Phase I study of 4SC's resminostat indicates efficacy in biliary tract cancer

- **Promising results of a Phase I study of resminostat in combination with S-1 chemotherapy in Japanese patients with biliary tract or pancreatic cancer were presented at the ESMO 2017 Congress**
- **4SC's partner Yakult Honsha have committed to continue clinical development of resminostat in patients with biliary tract cancer**

Planegg-Martinsried, Germany, 13 September 2017 – 4SC AG (4SC, FSE Prime Standard: VSC) today announced that the Company's development partner Yakult Honsha together with the investigators presented promising results of a multi-center, open-label Phase I study of 4SC's resminostat in combination with S-1 chemotherapy in 27 Japanese patients with pre-treated biliary tract or pancreatic cancer at the ESMO 2017 Congress. The study was conducted by Yakult Honsha in Japan. S-1 is a chemotherapy combination drug which is approved for the treatment of several solid tumor types including biliary tract or pancreatic cancer in Asia.

The primary objective of the study was to investigate the dose-limiting toxicities of resminostat monotherapy as well as the combination of resminostat and S-1 chemotherapy to determine the recommended regimen that should be used in a subsequent Phase II study. The secondary objectives included safety and efficacy parameters.

Chigusa Morizane, M.D., from the Department of Hepatobiliary and Pancreatic Oncology at the National Cancer Center Hospital in Tokyo, Japan, summarized the results: "As planned, from three different dose and schedule cohorts, we identified a well-tolerated regimen of resminostat/S-1 combination therapy. We observed tumor shrinkage or disease stabilization in all patients with biliary tract cancer receiving second-line study treatment according to the recommended regimen. Advanced biliary tract cancers are highly lethal, but in patients receiving the combination of resminostat and S-1 chemotherapy we saw a remarkable median overall survival of 10.2 months with no disease progression for 5.5 months (in median). Overall, 3 patients continued study treatment for over 180 days and the treatment of 1 patient is still ongoing."

Frank Hermann, M.D., Chief Development Officer of 4SC, commented: "We are very pleased with these promising data. Yakult Honsha confirmed further investigation of the efficacy of resminostat/S-1 combination treatment in Japanese second line biliary tract cancer patients in a subsequent Phase II study to commence in the near future. In parallel, 4SC is continuing to evaluate resminostat for maintenance treatment in patients with advanced-stage cutaneous T-cell lymphoma in our pivotal RESMAIN study in Europe."

- Press release ends -

Related articles

30 May 2017, Resminostat enhances immune cell cancer cell interaction

28 February 2017, 4SC to present supportive preclinical data on resminostat's potential as maintenance therapy for CTCL

26 June 2015, 4SC's partner Yakult Honsha enters with cancer compound resminostat further indications and starts clinical Phase I study in patients with pancreatic or biliary tract cancer in Japan

Further information

About resminostat

Resminostat is orally administered and potentially offers a novel approach to treating a wide variety of cancers, both as monotherapy and in combination therapy with other anti-cancer drugs. Resminostat inhibits tumor growth and proliferation, causes tumor regression, and strengthens the body's own immune response to cancer.

Resminostat has been shown to be well tolerated in patients with advanced cancers in Phase I studies. Its use in the treatment of cutaneous T-cell lymphoma (CTCL), Hodgkin's lymphoma and liver, lung, colon, pancreatic and biliary tract cancers has been and is being investigated in further clinical studies. Initial positive efficacy results for resminostat in monotherapy were observed in patients with Hodgkin's lymphoma and in combination with sorafenib in selected patients with advanced liver cancer (hepatocellular cancer, HCC).

About biliary tract cancer

Biliary tract cancers are highly lethal cancers that comprise a spectrum of carcinomas originating in the bile ducts, the gallbladder or the ampulla of Vater. According to epidemiologic studies the incidence has been increasing over the past few decades. In Japan, the incidence of biliary tract cancer and intrahepatic bile duct cancer is about 10 for every 100,000 people. These cancers typically have a poor prognosis, with 5-year survival rates in the range of 5 to 15%. In Japan, for patients with unresectable biliary tract cancer the combination of gemcitabine and cisplatin is recommended as the first-line chemotherapy. The oral fluoropyrimidine S-1 was also approved for biliary tract cancer in 2007 and is mainly used for second-line therapy.

About the resminostat partnering agreement with Yakult Honsha for Japan

4SC granted an exclusive license to Yakult Honsha for the development and commercialization of resminostat in Japan in April 2011. 4SC has received an upfront payment from Yakult Honsha of EUR 6 million and is eligible for up to approximately EUR 127 million payable upon achieving specified milestones including clinical and regulatory events in Japan. In addition to milestone payments, Yakult will pay 4SC double-digit royalties linked to product sales of resminostat. Yakult Honsha is responsible for all clinical requirements for resminostat development in Japan in oncology indications.

About 4SC

4SC AG is a clinical-stage biopharmaceutical company developing small-molecule drugs that can target key indications in cancer with high unmet medical needs. Such drugs are intended to provide patients with innovative treatment options that are more tolerable and efficacious than existing therapies and provide a better quality of life. 4SC's pipeline is protected by a comprehensive

portfolio of patents and comprises promising products that are in various stages of preclinical and clinical development. 4SC's core assets include resminostat, 4SC-202 and 4SC-208.

4SC's aim is to generate future growth and enhance its enterprise value by entering into partnerships with pharmaceutical and biotech companies and/or the eventual marketing and sales of approved drugs in select territories by 4SC itself. Founded in 1997, 4SC had 45 employees as of 12 June 2017. 4SC has been listed on the Prime Standard of the Frankfurt Stock Exchange since December 2005.

Forward-looking information

Information set forth in this press release contains forward-looking statements, which involve risks and uncertainties. The forward-looking statements contained herein represent the judgement of 4SC as of the date of this press release. Such forward-looking statements are neither promises nor guarantees, but are subject to a variety of risks and uncertainties, many of which are beyond 4SC's control, and which could cause actual results to differ materially from those contemplated in these forward-looking statements. 4SC expressly disclaims any obligation or undertaking to release any updates or revisions to any such statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based.

Contact

Anna Niedl, Ph.D.
Corporate Communications & Investor Relations
anna.niedl@4sc.com
+49 89 700763-66