1. **STUDY IN SUMMARY**

The aim of this study was to compare the efficacy and tolerability of budesonide (bud) nasal powder, given to patients with seasonal allergic rhinitis only at the onset of symptoms or given also before/early in the pollen season. The study was carried out in 14 centres as a randomised, double-blind, parallel-group comparison of 5 alternative treatment regimens given for 4 weeks pre-pollen and early season (PPS) and 6 weeks during the pollen season (PS) as follows:

- **Group A**: bud 400 mcg (PPS), bud 200 mcg (PS)
- **Group B**: placebo (PPS), bud 400 mcg (PS)
- **Group C**: bud 400 mcg (PPS), bud 400 mcg (PS)
- **Group D**: bud 200 mcg (PPS), bud 200 mcg (PS)
- **Group E**: placebo (PPS), bud 200 mcg (PS)

A total of 364 patients with grass pollen-induced seasonal rhinitis entered the study. There were 219 men and 145 women aged 14 - 67 years (mean 31 years) with a history of at least one season of pollen-induced allergic rhinitis. They recorded nasal symptoms as 0 = none, 1 = mild, 2 = moderate, 3 = severe in daily diary cards. Mean daily scores were calculated for sneezing, blocked nose, runny nose and for combined total symptoms. These were related to the daily pollen count in the analysis. Both 200 mcg and 400 mcg budesonide induced a significant improvement in total symptoms ($p=0.0003$), runny nose ($p=0.0001$) and sneezing ($p=0.001$) PPS compared with placebo. Groups A and C were significantly better than B and E during the first week PS ($p=0.038$), suggesting that pre-treatment with 400 mcg budesonide helps to control symptoms during the first week PS. During PS there were no significant differences between 200 mcg and 400 mcg budesonide.
Tolerability profiles were similar for all groups. Three patients discontinued treatment due to adverse events, 1 for cutaneous erythema, 1 for sneezing, 1 for periorbital oedema. It is concluded that either budesonide 200 mcg or 400 mcg provides significant control of symptoms experienced during PFS (compared with placebo) and the 400mcg dose given PFS provides additional prophylactic protection against symptoms during the first week of the pollen season.