Drugs recently approved or pending approval

ADREVIEW

The US Food and Drug Administration (FDA) has given approval to GE Healthcare (Arlington Heights, IL) to market AdreView (lobenguane I 123 injection), a molecular imaging agent, to be used as an adjunct to other diagnostic tests in the detection of primary or metastatic pheochromocytoma or neuroblastoma. The safety and efficacy of AdreView were evaluated in an open-label, multicenter, multinational trial involving 251 patients with known or suspected neuroblastoma or pheochromocytoma. Diagnostic efficacy was determined by comparing focal increased radionuclide uptake on planar scintigraphy at 24 ± 6 hours postadministration of AdreView with the definitive diagnosis (standard of truth), as determined by histopathology or, when histopathology was unavailable, a composite of imaging (ie, computed tomography, magnetic resonance imaging, [^{131}I]-mIBG scintigraphy), plasma/urine catecholamine and/or catecholamine metabolite measurements, and clinical follow-up. A definitive diagnosis was available for 211 individuals from whom efficacy was established. Of the 211 individuals, all had planar scintigraphy and 167 had single photon emission computed tomography (SPECT) in addition to planar imaging. All images were assessed independently by 3 readers blinded to all clinical data. Performance characteristics (sensitivity and specificity) of AdreView planar imaging in patients with neuroblastoma were similar to those in patients with pheochromocytoma. Among patients who also underwent SPECT imaging, similar performance characteristics of AdreView scintigraphy were seen when SPECT plus planar imaging was compared with planar imaging alone. The most common adverse effects were dizziness, rash, pruritus, flushing, or injection site hemorrhage.

NASACORT AQ

The FDA has given approval to sanofi-aventis (Bridgewater, NJ) to market Nasacort AQ nasal spray (triamcinolone acetonide) for treatment of nasal symptoms of seasonal and perennial allergic rhinitis in children aged 2 to 5 years. The safety and efficacy of Nasacort AQ in children (aged, 2–5 yr) were established in a 4-week, double-blind, placebo-controlled study (N = 464) with a 24-week open label extension conducted in the United States. Patients received either once-daily Nasacort AQ 110 µg or placebo. Efficacy was determined based on the total nasal symptom score (TNSS), measured by patients' parent or guardian recordings of 4 nasal symptoms (congestion, itching, rhinorrhea, and sneezing) on a 0 to 3 categorical severity scale once daily. Symptom severity over the previous 24 hours (reflective TNSS) and immediately prior to dosing (instantaneous TNSS) was also measured. Baseline symptom severity was comparable between Nasacort AQ and placebo, respectively, for instantaneous TNSS (7.52 versus 7.61) and reflective TNSS (7.96 versus 7.87). Although the 24-hour instantaneous TNSS showed greater reduction from baseline with Nasacort AQ versus placebo (–2.28 versus –1.92), the difference was not statistically significant (difference, –0.36 [95% confidence interval {CI}, –0.77 to 0.06]; $P = 0.095$). For the 24-hour reflective TNSS, once-daily Nasacort AQ 110 µg provided statistically significantly greater improvement from baseline as compared with placebo (–2.31 versus –1.87; difference, –0.44 [95% CI, –0.84 to –0.04]; $P = 0.033$). The most common adverse effects were headache, pharyngolaryngeal pain, epistaxis, and nasopharyngitis.

SANCUSO

ProStrakan Group (Bedminster, NJ) has received FDA approval to market Sancuso (granisetron) transdermal system for the prevention of nausea and vomiting in patients receiving moderately and/or highly emetogenic chemotherapy regimens of up to 5 consecutive days' duration. The effectiveness of Sancuso was evaluated in a phase 3 randomized, parallel group, double-blind, double-dummy study involving 641 patients receiving multiday chemotherapy. Patients were randomized to Sancuso transdermal system (applied 24–48 hr before the first dose of chemotherapy and kept in place for 7 days) or once-daily granisetron 2 mg orally (administered daily for the duration of the chemotherapy regimen 1 hr before each dose of chemotherapy). The primary endpoint was the proportion of patients achieving no vomiting and/or retching, no more than mild nausea, and no rescue medication from the first administration until 24 hours after the start of the last day's administration of multiday chemotherapy. The effect of Sancuso was established in 60.2% of patients in the Sancuso arm and 64.8% of patients in the oral granisetron arm (difference, –4.89% [95% CI, –12.91% to 3.13%]). The most common adverse effect was constipation.

Compiled from press reports and pharmaceutical company press releases. For more information, contact Farrawh Charles, Hospital Physician, *125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.*

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