Cristal Therapeutics to present data at the American Society of Clinical Oncology (ASCO) 2019 Annual Meeting on lead clinical candidate CPC634 in patients with solid tumors

- Three poster presentations will be given by the company and its collaborators
- Florence Atrafi, MD, a clinical investigator on the phase 1 NAPOLY study, has received a prestigious ASCO Merit Award in recognition of her abstract that highlights important research findings

Maastricht, The Netherlands, 17 May 2019 – Cristal Therapeutics, a clinical-stage pharmaceutical company developing targeted nanomedicines for the treatment of cancer and other diseases with high unmet patient need, today announced three upcoming poster presentations that highlight CPC634 positive data from its three phase 1 safety and biodistribution studies at the ASCO 2019 meeting, Chicago, Illinois May 31st - June 4th.

CPC634 is Cristal Therapeutics' lead nanomedicine candidate. It is a new drug modality that entraps the clinically validated chemotherapy docetaxel as its therapeutic payload with CriPec® nanoparticles.

Axel Mescheder, M.D., CEO/CMO, Cristal Therapeutics said*, "We are excited to present data from our ongoing CPC634 clinical development program at ASCO. The results presented are from the first human trials that utilize Cristal Therapeutics' CriPec® nanoparticle technology. CPC634 was specifically designed to overcome the toxic systemic side effects associated with current docetaxel products by enabling enhanced accumulation and ensure sustained release at the tumor site to optimize the therapeutic/safety balance.*

Convincing safety, pharmacokinetic and biodistribution data from our first-in-human studies further strengthen our approach to clinically develop CPC634 as the superior nanomedicine alternative to Taxotere®, a conventional docetaxel product."

The poster presentation details are as follows:

Session (for all posters): Developmental Therapeutics and Tumor Biology (Nonimmuno)

Date and Time (for all posters): Saturday June 1st, 2019 - 8:00-11:00h CT

Location (for all posters): Hall A

1. Abstract # 3026 - NAPOLY Study

Poster Title: A phase I dose-finding and pharmacokinetics study of CPC634 (nanoparticle entrapped docetaxel) in patients with advanced solid tumors.

Presented by: Florence Atrafi, Erasmus MC Cancer Institute, Rotterdam, Netherlands

Results from this pharmacokinetics, safety and tolerability study demonstrated that CPC634 could be safely administered to patients with advanced solid tumors.

A Recommended Phase 2 Dose (RP2D) of 60 mg/m^2 Q3W with corticosteroid pre-treatment was deduced, with minimal reports of dose-limiting toxicities compared to Taxotere®. This included substantially less neutropenia, a life-threatening side effect that typically affects a significant number of Taxotere® patients. Other side effects that were considerably less compared to Taxotere® included, fatigue, peripheral sensory and motor neuropathy, stomatitis, infections, hypomagnesemia and alopecia. Skin toxicity, also known from Taxotere®, was cumulative but manageable and resolved post-treatment.

Compared to pharmacokinetic parameters reported for Taxotere®, CPC634 indicated a higher systemic exposure, measured as longer elimination half-life and Area Under the Plasma Concentration Curve (AUC), which both promote increased tumor uptake.

Florence Atrafi, MD, one of the clinical investigators, received a prestigious ASCO Merit Award, which is given to a select number of young oncology professionals in recognition of a poster abstract that highlights important research findings.

2. Abstract # 3096 – CRITAX study

Poster Title: Nanoparticle entrapped docetaxel (CPC634) enhances intratumoral docetaxel exposure compared to conventional docetaxel (Cd) in patients with solid tumors.

Presented by: Cristianne Rijcken, PharmD Ph.D., Founder and CSO, Cristal Therapeutics (with Florence Atrafi, MD, as first author)

Compared to Taxotere® at a similar dose administration, data from this unique cross-over design phase 1 study illustrated a 4-times higher accumulation of total docetaxel in tumors after CPC634 administration. This is the first time ever that the tumor residence of nanoparticulate-docetaxel has been monitored in patients for a duration that lasts up to several days. The CRITAX study confirms the clinical enhanced permeability and retention (EPR) effects of CPC634, thereby supporting the increased therapeutic index.

3. Abstract # 3093 – PICCOLO study

Poster Title: First-in-human imaging of nanoparticle entrapped docetaxel (CPC634) in patients with advanced solid tumors using ^{89}Zr-Df-CPC634 PET/CT.

Presented by: Iris H.C. Miedema, Amsterdam UMC, Vrije Universiteit Amsterdam, Department of Medical Oncology, Cancer Center Amsterdam, Amsterdam, Netherlands.

PET/CT scanning illustrated the beneficial biodistribution of radiolabelled CPC634 and more importantly its high accumulation in solid tumors and metastases. More specifically, a microdose of ^{89}Zr-Df-CPC634 was shown to be sufficient for quantitative imaging up to 5 days after administration. Piccolo is the first non-invasive clinical study that has visualized a passively-targeted polymeric nanoparticle and demonstrates the EPR effect in patients.

This approach opens the exciting possibility of developing a non-invasive companion diagnostic for CPC634 and other CriPec®-based nanomedicines.

CPC634 is now in phase 2 clinical studies for patients with platinum-resistant ovarian cancer. The primary objective of the trial is to determine the response rate as measured by RECIST, a standard unbiased method for assessing whether a tumor shrinks, stays the same, or gets bigger, with CPC634 monotherapy. The company is exploring strategies towards accelerated development of CPC634 in additional oncology indications.

As well as Cristianne Rijcken, PharmD Ph.D., Founder and CSO, representing Cristal Therapeutics at ASCO, Axel Mescheder, M.D., CEO/CMO and Jeroen Tonnaer, Ph.D. CBO

will also be attending. The poster abstracts are available at the ASCO meeting library or can be viewed on Cristal Therapeutics' Scientific publications page after presentation at the conference.

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About Cristal Therapeutics

Cristal Therapeutics is a clinical-stage pharmaceutical company developing targeted nanomedicines for the treatment of cancer and other diseases with high unmet patient need and considerable commercial potential. The Company's product candidates are based on its proprietary CriPec® polymeric nanoparticle technology platform, which enables the design of customized nanomedicines with superior therapeutic profiles. CriPec®-based products have the potential to provide enhanced efficacy and reduced side effect profiles, thus offering improved disease treatment.

The Company's lead product, CPC634, is in clinical phase 2 studies for the treatment of solid tumors. The Company has several other products in preclinical development focussed on the treatment of cancer.

Cristal Therapeutics is a private company that has raised over €20M equity financing to date. The Company's headquarters and laboratories are located in Maastricht, The Netherlands.

Find out more: www.cristaltherapeutics.com

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