ASX Announcement

DEP® cabazitaxel data presentation at ASCO GI cancer meeting

Melbourne, Australia; 19 January 2024: Starpharma (ASX: SPL, OTCQX: SPHRY) today announces the presentation of the positive results from its Phase 2 clinical trial of DEP® cabazitaxel at the American Society of Clinical Oncology (ASCO) Gastrointestinal (GI) Cancers Symposium[1], which is being held from 18 to 20 January 2024 in San Francisco, US. ASCO is the world's leading professional organisation for physicians and oncology professionals. The ASCO GI Cancers Symposium is the only global meeting of its kind focusing on the latest innovative science and clinical developments in GI cancer treatment, research, and care. It brings together oncology thought leaders, practising clinicians, novel drug developers, and GI specialists from around the world.

Starpharma's scientific poster presents the key results from the Phase 2 trial of DEP® cabazitaxel in patients with advanced gastro-oesophageal cancers, announced on 18 October 2023[2], and additional efficacy data for DEP® cabazitaxel in two subgroups of the gastro-oesophageal cohort with different types of cancers: adenocarcinoma and squamous cell carcinoma (SCC). DEP® cabazitaxel achieved disease control rates of 100% and 50%, respectively, in these advanced and typically hard-to-treat gastro-oesophageal cancers, which have a one-year survival rate of approximately 20%[3,4].

The ASCO GI Cancers Symposium poster will be presented by Associate Professor David Pinato, a leading Clinician Scientist and Consultant Medical Oncologist at the Imperial College London and an investigator for the DEP® cabazitaxel study.

Associate Professor David Pinato, MD, MRCP (UK), MRes, PhD, Clinical Reader and Consultant Medical Oncologist, Director of Developmental Cancer Therapeutics Imperial College London, and Investigator for the trial, said:

"I am excited to share the impressive data on Starpharma's novel dendrimer formulation of cabazitaxel with the gastrointestinal cancer community at this specialist ASCO GI cancers conference.

"DEP® cabazitaxel showed very encouraging efficacy signals in hard-to-treat gastro-oesophageal cancers, in addition to prostate cancer and advanced platinum-resistant ovarian cancer. The patients in this trial had a poor prognosis with few treatment options remaining.

"In the study, DEP® cabazitaxel was well tolerated, including in patients with high-risk clinical features. A number of our patients experienced reduced cancer-related pain, leading to reduced opiate usage, and other improvements in quality of life.

"Based on the data and my experience with DEP® cabazitaxel, it represents a well-tolerated and promising treatment alternative for gastro-oesophageal cancers, with the benefit of less frequent treatment than the standard-of-care taxane option."

The key results from the Phase 2 trial of DEP® cabazitaxel demonstrated highly encouraging anti-tumour activity in advanced gastro-oesophageal cancers in multiple anatomic locations (oesophagus, gastro-oesophageal junction and stomach), including a median progression-free survival (PFS) of 4.0 months and a median overall survival (OS) of 8.6 months.

The results for DEP® cabazitaxel in advanced gastro-oesophageal cancers compare very favourably to standard-of-care paclitaxel treatment in patients with oesophageal or gastro-

[1] https://conferences.asco.org/gi/attend
[2] ASX Announcement dated 18 October 2023: Positive DEP® Cabazitaxel Phase 2 Results in Multiple Cancers
[3] https://www.cancerresearchuk.org/about-cancer/stomach-cancer/survival
[4] https://www.cancerresearchuk.org/about-cancer/oesophageal-cancer/survival

oesophageal junction cancers. DEP® cabazitaxel achieved clinically meaningful improvements with a more than 50% longer median progression-free survival and a 29% longer median overall survival than published data on paclitaxel administered weekly as a second-line treatment[5].

Despite the majority of patients with gastro-oesophageal cancer in Starpharma's study being refractory to first-line therapy, DEP® cabazitaxel achieved a disease control rate (DCR) of 80% and an objective response rate (ORR) of 30%, including stable disease (SD) for up to 27 weeks and partial responses (PR) for up to 17 weeks in evaluable gastro-oesophageal cancer patients.

