SER150 – First Disease-Modifying, Immuno-Modulating Therapy of Diabetic Kidney Disease

(Status: September 2019)

Epidemiology

In 2017, there were 425 Mio. diabetic patients globally, in 2045, the number of diabetic patients is estimated to rise to 629 Mio., which is an increase of 48% within that time span. 30 - 40% of T1D/T2D patients develop diabetic kidney disease in the course of time. Costs for dialysis, kidney transplantation and follow up costs can easily reach between 50 -100 k€ per patient year.

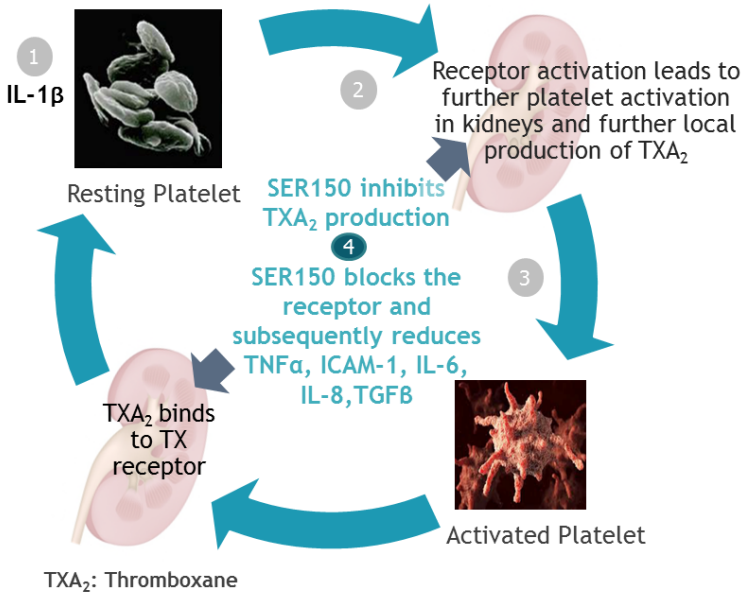
Current Treatment Options

Low grade inflammation drives the progression of T2D and its complications. For the time being, there is no disease-modifying (=immuno-modulating) medication for the treatment of diabetic kidney disease available. In diabetic patients with hypertension, treatment with ACEs or ARBs has shown beneficial effects in several outcome studies on the progression of diabetic kidney disease due to a reduction of blood pressure in the kidneys. The SGTL2 inhibitor canaglifozin has also shown beneficial effects in T2D patients with kidney disease. J&J is in discussion with the FDA regarding a respective label claim.

SER150 – Breaking the Vicious Cycle of Inflammation

SER150, a dual thromboxane A2 (TXA) receptor antagonist and TXA2 synthase inhibitor, will become the first disease modifying (=immuno-modulating) medication on the market for the treatment of diabetic kidney disease. SER150 is a small molecule, given orally 15 mg bid. SER150 is protected by both a Composition of Matter Patent (expires in 2027) and a newly filed Medical Use Patent (expires in 2039). SER150 offers a huge cost saving potential for healthcare insurances due to a significant delay in the loss of kidney function as well as a significant improvement of the quality of life for the diabetic patient with kidney disease.

SER150 – Mode of Action



1. Resting platelets are activated by IL-1ß.
2. Thromboxane is produced by activated platelets aggregated locally in the diabetic kidney.
3. Thromboxane in turn activates more resting platelets, converting them into activated platelets.
4. **SER150 inhibits thromboxane synthesis and blocks the receptor.**

Source:, Navarro-Gonzalez 2008, Brown 1998, Reale 1996

SERODUS

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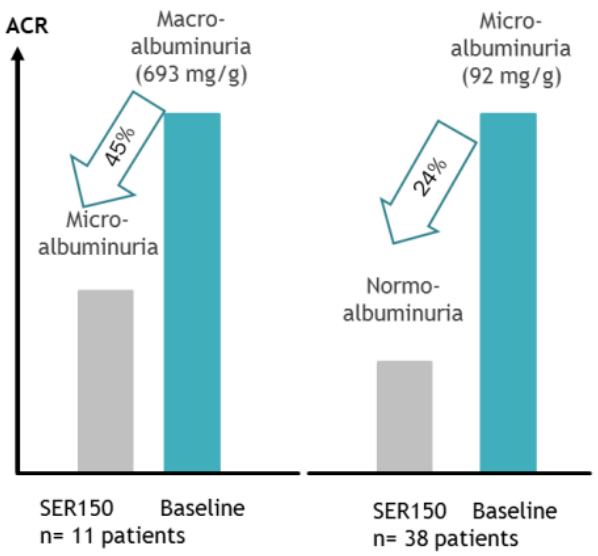
SER150 – Status Clinical Development Program

Short term tox studies have confirmed the safety of SER150, long term tox studies are currently ongoing and will be finalized in Q1 2020. A placebo-controlled Phase 2a study in T2D patients has demonstrated excellent efficacy (=reduction in urinary protein) and safety of SER150 already after 4 weeks of treatment.

The pivotal SER150 Phase 2/3 development program in T2D patients with macro-albuminuria is going to start in Q2 2020. Both FDA and EMA are expected to accept ACR as primary surrogate endpoint in studies with diabetic patients with pronounced kidney disease. The pivotal Phase 2/3 development program will be finalized end of 2023. Study centers will be located both in Europe and the US.



*ACR: Urine albumin corrected for creatinine

Source: Macro/Micro, Micro/Normo. Post hoc analysis SER150 CLII-R007

SER150 – Regulatory Affairs Strategy

Serodus is in discussion with FDA regarding breakthrough treatment designation and EMA regarding Prime status for SER150 in T2D patients with kidney disease as of to date, there is no disease-modifying treatment available for these patients.

Serodus ASA

Serodus ASA was founded in 2008 in Oslo as spin-off from Biomedicine Innovation. It is a virtual, innovative biopharmaceutical company with a lean management structure and a strong pipeline of four immuno-modulating compounds for the treatment of diabetic complications. The lead compound is SER150. Serodus' Management Team has ample experience in diabetes research, drug development and in the management of Life Science Start Up companies. The Scientific Advisory Board comprises diabetes experts from both Europe and the USA.

Serodus ASA Finance History and Current Financing Round

Serodus' ownership is tightly controlled. The three major shareholders account for 71% of its equity. Serodus is currently looking for 45 Mio. € to finance the pivotal SER150 Phase 2/3 clinical development program and its operations during the period 2020 – 2024.

Exit Strategy

It's envisaged to complete the SER150 clinical pivotal development program by 2023. Afterwards a Trade Sale of the SER150 Package to a major global pharmaceutical company with focus on diabetes in an auction process is planned in 2024.

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