Clinical Development of Mannan conjugated birch pollen allergoids for the treatment of birch pollen allergic patients – from first-in-human to clinical validation in 3 studies

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Rationale

The aim of a drug development program for allergen immunotherapies is to get market authorization based on a good efficacy and safety/tolerability profile. Here, we describe the clinical development of Mannan conjugated birch pollen allergoids (T502) for the treatment of allergic rhinitis/rhinoconjunctivitis.

Methods

The Phase IIa study was planned as a first-in-human DBPC dose finding hybrid study, which covered both, safety/tolerability and efficacy. The second trial was then conducted as an open Phase II/III study with patients from the first study, with all patients being treated with the most effective dose. The third (Phase III) trial was also designed as a DBPC trial in a larger patient population.

Conclusions

Early efficacy data can be collected already in a dose-finding study. Through the subsequent open design, further data on safety, tolerability and efficacy can be collected.

Results

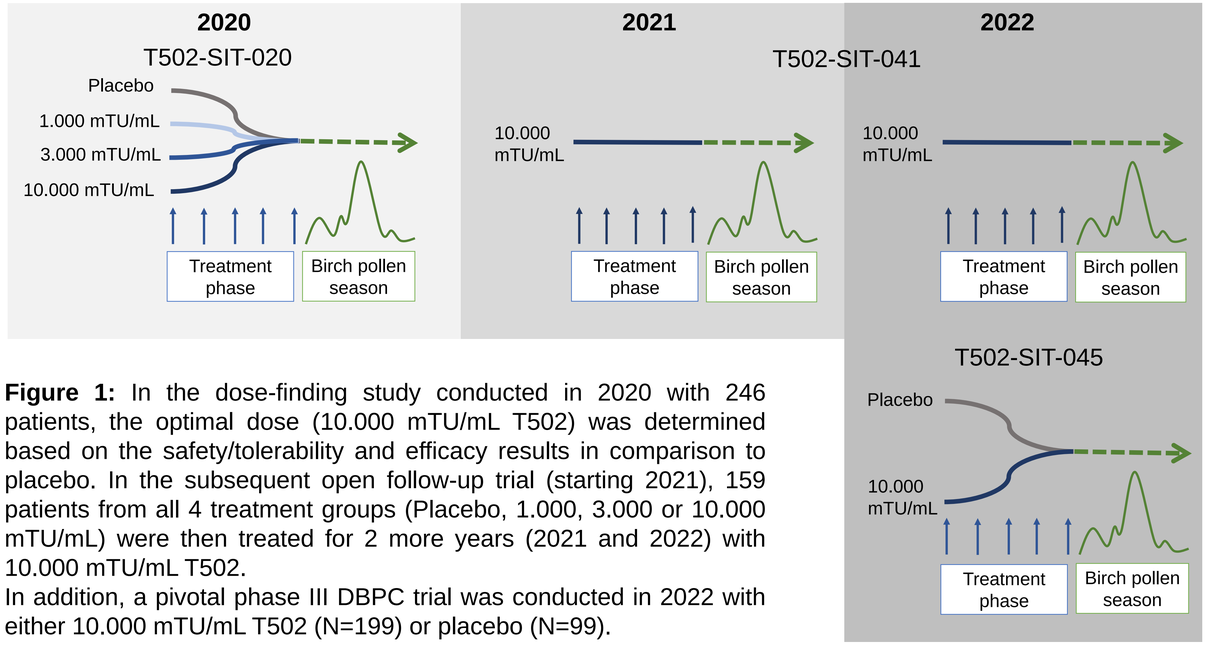

Figure 1: In the dose-finding study conducted in 2020 with 246 patients, the optimal dose (10.000 mTU/mL T502) was determined based on the safety/tolerability and efficacy results in comparison to placebo. In the subsequent open follow-up trial (starting 2021), 159 patients from all 4 treatment groups (Placebo, 1.000, 3.000 or 10.000 mTU/mL) were then treated for 2 more years (2021 and 2022) with 10.000 mTU/mL T502.
In addition, a pivotal phase III DBPC trial was conducted in 2022 with either 10.000 mTU/mL T502 (N=199) or placebo (N=99).

2020		2021		2022	
T502-SIT-020		T502-SIT-041			
Treatment	N Patients	Treatment	N Patients	Treatment	N Patients
Placebo	61	10.000 mTU/mL	141	10.000 mTU/mL	116
1.000 mTU/mL	60				
3.000 mTU/mL	60				
10.000 mTU/mL	61				

T502-SIT-045	
Placebo	99
10.000 mTU/mL	199

Table 1: In total, 419 patients were treated with 10.000 mTU/mL T502 over a time period of up to 3 consecutive years and 160 patients were treated with placebo.

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