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Development of a generic drug with different pharmaceutical features: A study of the therapeutic equivalence of mometasone nasal spray in patients with seasonal allergic rhinitis (Japanese cedar pollinosis)Minoru Gotoh¹, Kumi Sugita², Akihiro Saito³, Takayuki Honda³, Koichiro Hoashi³ and Takashi Miyazaki⁴¹Nippon Medical School, Japan²Ujigawa Hospital, Japan³Taiho Pharmaceutical Co, Japan⁴Toko Yakuhin Kogyo Co. Ltd., Japan

TAC-203 is under development as a generic drug for mometasone furoate, and it has pharmaceutical features different from those of original mometasone (OM): As a gel with a different viscosity is used, dripping after spraying and/or pouring the drug solution into the throat is greatly reduced. After the upper exhaust pressure airless spray container is adopted, there is no longer a difference in spraying performance due to differences in the angle of the container. As it is a homogeneous suspension, shaking before use has become unnecessary. No clinical studies in humans have been conducted so far for the development of generic steroid nasal sprays in Japan. However, since this drug has different pharmaceutical features from those of OM, we evaluated the efficacy and safety of the drug by conducting a high-quality therapeutic equivalence study in patients with seasonal allergic rhinitis. We conducted a randomized, evaluator-blinded, active and placebo-controlled study. Patients were randomly (2:2:1) assigned to receive TAC-203 (mometasone 200 µg/day), OM 200 µg/day, or placebo once daily for 2 weeks. The primary efficacy endpoint was the change from baseline in total nasal symptom score (TNSS) at 2 weeks. In addition, blood sample was collected at 1 hour after first administration for evaluating plasma mometasone concentration. 180 patients enrolled (TAC-203: 72, OM: 72, placebo: 36 patients, respectively). 95% confidence interval (-0.427 to 1.112) for the difference between treatments TAC-203 OM in the change from baseline in TNSS at 2 weeks was within the preplanned range of equivalence (-1.13 to 1.13). The geometric mean of mometasone furoate concentration in plasma was 8.85 pg/mL in TAC-203 and 4.87 pg/mL in OM. The therapeutic equivalence of TAC-203 and OM was confirmed by this study. Furthermore, TAC-203 has similar tolerability and safety profiles as OM.

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