

## **The SQ tree SLIT-tablet reduces rhinoconjunctivitis symptoms and medication use during the tree pollen season (hazel, alder and birch pollen seasons) – Results from a large multi-centre phase 3 trial**

Immunotherapy / Immunotherapy: clinicals

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### **Background**

The SQ tree SLIT-tablet (ALK, Denmark) is in development for once-daily, home-administered treatment of moderate to severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group. Here, we report the results of a phase 3 trial.

### **Method**

The TT-04 trial (EudraCT 2015-004821-15) was a randomised, DBPC, phase 3 trial. 634 subjects were randomised 1:1 to the SQ tree SLIT-tablet (12 DU dose) or placebo. All subjects received at least 16 weeks of treatment before start of the 2017 tree pollen season, i.e., hazel, alder and birch pollen seasons. The efficacy endpoints assessed daily rhinoconjunctivitis symptom score (DSS), daily rhinoconjunctivitis medication score (DMS) and the sum of these; i.e., total combined score (TCS) during the birch pollen season (BPS) and TPS. The primary endpoint was average TCS during the BPS. Safety endpoints primarily included adverse events.

### **Results**

The treatment effects on the average TCS, DSS and DMS in the BPS and TPS were all statistically significantly greater for the SQ tree SLIT-tablet compared to placebo. The primary endpoint of average TCS during the BPS showed an estimated absolute difference of 3.02 corresponding to a reduction of 39.6% in favour of the SQ tree SLIT-tablet relative to placebo ( $p < .0001$ ). For the average TCS during the TPS the estimated absolute difference was 2.27, corresponding to a difference of 36.5% relative to placebo ( $p < .0001$ ). For the average DSS, the estimated absolute differences were 1.32 for the BPS, corresponding to a difference of 36.8% relative to placebo ( $p < .0001$ ), and 0.99 for the TPS, corresponding to a difference of 32.7% relative to placebo ( $p < .0001$ ). DSS and DMS contributed almost equally to the observed treatment effect during both the BPS and TPS. The TCS during the alder and hazel season was analysed post-hoc and demonstrated an estimated absolute difference between the SQ tree SLIT-tablet and placebo of 1.21, corresponding to a difference of 29.7% relative to placebo ( $p = 0.0015$ ).

Treatment was well-tolerated with local reactions in the mouth and throat as the most common treatment-related adverse events; the majority were mild or moderate in severity and had onset on day 1-2. No deaths or anaphylactic reactions were reported with the SQ tree SLIT-tablet.

### **Conclusion**

The TT-04 trial demonstrated a positive benefit-risk balance with a clinically relevant treatment effect

of the SQ tree SLIT-tablet during the entire TPS.