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Starpharma to commence DEP cabazitaxel phase 1/2 trial

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Australia's Starpharma today announced that it has received regulatory and ethics approvals to commence its phase 1/2 clinical trial for DEP cabazitaxel. The objectives of the trial are to evaluate the safety, tolerability and pharmacokinetics of DEP cabazitaxel, to define a recommended phase 2 dose (RP2D), and then to determine anti-tumour efficacy of the product in select tumour types.

The trial will be conducted at multiple sites, with Guy's Hospital London and University College London Hospital (UCLH) in the UK being the first sites to open for recruitment. Further sites will open and commence recruitment as dose escalation progresses and the phase 2 part of the trial gets underway. Approximately 35 patients will be enrolled across the phase 1/2 trial.

DEP cabazitaxel is Starpharma's detergent-free version of cancer drug, Jevtana, which is marketed by Sanofi Aventis to treat advanced prostate cancer, and is also under clinical development for a range of other cancer types, including testicular, ovarian, breast, bladder, and head and neck. Jevtanas ales are estimated to reach approximately US$500 million this year.

DEP cabazitaxel is the second product from Starpharma's DEP platform to enter the clinic, and follows DEP docetaxel, which delivered positive phase 1 clinical results in 2017 and recently progressed to phase 2. The reproducible benefits observed for DEP docetaxel and DEP cabazitaxel in preclinical models include decreased bone marrow toxicity and enhanced efficacy, and in both cases DEP has also allowed for a detergent-free formulation resulting in significant additional benefits for patients.

In parallel, AstraZeneca's first DEP product, AZD0466, has been developed under licence with Starpharma and has also demonstrated preclinical improvements consistent with findings for DEP docetaxel and DEP cabazitaxel.

The phase 1/2 study for DEP cabazitaxel will enrol patients with advanced solid tumours and is an open-label study. In phase 1, DEP cabazitaxel will be administered once every three weeks at escalating doses to determine if there are any Dose Limiting Toxicities (DLTs) and to establish the Maximum Tolerated Dose (MTD). The characterisation of the safety, tolerability and PK profile of DEP cabazitaxel will help establish and characterise the RP2D.

The adaptive trial design employed enables Starpharma to move seamlessly from phase 1 to phase 2 and to explore efficacy as early as possible. As the trial progresses, decisions will be made as to which tumour types to focus on and any additional patients required to further characterise efficacy in specific tumour types.

Dr Jackie Fairley, Starpharma CEO, commented: “We are delighted to advance DEP cabazitaxel – our second DEP product from our internal portfolio to the clinic. DEP cabazitaxel has already delivered exciting preclinical results showing sustained efficacy and survival benefits, as well as eliminating neutropenia, which is a significant dose-limiting side effect of many anti-cancer drugs, including Jevtana.

“These benefits for DEP cabazitaxel are consistent with the recent positive phase 1 results for our lead internal DEP product, DEPd ocetaxel and findings in partnered DEP programs. The growing body of data from our DEP products illustrates the broad applicability of the DEP platform and the compelling commercial advantages of enhancing drug performance and reducing toxicity for patients, while extending patent life”, concluded Dr Fairley