The DEP® cabazitaxel efficacy results in gastro-oesophageal cancer patients, along with highly encouraging efficacy results in patients with metastatic castrate-resistant prostate cancer and platinum-resistant ovarian cancer, indicate the promising clinical potential of DEP® cabazitaxel in multiple cancer types, including cancers for which conventional cabazitaxel is not indicated[6].

As reported previously, DEP® cabazitaxel was also well-tolerated, with most treatment-related adverse events (TRAEs) being mild to moderate (Grade 1/2, 83%).

Starpharma Chief Executive Officer, Cheryl Maley, commented:

"We are pleased to present the data on DEP® cabazitaxel in gastro-oesophageal cancers at the ASCO GI cancers meeting. Starpharma's dendrimer platform has shown promise in multiple therapeutic areas, and the recent Phase 2 results have clinically validated the effectiveness and safety of Starpharma's DEP® technology, which is designed to improve the therapeutic benefits of drugs while minimising their side effects. We are encouraged by these results and the feedback from patients and clinical trial investigators, which underscore the potential of Starpharma's DEP® technology and its ability to improve treatment outcomes for patients."

The poster is appended.

About DEP® cabazitaxel

Developed by Starpharma, DEP® cabazitaxel is a patented, dendrimer nanoparticle version of conventional cabazitaxel, which is marketed as Jevtana® and widely used in the treatment of prostate cancer. Unlike standard cabazitaxel, DEP® cabazitaxel is highly water soluble, does not contain toxic detergent-like excipients associated with anaphylaxis, and avoids the need for steroid pre-medication. In both preclinical and clinical studies, DEP® 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 reportedly experienced by a significant proportion of patients treated with Jevtana®.

About Starpharma's DEP® platform

Starpharma has developed a unique and valuable delivery platform known as DEP® (Dendrimer Enhanced Product), which utilises dendrimers to improve the effectiveness and safety of conventional and new drugs. DEP® has been widely applied in oncology but also has application to other classes of drugs, such as anti-infectives. DEP® opens new possibilities for more controlled and precisely targeted drug delivery, enhancing therapeutic and commercial opportunities and creating significant optionality. Additionally, the use of DEP® can create new intellectual property and extend the patent life for value-added versions of existing drugs.

Starpharma has developed a deep pipeline of novel DEP® oncology assets. Its clinical-stage assets, DEP® cabazitaxel, DEP® docetaxel and DEP® irinotecan, are improved versions of commonly used chemotherapeutic drugs that have demonstrated improved anti-cancer effects and safety profiles. Additionally, Starpharma has a promising preclinical pipeline, including DEP® Antibody-Drug Conjugates (ADCs) and DEP® radiotheranostic products.

In addition to its internal programs, Starpharma has a number of partnered DEP® programs with global companies, including MSD, Genentech, Chase Sun, and AstraZeneca.

[5] Stockton S, et al., *The Oncologist*, 2023;28(9):827-e822
[6] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/201023s026lbl.pdf

About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHRY) is a world leader in dendrimer technology for medical applications. As an innovative Australian biopharmaceutical company, Starpharma is focused on developing and commercialising novel therapeutic products that address significant global healthcare needs. Starpharma boasts a strong portfolio of products, partnerships, and intellectual property.

Starpharma's innovative technology is based on proprietary polymers called dendrimers, which are precise, synthetically manufactured, nanoscale molecules. The unique properties of dendrimers – including their size, structure, high degree of branching, polyvalency, and water solubility – are advantageous in medical and pharmaceutical applications.

Starpharma uses its dendrimer technology to develop novel therapeutics and to improve the performance of existing pharmaceuticals. Starpharma's portfolio includes multiple clinical-stage oncology products, which utilise its Dendrimer Enhanced Product ('DEP®') drug delivery technology, and marketed products, including VIRALEZE™ and VivaGel® BV, which utilise SPL7013, a proprietary dendrimer with antimicrobial properties.

