HealthCare Pharmaceuticals Announces ASCO Presentation of DKN-01 Clinical Study in Non-Small Cell Lung Cancer and First Patients Dosed in Clinical Study for DKK1+ Esophageal Cancer

-- Encouraging clinical results seen in Phase 1b study
-- Represents targeted therapy for Esophageal Cancer

Cambridge, MA June 2, 2014 – HealthCare Pharmaceuticals, Inc., a privately-held biopharmaceutical company developing novel, targeted drugs for the treatment of cancer, today announced the presentation of data at the 50th Annual Meeting of the American Society for Clinical Oncology from the clinical development of its DKN-01 monoclonal antibody for the treatment of non-small cell lung cancer (NSCLC) and the dosing of its first patients in a clinical trial of DKN-01 for DKK1 positive (DKK1+) Esophageal Cancer (EC).

DKN-01 is a humanized monoclonal antibody targeting extracellular dickkopf-1 (DKK1). DKN-01 has demonstrated an antitumor effect in DKK1-expressing cell lines, solid tumor xenograft models, and multiple myeloma models. Three DKN-01 clinical studies in oncology have been completed or are ongoing. A Phase 1b trial in patients with advanced malignancies emphasizing NSCLC (P100) is complete. In multiple myeloma, where secretion of DKK1 is known to lead to harmful bone effects, the clinical trial (P101) compares DKN-01 plus lenalidomide and dexamethasone to lenalidomide and dexamethasone alone. The EC study (P102) is evaluating DKN-01 in combination with paclitaxel in patients whose tumors are histologically DKK1+.

Study P100: ASCO Presentation of Non-Small Cell Lung Cancer Data

At the 50th Annual Meeting of the American Society for Clinical Oncology, data was presented from a completed two-part Phase 1b study of DKN-01 in patients with advanced malignancies, with an emphasis on patients with NSCLC. Beyond safety and tolerability, endpoints were progression free survival (PFS), overall response rate (ORR), and overall survival (OS).

Thirty-two patients were enrolled in this two-part study (dose escalation and confirmation), 24 of whom were patients with NSCLC. DKN-01 was well tolerated with no dose limiting toxicities or serious adverse events that were related to DKN-01 treatment. No treatment related adverse events were Grade 3 (Severe), Grade 4 (Life-Threatening) or Grade 5 (Death); no treatment related adverse events led to patient discontinuation. Common treatment related adverse events in this trial where the majority of patients had advanced NSCLC were nausea, fatigue, decreased appetite, dyspnea and vomiting.

Administration of DKN-01 in patients with advanced, heavily pretreated NSCLC in the dose confirmation phase demonstrated clinical activity, with an overall clinical benefit rate of 47.4%
and ORR of 5.3% including 1 patient with a partial response per RECIST criteria with confirmed complete resolution of target disease. Median monotherapy PFS for NSCLC patients receiving 300 mg of DKN-01 every two weeks during the dose confirmation phase was 2.2 months and median OS was 6.6 months.

“With these encouraging results using DKN-01 monotherapy in NSCLC patients, further development is justified. DKN-01 represents an important innovative approach that could eventually provide a paradigm-changing treatment for patients with DKK1+ EC and NSCLC,” said Cynthia Sirard, MD, Chief Medical Officer of HealthCare Pharmaceuticals. “The clinical program is aimed at building on the strong results in preclinical studies and demonstrating proof-of-concept for targeted therapy of DKN-01 in combination with other anti-cancer agents.”

**Study P102: Combination of DKN-01 and paclitaxel in patients with DKK1+ Esophageal Cancer**

HealthCare Pharmaceuticals is currently conducting a two part, Phase 1b study of DKN-01 in combination with paclitaxel in patients with relapsed or refractory, DKK1+ EC tumors. The first patients are enrolled and now being treated. The study will establish the safety of DKN-01 in combination with paclitaxel. The secondary endpoints are ORR, PFS, duration of response, and OS.

“Current treatments for metastatic esophageal cancer are inadequate, and new therapies are desperately needed.” David Ryan, MD, Professor at Massachusetts General Hospital and a principal investigator on the study, noted. “DKN-01 offers a novel opportunity for targeting DKK1, a protein that is overexpressed in many patients with esophageal cancer. This approach could be an important positive step for offering personalized treatment to esophageal cancer patients in need,” said Dr. Ryan.

**About Esophageal Cancer**

Esophageal cancer (EC) is a malignancy of the esophagus. Greater than two-thirds of patients are diagnosed with advanced or inoperable disease. Five-year survival rates for patients with unresectable disease are approximately 15%. For such patients, palliative treatment is frequently proposed to control disease-related symptoms and possibly prolong survival. There are currently no FDA approved therapies for previously treated late stage EC. Studies suggest that 60-80% of EC patient tissue samples with squamous or adenocarcinoma histology are DKK1+.

The American Cancer Society estimated that during 2014, approximately 18,170 new esophageal cancer cases will be diagnosed in the United States and will result in 15,450 deaths. EC is the 7th leading cause of cancer death among males (making up 4% of the total). As of 2012, esophageal cancer is the eighth most common cancer globally with 456,000 new cases, causing about 400,000 deaths.

**About DKN-01 (anti-DKK1 monoclonal antibody)**

DKN-01 is a humanized monoclonal antibody targeting dickkopf-1 (DKK1). DKN-01 has demonstrated an antitumor effect in DKK1-expressing cell lines, xenograft models and multiple myeloma models. HealthCare Pharmaceuticals is studying the use of DKN-01 as targeted
therapy in NSCLC and EC patients whose tumors are DKK1+ and in multiple myeloma patients, where DKK1 is associated with adverse bone effects.

**About HealthCare Pharmaceuticals**
HealthCare Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on discovering and developing novel, targeted therapies for the treatment of patients with cancer. DKN-01, our clinical-stage monoclonal antibody, is currently being tested in Phase 1b and Phase 2 clinical trials for patients with DKK1+ esophageal cancer and multiple myeloma.

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