PRESS RELEASE

Heidelberg Pharma's Partner Telix Reports Positive Data on the Pivotal ZIRCON Study

Ladenburg, Germany, 7 November 2022 – Heidelberg Pharma AG (FSE: HPHA) announced today that its licensing partner Telix Pharmaceuticals Limited, Melbourne, Australia, (Telix) presented positive top-line data on its pivotal ZIRCON Phase III study with the imaging agent TLX250-CDx, reporting that the study has meet all of its primary and secondary endpoints.

TLX250-CDx (^{89}Zr-DFO-girentuximab) is an antibody radioactively labeled with zirconium-89 and has been tested by Telix in the ZIRCON study for imaging diagnostics of renal cancer using PET since August 2019. The study was carried out as a global multicenter Phase III trial at 36 study sites in Europe, Turkey, Australia, Canada and the USA. A total of 300 renal cell cancer patients were dosed with TLX250-CDx resulting in 284 evaluable patients. Each patient received a single dose of TLX250-CDx followed by imaging, and a histological tumor sample from surgical resection was provided. The study determined the sensitivity and specificity of TLX250-CDx PET imaging to detect clear cell renal cell cancer (ccRCC) in comparison with histology as standard of truth determined from surgical resection specimens.

The study results delivered a sensitivity of 86% and specificity of 87%, thus exceeding the thresholds required to demonstrate the ability of TLX250-CDx to reliably detect the clear cell phenotype and provide a non-invasive method of diagnosing the presence and spread of ccRCC.

The study has also met the key secondary endpoint, achieving 85% sensitivity and 89% specificity in detecting ccRCC in tumors <4 cm ("T1a" classification), currently a significant clinical challenge in the diagnosis of ccRCC.

These highly positive results demonstrate that TLX250-CDx provides a way to non-invasively diagnose clear cell renal cancer – until now this could only be determined by invasive biopsy or surgery which presents a higher burden or danger for patients.

TLX250-CDx has received "Breakthrough Designation" for TLX250-CDx from the US Food and Drug Administration (FDA). Based on these positive results Telix intends to file a Biologics License Application (BLA) for regulatory approval with the FDA and global regulatory agencies as a positron emission tomography/computed tomography (PET/CT) imaging agent for use in the characterization of indeterminate renal masses previously identified on CT or MRI as ccRCC or non-ccRCC. Potential future utility may include active surveillance, surgical staging and treatment response assessment. Telix is actively engaged in clinical research at leading cancer centres to demonstrate the potential of these indications.

Furthermore, Telix is preparing to launch an Expanded Access Program (EAP) to enable eligible patients to access TLX250-CDx to address unmet need and requests for access under the healthcare professional responsibility prior to marketing authorization.

Dr Colin Hayward, Chief Medical Officer at Telix said: "The excellent sensitivity and specificity demonstrated in the ZIRCON study, validates that the CAIX target could be just as ground-

breaking in ccRCC, as PSMA[1] and its application in PSMA-PET imaging has been for prostate cancer. It could optimize surgical intervention – particularly in the incidence of very small renal masses. These results provide confidence that TLX250-CDx is an important tool not only for diagnosis but for active surveillance and disease staging."

Dr. Jan Schmidt-Brand, Chief Executive and Chief Financial Officer of Heidelberg Pharma AG commented: "We are thrilled about the positive outcome of the ZIRCON study and congratulate the entire Telix team for this outstanding effort in managing this multicenter trial during the pandemic. We at Heidelberg Pharma were aware of the excellent potential of this breakthrough imaging agent for renal cancer and are very pleased to have placed this promising product candidate in the hands of our highly valued partner Telix."

Heidelberg Pharma AG is entitled to milestone payments and double-digit royalties if the product receives marketing approval.

About Heidelberg Pharma

Heidelberg Pharma is an oncology specialist and the first company to develop the toxin Amanitin into cancer therapies using its proprietary ATAC® technology and to advance the biological mode of action of the toxin as a novel therapeutic principle. The proprietary technology platform is being applied to develop the Company's own therapeutic ATACs® as well as in third-party collaborations. The lead candidate HDP-101 is a BCMA ATAC in clinical development for multiple myeloma. HDP-102, a CD37 ATAC for Non-Hodgkin lymphoma and HDP-103, a PSMA ATAC for metastatic castration-resistant prostate cancer, are in preclinical testing.

Heidelberg Pharma AG is based in Ladenburg, Germany, and is listed on the Frankfurt Stock Exchange: ISIN DE000A11QVV0 / WKN A11QVV / Symbol HPHA. More information is available at http://www.heidelberg-pharma.com/.

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[1] Prostate specific membrane antigen, positron emission tomography.