Starpharma's DEP® drug delivery platform is being used to enhance the effectiveness of existing and novel therapies and to reduce drug-related toxicities through controlled and specified drug delivery.

In addition to Starpharma's internal DEP® programs, Starpharma has multiple DEP® partnerships with international biopharmaceutical companies, including AstraZeneca (oncology), MSD (Antibody-Drug Conjugates), Chase Sun (anti-infectives), and other world-leading pharmaceutical companies. Due to the broad applicability and optionality of Starpharma's DEP® platform, partnered DEP® programs have the potential to generate significant future milestones and royalties.

Starpharma's topical antiviral nasal spray, VIRALEZE™, is now registered in more than 35 countries*, including Europe, the UK, and Asia. Starpharma's novel non-antibiotic vaginal gel, VivaGel® BV, for the treatment of bacterial vaginosis (BV) and prevention of recurrent BV, is registered in more than 50 countries, including in the UK, Europe, Southeast Asia, South Africa, Australia and New Zealand.

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 non-executive director Dr Jeff Davies.

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", "outlook" 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.

Efficacy and safety of dendrimer-enhanced (DEP) cabazitaxel (CTX-SPL9111) in advanced esophago-gastric cancers in a phase 1/2 trial

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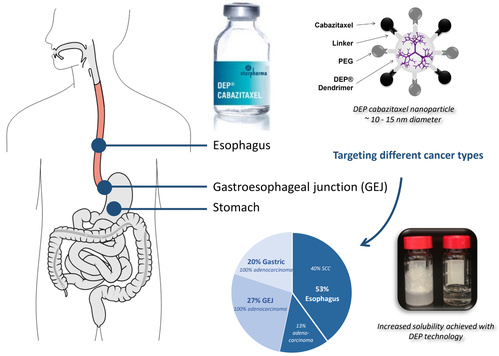
Abstract: 374
Poster H16

Background

- Advanced esophago-gastric cancers (EGC):
  - significant unmet medical need, very poor prognosis, limited available treatments
  - progress rapidly with 1-year survival rate of only 20%[1,2]
- DEP cabazitaxel:
  - novel, patented, poly-L-lysine dendrimer nanoparticle with polyethylene glycol (PEG), and cabazitaxel covalently attached via a hydrolysable linker
  - highly water-soluble, does not contain surfactants (detergents) so does not require routine pre-medication with steroids, H2 antagonists or antihistamines, unlike conventional formulations of cabazitaxel that contain polysorbate 80
  - DEP nanoparticle size restricts it to blood volume, but allows extravasation through leaky tumor vasculature[3], enabling sustained delivery of cytotoxic drugs within the tumor microenvironment
- Standard cabazitaxel is widely used for treatment of metastatic castrate-resistant prostate cancer (mCRPC), but is not indicated for use in other tumor types
- Objectives of this Phase 1/2 trial were to assess preliminary efficacy and safety of DEP cabazitaxel in patients with advanced, metastatic solid cancers
- We present the efficacy and safety of DEP cabazitaxel in a cohort of locally advanced and metastatic EGC patients recruited to the Phase 2 part of this trial
- Phase 1 dose escalation and efficacy in mCRPC patients was presented previously[4]



DEP cabazitaxel nanoparticle ~ 10 - 15 nm diameter

Targeting different cancer types

Patients' cancer primary distribution

Increased solubility achieved with DEP technology

Methods

- Patients with RECIST 1.1 measurable advanced EGC (squamous cell carcinoma [SCC] and adenocarcinoma) were enrolled to receive open label DEP cabazitaxel
- DEP cabazitaxel, equivalent to 20 mg/m^2 cabazitaxel (recommended dose), administered intravenously (IV, ~60 min infusion), once every 21 days (3-weekly)
- Antitumor activity assessed by RECIST v1.1 and, where applicable, tumor biomarker levels such as CEA and CA 19-9; safety assessed by physical and hematological examinations, and adverse events graded according to CTCAE v4.03

