Q1 Announcement 2019

ABOUT THIS ANNOUNCEMENT

This Q1 Announcement as of 31 March 2019 should be read in conjunction with 4SC's Annual Report for the 2018 financial year.

This document contains certain forward-looking statements that are subject to risks and uncertainties that are described, with no claim to be exhaustive, in the section titled "Report on opportunities and risks" in the Annual Report 2018 and in the "Opportunities and risks" section below. In many cases, these risks and uncertainties are outside of 4SC's control and may cause actual results to differ materially from those contemplated in these forward-looking statements. 4SC expressly does not assume any obligation for updating or revising forward-looking statements to reflect any changes in expectations or in events, conditions or circumstances on which such statements are based.

ABOUT 4SC

4SC is a clinical-stage biopharmaceutical company developing small-molecule drugs that target key indications in cancer with high unmet medical need.

4SC's pipeline is protected by a comprehensive portfolio of patents and currently comprises two drug candidates in clinical development: resminostat and domatinostat.

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 is headquartered in Planegg-Martinsried near Munich, Germany. The Company had 47 employees as of 31 March 2019 and is listed on the Prime Standard of the Frankfurt Stock Exchange (FSE Prime Standard: VSC; ISIN: DE000A14KL72).

BUSINESS REVIEW IN Q1 2019 / YTD AND OUTLOOK

Key events in Q1 2019 and beyond were each made public via a press release. Details can be found in the relevant releases available at www.4sc.com.

RESMINOSTAT

Resminostat is an orally administered class I, IIb and IV histone deacetylase (HDAC) inhibitor that potentially offers an approach to treating different kinds of cancer. Resminostat demonstrated that it is well tolerated and can inhibit tumor growth and proliferation, cause tumor regression, and strengthen the body's immune response to cancer.

Pivotal RESMAIN study in CTCL on track

In 2016, 4SC started the pivotal RESMAIN study – a randomized, double-blind, placebo-controlled clinical Phase II study of resminostat in cutaneous T-cell lymphoma (CTCL). RESMAIN is conducted in more than 50 study centers across 11 European countries and in Japan.

The RESMAIN study is focused on patients with advanced-stage CTCL. Such patients suffer from painful and itchy skin lesions resulting in disfigurement and a severely impaired quality of life. None of the current therapeutic options achieve sustainable clinical benefit, with most patients progressing within six months (on average). Resminostat is being evaluated as a maintenance treatment – prolonging the period patients are stable and not progressing combined with a beneficial decrease of disease-related itching.

More than two thirds of the expected number of patients required to unblind the study are enrolled to date. The Data Safety Monitoring Board, an independent committee of clinical and drug safety experts, evaluated data after 50 and 100 patients have been treated in the study and observed no safety issues. The committee recommended continuation without modification of the study protocol.

4SC expects to see top-line results in H1 2020. If the study results are positive, 4SC plans to submit applications for marketing approval of resminostat in CTCL in Europe and potentially the U.S. and Yakult Honsha will submit in Japan. If approved, resminostat would be the first HDAC inhibitor approved for CTCL in Europe and the first and only drug approved for maintenance therapy in this indication in either Europe, Japan or the U.S.

Phase II study in biliary tract cancer on track

In April 2018, Yakult Honsha Co., Ltd., 4SC's development partner in Japan, initiated a randomized, double-blind, placebo-controlled, multi-center Phase II study evaluating the combination of resminostat and S-1 chemotherapy versus S-1 chemotherapy plus placebo as second-line treatment in 100 Japanese patients with unresectable or recurrent biliary tract cancer. The study is based on a positive Phase I clinical study which was completed in September 2017.

S-1 is a chemotherapy combination drug which is approved for the treatment of several solid tumor types including biliary tract cancer in Asia. The main goal of the study is to prolong progression free survival (PFS) and secondary objectives include efficacy and safety parameters. Final results are expected to be available by mid-2020.

DOMATINOSTAT

Domatinostat is an orally administered small molecule class I selective HDAC inhibitor. It strengthens the body's own anti-tumor immune response, influences the tumor and tumor microenvironment, making the tumor more visible to the immune system and facilitates the infiltration of immune cells into the tumor.

Domatinostat has been investigated in a Phase I study in 24 heavily pretreated patients with several types of advanced hematologic cancers and was well tolerated. Positive signs of anti-tumor efficacy were also observed; with one complete remission (28 months) and one partial responder (8 months).

Domatinostat in combination with checkpoint inhibitors

4SC initiated the Phase Ib/II study SENSITIZE of domatinostat in combination with the anti-PD-1 checkpoint inhibitor pembrolizumab in patients with advanced-stage melanoma. In November 2017, the first patient was enrolled in the study's first dose cohort and since January 2019, patients are being recruited into the third dose cohort. The Safety Review Committee - consisting of clinical and drug safety experts – evaluated the safety data from the first and second dose cohorts respectively and recommended continuation of the study. The SENSITIZE study is expected to complete in H1 2019.

