Q1 Announcement 2020

ABOUT THIS ANNOUNCEMENT

This Q1 Announcement as of 31 March 2020 should be read in conjunction with 4SC's Annual Report for the 2019 financial year.

The report at hand contains certain forward-looking statements that are subject to risks and uncertainties that are described, with no claim to be exhaustive, in the section entitled "Report on opportunities and risks" in the Annual Report 2019, and also 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 can target key indications in cancer with high unmet medical needs.

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 46 employees as of 31 March 2020 and is listed on the Prime Standard of the Frankfurt Stock Exchange (FSE Prime Standard: VSC; ISIN: DE000A14KL72).

BUSINESS REVIEW IN Q1 2020 / YTD AND OUTLOOK

Key events in Q1 2020 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 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

The RESMAIN study is focused on patients with advanced-stage cutaneous T-cell lymphoma (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.

By the end of Q1 2020 155 patients had been enrolled into the RESMAIN study. Enrollment into the RESMAIN study has been impacted by the coronavirus crisis but 4SC has tried to minimize this by rapid implementation of measures to ensure ongoing treatment of patients and data integrity in the study. At the end of Q1 2020 it is obviously difficult to forecast when the 125 events – i.e. patients experiencing disease progression – will be reached such that the study can be unblinded. 4SC intends to keep investors informed of significant changes in the RESMAIN study as the coronavirus crisis progresses.

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 microenvironment, makes the tumor more visible to the immune system and facilitates the infiltration of immune cells into the tumor.

Domatinostat in combination with checkpoint inhibitors

In order to evaluate domatinostat's combination potential, two Phase Ib/II clinical trials were initiated, in 2017 and 2019 respectively, with domatinostat in combination with a checkpoint inhibitor.

The Phase Ib/II SENSITIZE study is a dose escalation/ dose expansion study of domatinostat in combination with the checkpoint inhibitor pembrolizumab – an anti-PD-1 antibody approved as a cancer immunotherapy against melanoma - in patients with advanced-stage melanoma who are refractory to anti-PD-1 antibody treatment.

Data from the first part of the SENSITIZE study was published at the ESMO Congress of the European Society of Medical Oncology in September 2019, where three patient cohorts were treated at three different dose levels of domatinostat in combination with pembrolizumab. 4SC expects to publish updated data from the SENSITIZE study in Q3 2020.

The Phase Ib/II EMERGE study, initiated in January 2019, is also a dose escalation/dose expansion study, conducted initially in up to 15 patients with micro-satellite-stable gastrointestinal cancer. The study will

evaluate domatinostat in combination with the check-point inhibitor avelumab (an anti-PD-L1 antibody) as part of an investigator sponsored trial (IST) conducted by Professor David Cunningham at The Royal Marsden NHS Foundation Trust (London, UK).

The third and final dose cohort of the first part of EMERGE started enrolling patients in January 2020, but enrollment has now been temporarily suspended due to the coronavirus crisis. It is currently difficult to predict when the study will recommence.

Domatinostat in Merkel cell carcinoma

Merkel cell carcinoma (MCC) is a highly immunogenic, orphan type of non-melanoma skin cancer. In 2017, avelumab was approved in both the EU and U.S. for advanced metastatic MCC followed in December 2018 by pembrolizumab which was approved in the U.S. for the same indication. Although PD-1 and PD-L1 inhibitors are now standard of care in metastatic MCC, around half of all such patients still progress and currently lack any effective therapeutic options and suffer from high mortality.

To address the unmet medical need in advanced-stage MCC, 4SC intends to initially evaluate domatinostat in combination with checkpoint inhibition in up to 40 MCC patients progressed on treatment with checkpoint inhibitors (MERKLIN 2 study), as well as in checkpoint naïve MCC patients (MERKLIN 1 study).

In April 2020 4SC received approval from the U.S. Food and Drug Administration (FDA) for its IND (Investigational New Drug) application for MERKLIN 2, domatinostat in combination with the checkpoint inhibitor avelumab, and will begin enrollment of patients as soon as the current coronavirus crisis allows.

Domatinostat as neoadjuvant therapy in melanoma

Neoadjuvant therapy refers to an approach in which a form of therapy is given as a first step to shrink a tumor before the main treatment, which is usually surgery. Neoadjuvant therapy is already an approved clinical strategy in breast cancer and is rapidly gaining support in melanoma.

Alongside addressing later stage patients (in the SENSITIZE, EMERGE and MERKLIN 2 studies), 4SC believes that utilizing domatinostat in combination with immunotherapy as neoadjuvant therapy is a novel and strategically important positioning for the drug and as such, the Company entered into a collaboration with the Netherlands Cancer Institute (Stichting Het Nederlands Kanker Instituut (NKI) – Antoni van Leeuwenhoek Ziekenhuis) in Amsterdam to support a Phase II clinical study (DONIMI) in 45 resectable stage III melanoma patients. The study is evaluating combining domatinostat and checkpoint blockade as neoadjuvant therapy in biomarker-selected sub-groups of such patients and successfully enrolled the first 4 patients in Q1 2020. Top-line data from this neo-adjuvant study could be available in H1 2021, although it is difficult to forecast the impact the coronavirus crisis will have on patient recruitment as recruitment of new patients has been temporarily suspended.

OUT-LICENSED PROGRAMS

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

DEVELOPMENT OF CASH FUNDS IN Q1 2020 AND FINANCIAL FORECAST

As of 31 March 2020, 4SC holds cash balance/ funds of €40,350 thousand as compared to €45,765 thousand as of 31 December 2019. The monthly use of cash from operations amounted to €1,677 thousand on average in the first quarter of 2020 (Q1 2019: €1,263 thousand) and was below the range of €2,200 thousand and €2,600 thousand forecast for 2020.

The increase in the monthly use of cash as compared to Q1 2019 is mainly a result of the expansion of clinical programs for domatinostat, especially for the preparation of the clinical activities for the MERKLIN 2 study. For the full year 2020, 4SC continues to forecast a monthly use of cash in the above-mentioned range.

The Management Board of 4SC believes that the funds should be sufficient to finance 4SC into the second half of 2021.

OPPORTUNITIES AND RISKS

At present, 4SC cannot accurately estimate the effect of the current CoVID-19 pandemic on the conduct of its ongoing clinical studies, although it is clear that 4SC's studies will be negatively impacted, particularly with respect to the recruitment of new patients.

Aside, as 4SC's opportunities and risks have remained largely unchanged, please see pages 20 to 27 of the Annual Report 2019 for a detailed description of the opportunities and risks arising from the Company's business activities as well as its IT-based risk manage-ment and controlling system.

The occurrence of any one of the risks described in this announcement or/and 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.

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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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