KEY ELIGIBILITY CRITERIA

Inclusion Criteria	Exclusion Criteria
• Patients with advanced or metastatic solid tumors • Measurable disease or evaluable tumor marker • Eastern Cooperative Oncology Group (ECOG) performance status 0-1 • Life expectancy ≥ 12 weeks	• Symptomatic brain metastases or untreated spinal cord compression • Absolute neutrophil count (ANC) < 1.5×10^9/L; platelet count < 100×109/L; haemoglobin < 10 g/dL • Bilirubin > ULN, or AST or ALT > 1.5 x ULN • Concurrent or planned treatment with inhibitors/inducers of CYP3A4/5 • Symptomatic grade 1 or ≥ grade 2 peripheral neuropathy (PN) • Anti-tumor therapy ≤ 30 days or 5 half-lives prior to dosing

EU Clinical Trials Register EudraCT: 2017-003424-76

Results

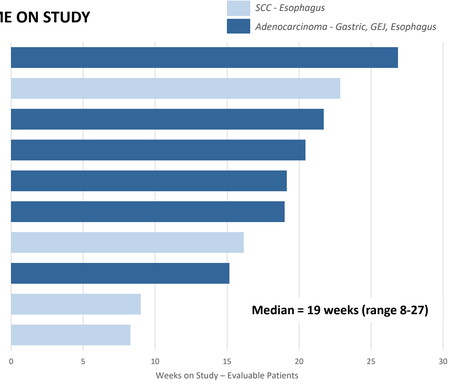
PATIENT BASELINE CHARACTERISTICS		All (N=15)	Adenocarcinoma (N=9)	Squamous Cell Carcinoma (N=6)
Age (years)	Median (Range)	61 (25 – 73)	60 (25 – 70)	68 (50 – 73)
Sex (% (n))	Male	67% (10)	67% (6)	67% (4)
	Female	33% (5)	33% (3)	33% (2)
Race (% (n))	Asian	13% (2)	11% (1)	17% (1)
	Black	7% (1)	0	17% (1)
	Black - Arabic	7% (1)	11% (1)	0
	Caucasian	67% (10)	78% (7)	50% (3)
	Not specified	7% (1)	0	17% (1)
Prior no. lines (incl neoadjuvant / adjuvant) (% (n))	1	53% (8)	67% (6)	33% (2)
	2	27% (4)	22% (2)	33% (2)
	≥3	20% (3)	11% (1)	33% (2)
Selected prior chemo-therapeutic / biologic agents (% (n))	Oxaliplatin	60% (9)	89% (8)	7% (1)
	Cisplatin	27% (4)	11% (1)	50% (3)
	Taxane	27% (4)	22% (2)	33% (2)
	Anti PD-1/PD-L1	27% (4)	0	67% (4)
Definitive Treatment (curative intent) (% (n))	**Yes**	**47% (7)**	**22% (2)**	**83% (5)**
	FLOT + surgery	7% (1)	11% (1)	0
	ECX + surgery	7% (1)	11% (1)	0
	CRT	27% (4)	0	67% (4)
	CRT + surgery	7% (1)	0	17% (1)
	No (metastatic at diagnosis)	**53% (8)**	**78% (7)**	**17% (1)**

FLOT (chemotherapy) + surgery = 5-FU + leucovorin + oxaliplatin + docetaxel + gastrectomy
ECX (chemotherapy) + surgery = epirubicin + cisplatin + capecitabine + esophagectomy
CRT = chemoradiotherapy (fluoropyrimidine / paclitaxel + platinum) + 50.4 Gy radiotherapy
CRT + surgery = carboplatin + paclitaxel + 40.4 Gy RT + esophagectomy

KEY OUTCOMES

- EGC patients received a median of 4.5 DEP cabazitaxel cycles (range 1-7)
- No routine steroid, antihistamine or H2 antagonist pretreatment
- Patients' prior anti-cancer therapy: median of 1 line and median of 6 cycles
- Overall ORR in evaluable patients was 30%, overall DCR was 80%
  - Partial responses (PR) in both adenocarcinoma and SCC subtypes
  - Stable disease (SD) for up to 27 weeks and PR for up to 17 weeks in evaluable EGC patients
- Median progression free survival (PFS) (all enrolled) was 4.0 months
- Median Overall Survival (OS) (all enrolled) was 8.6 months

