Positive DSMB safety review of 4SC's pivotal RESMAIN study of resminostat in CTCL

- **Independent Data Safety Monitoring Board (DSMB) recommends RESMAIN study to continue without modification**
- **RESMAIN – pivotal study to evaluate resminostat for maintenance treatment of patients with advanced-stage cutaneous T-cell lymphoma (CTCL)**
- **Top-line results expected in the first half of 2019**

Planegg-Martinsried, Germany, 31 January 2018 – 4SC AG (4SC, FSE Prime Standard: VSC) today announced, that the Data Safety Monitoring Board (DSMB), an independent committee of clinical and drug safety experts, recommends continuation of the ongoing pivotal RESMAIN study without modification of the study protocol. Per the protocol's pre-specified DSMB charter, the first DSMB meeting was scheduled recently to review cumulative safety data after 50 patients have been enrolled and completed at least one treatment cycle.

The pivotal RESMAIN study, which is conducted as a multi-center, double blind, randomized, placebo-controlled, 150 patients study, evaluates resminostat for maintenance treatment of patients with advanced-stage cutaneous T-cell lymphoma (CTCL) who have achieved disease control with prior systemic therapy, at more than 50 clinical centers in 11 European countries. The study is progressing on track and top-line results are expected in the first half of 2019.

Susanne Danhauser-Riedl, M.D., Chief Medical Officer of 4SC, commented: "Safety and tolerability are key requirements for patients and physicians considering a drug especially for the treatment of patients in the maintenance setting. Advanced-stage CTCL patients usually respond to available treatment options but the duration of response is often short-lived and declines as the severity of the disease increases. The aim of a maintenance therapy and thus of our RESMAIN study is to make such remissions more durable, halting disease progression and improving the quality of life of patients.

We are encouraged by the positive outcome of the first independent DSMB safety review. So we continue the trial as planned with the aim of bringing resminostat to patients as quickly as possible."

- Press release ends -

Related articles

20 December 2017, 4SC receives Pediatric Investigation Plan Waiver for resminostat in CTCL from the European Medicines Agency

5 December 2017, Significant milestone reached for pivotal RESMAIN study of resminostat as maintenance therapy in CTCL

10 October 2017, Resminostat demonstrates potential to significantly alleviate itching in CTCL patients

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 immune response to cancer.

Resminostat has been shown to be well tolerated in several clinical trials. Resminostat is currently being investigated in a pivotal study in cutaneous T-cell lymphoma (CTCL) by 4SC. A Phase II study in biliary tract cancer is planned by 4SC's development partner Yakult Honsha in Japan. Amongst others, resminostat has previously been investigated in biliary tract or pancreatic cancer and hepatocellular carcinoma (HCC).

About cutaneous T-cell lymphoma (CTCL)

CTCL is a rare disease with approximately 5,000 patients being newly diagnosed in Europe each year. The disease arises from malignant transformation of T cells, a specialized subgroup of immune cells, primarily affects the skin, but may ultimately involve lymph nodes, blood and visceral organs.

Currently, CTCL is not curable and treatment options for advanced-stage CTCL are limited. Although patients respond to the available treatment options, the duration of response is often short-lived and declines as the severity of the disease increases. The key therapeutic challenge in advanced-stage CTCL is therefore to make remissions more durable, halting disease progression, improving quality of life and prolonging progression free and overall survival.

About the RESMAIN study – Resminostat for maintenance treatment of CTCL

The pivotal RESMAIN study is being conducted at more than 50 clinical centers in 11 European countries. It will include 150 patients who suffer from advanced-stage cutaneous T-cell lymphoma (CTCL) and have achieved disease control with systemic therapy. The patients are randomized 1:1 to receive either resminostat or placebo. Patients who experience disease progression – while being on placebo – will be offered resminostat in an open label treatment arm.

The primary goal of the study is to determine whether maintenance treatment with resminostat prolongs progression-free survival and the key secondary objective is to prolong the time to symptom worsening (itching). A comprehensive biomarker program is also included in the study to ensure vital knowledge about the biological background of resminostat treatment and CTCL is acquired. 4SC anticipates top-line data to be available in 2019.

The concept of maintenance therapy

The pivotal RESMAIN study is focused on patients with advanced-stage, incurable cutaneous T-cell lymphoma CTCL. Such patients suffer from painful and itchy skin lesions resulting in disfigurement and a severely impaired quality of life. Furthermore, lymph nodes, blood or visceral organ can be involved. None of the current therapeutic options achieve stable disease for long periods, with most patients progressing within six months on average.

Resminostat is being evaluated as maintenance treatment – prolonging the period patients are stable and not progressing. Recent preclinical data further suggests that resminostat has the

potential to alleviate the itching in CTCL patients, thereby additionally improving the quality of life for patients.

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 currently comprises three key drug candidates in various stages of preclinical and clinical development: resminostat, 4SC-202 and 4SC-208.

4SC aims 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. 4SC had 47 employees as of 30 September 2017 and is listed on the Prime Standard of the Frankfurt Stock Exchange (FSE Prime Standard: VSC; ISIN: DE000A14KL72).

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.

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