Exclusion criteria and prohibited medications

Exclusion criteria included history of life-threatening asthma, clinically significant uncontrolled disease or respiratory infection, and an asthma exacerbation requiring oral corticosteroids within 3 months or hospitalisation or within 6 months prior to screening. Current smokers and those with a recent (1 year) or heavy (≥10 pack-years) smoking history, patients with history of severe milk protein allergy and patients with any evidence of oral candidiasis were also excluded.

The following medications were not permitted during the study: immunosuppressive medications; systemic, oral or depot corticosteroids within 12 weeks of screening; and potent cytochrome P450 3A4 inhibitors within 4 weeks. Patients were also excluded if they had any adverse reaction or hypersensitivity to any beta2 agonist, sympathomimetic drug or corticosteroid therapy.

Study design. Randomisation schedule and blinding

The central randomisation schedule was generated by the sponsor using a validated computerised system (RandAll). Patients were randomised using Registration and Medication Ordering System (RAMOS), an automated, interactive telephone based system that was used by the investigator or designee to register the patient, randomise the patient and receive medication assignment information.

Patients and investigators were blinded to treatment assignment. Study medication was identical in appearance for all treatment groups and labelled in accordance with all applicable regulatory requirements. Based on the double-dummy design of this study, each patient received two devices at each drug dispensing visit, one novel dry powder inhaler (DPI) and one Diskus™/Accuhaler™. Patients assigned to fluticasone furoate received double-blind active study drug via the novel DPI once-daily in the evening and also received
double-blind placebo twice-daily via Diskus/Accuhaler. Patients assigned to receive fluticasone propionate 500 mcg received double-blind active study drug via the Diskus/Accuhaler twice-daily and also received double-blind placebo via the novel DPI once-daily in the evening. Patients receiving placebo received placebo via the novel DPI once-daily in the evening and placebo via the Diskus/Accuhaler twice-daily.