In a second Phase II study, named EMERGE, since January 2019, domatinostat is tested in combination with another checkpoint inhibitor, the anti-PD-L1 antibody avelumab, for treating microsatellite-stable gastrointestinal tumors. Such tumors are largely unresponsive to checkpoint inhibition. The investigator-sponsored study is conducted by Prof. David Cunningham, MD FRCP FMedSci, Head of the Gastrointestinal and Lymphoma Unit and Director of Clinical Research at The Royal Marsden NHS Foundation Trust, London, UK. 4SC expects safety data in Q3 2019 and early efficacy data in Q4 2019.

These two studies – SENSITIZE and EMERGE – are designed to serve several purposes:

- Together they provide safety data for domatinostat in combination with the two main classes of commercially available checkpoint inhibitors, anti-PD-1 and anti-PD-L1,
- Potentially provide evidence to support the efficacy of domatinostat in checkpoint inhibitor refractory/non-responding patients in a major immunogenic tumor indication (melanoma) or in a checkpoint inhibitor non-responsive major indication (microsatellite-stable gastrointestinal cancer),
- Provide sufficient data to initiate clinical trials with domatinostat in combination with a checkpoint inhibitor in Merkel cell carcinoma (MCC).

Domatinostat's mode of action in Merkel cell carcinoma

A clinical cooperation partner presented preclinical data at the American Association for Cancer Research Annual Meeting (AACR) in April 2019 that confirmed domatinostat's mode of action in the aggressive skin cancer MCC. Domatinostat increased the presentation of tumor signals on the cells' surface, stopped MCC cells from dividing and induced cell death. All these effects were specific for MCC cell lines and did not occur in healthy control cells.

The fact that domatinostat counteracts the immune escape of MCC at different levels suggests that the combination of domatinostat with checkpoint inhibitors is potentially a promising therapeutic strategy in MCC and 4SC plans to initiate a number of clinical trials later this year.

Evaluation of further combination partners

In 2018, 4SC presented a poster with preclinical data supporting double and triple combinations of domatinostat and checkpoint inhibitors and a collaborator of 4SC presented an additional poster with preclinical data supporting the combination of domatinostat with chemotherapy in cancer.

In April 2019, Dynavax Technologies Corporation (Dynavax) presented preclinical data at AACR on the combination of orally available domatinostat with Dynavax's intra-tumoral TLR9 agonist SD-101. The combined treatment induced a systemic anti-tumoral immune response in tumor mouse models, resulting in significant decrease in tumor size of both target tumors and distant site metastases. Dynavax also compared domatinostat to other class-I-selective HDAC inhibitors, with domatinostat demonstrating the most significant benefit in combination with SD-101.

Based on these promising preclinical results, 4SC is currently evaluating further clinical studies of domatinostat in different combinations.

4SC-208

4SC-208, an orally-available hedgehog/GLI signaling inhibitor, is currently being evaluated in preclinical models.

OUT-LICENSED PROGRAMS

4SC continues to explore partnering opportunities in line with its strategy to monetize non-core assets.

In April 2019, Immunic, Inc. (Immunic) completed a merger with Vital Therapies, Inc. leading to a NASDAQ

listing (ticker symbol: IMUX). Following such merger and as part of the agreement concluded in September 2016 with Immunic to sell 4SC's non-core immunology portfolio to Immunic, 4SC became a small shareholder of the listed entity and continues to be entitled to receive royalties.

DEVELOPMENT OF CASH FUNDS IN Q1 2019 AND FINANCIAL FORECAST

As of 31 March 2019, 4SC holds cash balance/funds of €21,247 thousand as compared to €25,036 thousand as of 31 December 2018. The monthly use of cash from operations amounted to €1,263 thousand on average in the first quarter of 2019 (Q1 2018: €1,812 thousand) and was below the range of €1,400 thousand and €1,600 thousand forecast for 2019.

The decrease in the monthly use of cash as compared to Q1 2018, and the decrease in cash balance/funds in the first quarter of 2019 as compared to the end of 2018, were both predominantly due to costs for the ongoing clinical studies RESMAIN and SENSITIZE.

The Management Board of 4SC believes that these funds should be sufficient to finance 4SC into Q2 2020.

OPPORTUNITIES AND RISKS

As 4SC's opportunities and risks have remained virtually unchanged, please see pages 18 to 24 of the Annual Report 2018 for a detailed description of the opportunities and risks arising from the Company's business activities as well as its IT-based risk management and controlling system.

The occurrence of any one of the risks described in the Annual Report – alone or in conjunction with each other – could have a negative impact on the results of operations, financial position and net assets of 4SC.

PUBLISHING INFORMATION

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18 April 2019

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4SC ON THE INTERNET

More information about 4SC, its products and development programs, is available on the Company's website, www.4sc.com, as well as the following information:

- Previous reports on 4SC's progress and outlook
- Audio recordings of conference calls
- Presentations
- General investor information

CORPORATE COMMUNICATIONS & INVESTOR RELATIONS

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