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

No pediatric clinical studies required to support resminostat Marketing Authorization Application in Europe in cutaneous T-cell lymphoma (CTCL)

Planegg-Martinsried, Germany, 20 December 2017 – 4SC AG (4SC, FSE Prime Standard: VSC) today announced that it received a Pediatric Investigation Plan waiver from the European Medicines Agency (EMA) for resminostat in advanced-stage cutaneous T-cell lymphoma (CTCL).

As part of the regulatory process for the registration of new medicines with the EMA, pharmaceutical companies are required to provide a Pediatric Investigation Plan that outlines the clinical development strategy for studying the investigational product in children. In some instances, a waiver from developing a Pediatric Investigation Plan for certain conditions may be granted by the EMA when development of a medicine for use in children is not feasible or appropriate. CTCL is extremely rare in children and if present, is usually an early stage disease that can be controlled quite well with existing therapies.

“This waiver represents an important milestone in the regulatory process for resminostat, and will allow 4SC to submit a Marketing Authorization Application for resminostat to the EMA following successful completion of the pivotal RESMAIN study without the requirement to conduct additional clinical studies in children before or after approval,” said Jason Loveridge, CEO of 4SC.

Resminostat is being evaluated as maintenance therapy in advanced-stage CTCL patients in the pivotal RESMAIN study, which is currently being conducted at more than 50 clinical centers in 11 European countries. Top-line results are expected to be available in the first half of 2019.

- Press release ends -

Related articles

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

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

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 Phase II 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 RESMAIN pivotal study is open for recruitment since November 2016 and 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 results in the first half of 2019. If the results are positive, 4SC will submit the data to the relevant regulatory agencies for market approval of resminostat as maintenance treatment of CTCL.

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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