TIME ON STUDY



PHASE 2 ESOPHAGO-GASTRIC CANCER COHORT EFFICACY OVERVIEW

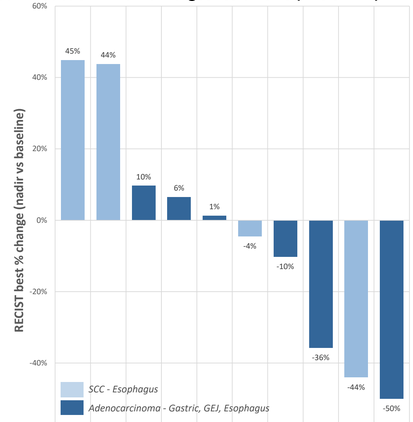
DEP Cabazitaxel					
Tumor type	**Evaluable***	**Disease Control Rate (RECIST)**	**Objective Response Rate (ORR)**	**Median PFS (months)**	**Median OS (months)**
Esophageal / GEJ / Gastric (N=15)	**10**	**80%**	**30%**	**4.0**	**8.6**
Adenocarcinoma (N=9)	6	100%	33%	4.1	ND
SCC (N=6)	4	50%	25%	2.9	ND

**Evaluable = received ≥ 1 dose of DEP cabazitaxel and had a CT scan at ≥ 8 weeks*
ORR, objective response rate (CR+PR)
DCR, disease control rate (CR+PR+SD)
ND, not determined

Unsolicited investigator reports of improvements in patient Quality of Life (QoL) factors included:

- Reduced cancer-related pain and opiate usage
- Improved performance status
- Weight gain

Best % Reduction in Tumor Target Lesion Size (RECIST 1.1)



Primary tumor location	E	E	G	E	GEJ	E	GEJ	E	E	GEJ
Sub-type	SCC	SCC	Ad.	Ad.	Ad.	SCC	Ad.	Ad.	SCC	Ad.
Metastatic at diagnosis	N	N	N	Y	Y	N	Y	Y	N	N
1st line Best Response of PD	N	N	N	Y	N	N	N	Y	Y	N
Prior chemo lines	3	3	2	1	3	1	1	1	1	2
Prior anti-PD-1 / PD-L1	Y	Y	N	N	N	Y	N	N	Y	N
Best % Reduction in Tumor Biomarkers (where applicable)										
CEA	0%	0%	0%	-67%	N/A	-50%	-40%	N/A	-20%	N/A
CA 19-9	9%	-33%	38%	-81%	>100%	-35%	-77%	-99%	-5%	-11%

PD = Progressive Disease
CEA = carcinoembryonic antigen
CA 19-9 = cancer antigen 19-9 / carbohydrate antigen 19-9

SAFETY OVERVIEW

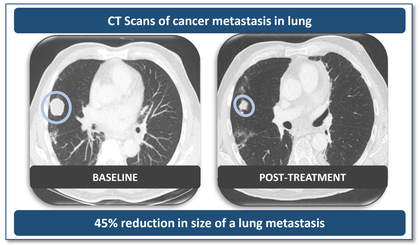
- DEP cabazitaxel was well-tolerated, with mostly Grade 1 (62.9%) / moderate (20%, Grade 2) treatment-related adverse events (TRAEs), with few ≥ severe (grade 3) events
- Limited myelosuppression, including ≥ severe (grade 3) neutropenia – only 1 pt had G-CSF treatment, 1 patient had secondary G-CSF prophylaxis
- Of severe TRAEs (G3/4; 17%) most (80%) were observed in 2 patients, including neutropenia, anemia, thrombocytopenia, fistula, sepsis, elevated liver enzymes
- TRAEs were like those observed for standard cabazitaxel treatment

DEP Cabazitaxel Treatment-related Adverse Events (% of all TRAEs) in EGC patients			
Grade 1	Grade 2	Grade 3	Grade 4
63%	20%	7%	10%

