**Next steps**

Starpharma is currently undertaking the activities required to commence the FIH phase 1 study and remains on track to begin in H2 CY 2026. Clinical site selection is complete, and the company is progressing radiopharmacy preparations, site onboarding and required ethics and regulatory approvals.

Cheryl Maley, Starpharma's Chief Executive Officer, commented:

"DEP® HER2 is a key strategic asset for Starpharma, supported by comprehensive preclinical data and a clinically validated platform technology. We are particularly excited by the encouraging data generated to date, which have shown important benefits in targeted delivery for radiotherapeutics.

"This FDA feedback is an important milestone, providing regulatory clarity and validation for the proposed clinical development pathway and marking the exciting transition from preclinical to clinical development. The guidance provides confidence that our current preclinical package, together with the data generated in the forthcoming first-in-patient study, would support a subsequent IND application and clinical development in the US.

"By exemplifying the value of DEP® technology in the high-growth area of radiotherapy in a clinical setting, Starpharma aims to broaden the therapeutic applications and commercial opportunities of its dendrimer platform, whilst continuing to deliver meaningful outcomes for patients."

**About Starpharma**

Starpharma ASX: SPL, US OTC: SPHRY) is an innovative biotechnology company with two decades of experience in advancing dendrimer technology from the lab to the patient. Our mission is to help patients with significant illnesses, such as cancer, achieve improved health outcomes and quality of life through the application of our unique dendrimer technology.

Dendrimers are precise, synthetically manufactured, nanoscale molecules. Their unique properties—including their size, structure, high degree of branching, polyvalency, and water solubility—are advantageous in medical and pharmaceutical applications.

Starpharma's portfolio of dendrimer-based products includes three clinical-stage DEP® (dendrimer enhanced product) assets, preclinical radiopharmaceutical assets, research collaborations, and three commercially marketed over-the-counter (OTC) products.

For more information about Starpharma, visit www.starpharma.com or connect with Starpharma on LinkedIn.

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**Disclosure**
This ASX Announcement was authorised for release by the Chair, 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.