Treatment-Related Adverse Events (Most Extreme Grade) Experienced by ≥ 10% Patients or ≥ Grade 3 (N=15)					
System Organ Class MedDRA Preferred Term	All Grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood and Lymphatic System Disorders					
Anemia	7 (47)	1 (7)	4 (27)	2 (13)	
Neutropenia	7 (47)	2 (13)	1 (7)	1 (7)	3 (20)
Thrombocytopenia	2 (13)	1 (7)		1 (7)	
Gastrointestinal Disorders					
Esophago-pulmonary fistula	1 (7)				1 (7)
Nausea	5 (33)	5 (33)			
Vomiting	3 (20)	2 (13)	1 (7)		
General Disorders and Administration Site Conditions					
Fatigue	5 (33)	4 (27)	1 (7)		
Infections and infestations					
Sepsis	1 (7)				1 (7)
Investigations					
Alanine aminotransferase (ALT) increased	2 (13)	1 (7)			1 (7)
Aspartate aminotransferase (AST) increased	3 (20)	2 (13)			1 (7)
White blood cell count decreased	2 (13)		1 (7)	1 (7)	
Nervous system Disorders					
Peripheral neuropathy	9 (60)	5 (33)	3 (20)	1 (7)	
Skin and Subcutaneous Tissue Disorders					
Nail distrophy	2 (13)	2 (13)			

CASE REPORT: 73-year-old man with Stage IV esophageal SCC

- Developed multiple new lung metastases within 3 months of completing an initial course of chemoradiotherapy with curative intent (first line)
- Achieved partial response following 5 cycles of DEP cabazitaxel:
  - 44% overall decrease in tumor burden
  - 45% reduction in size of a lung metastasis
  - Disease control maintained for 24 weeks



DEP CABAZITAXEL MONOTHERAPY (Q3W DOSE REGIMEN)

HIGHLY ENCOURAGING ANTI-TUMOR ACTIVITY IN ADVANCED ESOPHAGO-GASTRIC CANCERS OF BOTH ADENOCARCINOMA AND SCC HISTOLOGY

- durable responses in esophageal, GEJ and gastric cancers
- concomitant tumor biomarker reductions

WELL-TOLERATED IN ADVANCED CANCER PATIENTS WITH HIGH-RISK CLINICAL FEATURES INCLUDING POOR NUTRITIONAL STATUS

- mostly mild / moderate TRAEs
- limited myelosuppression, lack of need for G-CSF treatment or prophylaxis
- no severe hypersensitivity even in the absence of routine steroid, H2 antagonist and antihistamine premedication

Conclusion

DEP cabazitaxel administered as a monotherapy, once every 3 weeks exhibited highly encouraging anti-tumor activity in >1L, advanced EG cancers:

- multiple anatomic locations (esophagus, GEJ and stomach)
- different histological sub-types: adenocarcinoma and SCC
- included many patients who were refractory to 1st line therapy
- achieved excellent efficacy responses:
  - median progression-free survival (PFS) of 4.0 months
  - median overall survival (OS) of 8.6 months
  - 30% ORR and 80% DCR in evaluable patients

The DEP cabazitaxel results compare very favorably to standard-of-care paclitaxel treatment in patients with esophageal or gastro-esophageal junction cancers, with DEP cabazitaxel achieving a more than 50% longer median PFS and a 29% longer median OS than paclitaxel administered weekly as a second-line treatment[5]. The DEP cabazitaxel efficacy results in advanced EGC patients, along with highly encouraging efficacy results in patients with mCRPC and platinum-resistant ovarian cancer, indicate the promising clinical potential of DEP cabazitaxel in a range of cancer types, including cancers for which conventional cabazitaxel is not indicated[6].

ACKNOWLEDGEMENTS

We would like to thank the patients and their families, and caregivers, for their participation in this study. Starpharma would like to thank participating investigators and their study team for their support on this study, and their dedication to patients, particularly during the challenges attributable to the COVID-19 pandemic.

Study sponsored by Starpharma Pty Ltd, Abbotsford, Australia

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