Drugs recently approved or pending approval

DEPOCYT

The US Food and Drug Administration (FDA) has given approval to Enzon Pharmaceuticals, Inc. (Bridgewater, NJ) to market DepoCyt (cytarabine liposome injection) for the intrathecal treatment of lymphomatous meningitis. DepoCyt was evaluated in 2 randomized, multicenter, multi-arm studies involving 57 patients. Study 1 randomized patients to either 50 mg of DepoCyt administered every 2 weeks (n = 17) or standard intrathecal chemotherapy (50 mg unencapsulated cytarabine) administered twice weekly (n = 16). In study 2, patients were randomized to DepoCyt 50 mg twice weekly (n = 12) or cytarabine (n = 12). All patients in both studies received concurrent treatment with dexamethasone to minimize symptoms associated with chemical arachnoiditis. In both studies, the main outcome measure was complete response, which was prospectively defined as conversion from a positive examination of the cerebrospinal fluid for malignant cells to a negative examination on 2 separate occasions (≥ 3 days apart, on day 29 and later) at all initially positive sites as well as an absence of neurologic progression during the treatment period. In both studies, more patients treated with DepoCyt achieved complete response as compared with cytarabine-treated patients (41% versus 6% in study 1 and 33% versus 17% in study 2). The most common adverse effects associated with DepoCyt were headache and arachnoiditis.

RECLAST

Novartis Pharmaceuticals Corporation (East Hanover, NJ) has been given FDA approval to market Reclast (zoledronic acid) injection for the treatment of Paget's disease of the bone. The efficacy of Reclast was evaluated in 2 identically designed 6-month randomized, double-blind trials involving 349 male and female patients (aged > 30 yr; mean age, 70 yr) with moderate to severe disease (serum alkaline phosphatase [SAP] ≥ twice the upper limit of the age-specific normal reference range) who had confirmed Paget's disease of the bone. Patients were randomized to receive either a single-dose infusion of 5 mg Reclast or oral daily doses of 30 mg risedronate for 2 months. Therapeutic response was defined as either normalization of SAP or a reduction of at least 75% from baseline in total SAP excess (defined as the difference between the measured level and midpoint of normal range) at the end of 6 months. The 6-month combined results from both trials showed that 96% of Reclast-treated patients achieved a therapeutic response (most by day 63) as compared with 74% of risedronate-treated patients. In addition, more patients treated with Reclast achieved normalization of SAP levels as compared with patients treated with risedronate (89% and 58%, respectively). The most common adverse effects in Reclast-treated patients were influenza-like illness, pyrexia, and rigors. The recommended dose of Reclast is 5 mg in a 100 mL ready-to-infuse solution administered intravenously through a vented infusion line.

SINGULAIR

The FDA has given approval to Merck & Co., Inc. (Whitehouse, NJ) to market Singulair (montelukast sodium) for the prevention of exercise-induced bronchoconstriction (EIB) in patients aged 15 years and older. The efficacy of Singulair was evaluated in 3 randomized, double-blind, placebo-controlled crossover studies involving 160 patients with EIB. Patients in all 3 studies were randomized to either Singulair 10 mg or placebo administered 2 hours prior to exercise, and exercise challenge testing was conducted at 2, 8.5 or 12, and 24 hours following administration of the study drug. In all studies, the primary endpoint was mean maximum percent decrease in forced expiratory volume in 1 second (FEV_1) following the 2-hour postdose exercise challenge. All Singulair-treated patients in study 1 experienced a statistically significant protective benefit against EIB when the medication was taken 2 hours prior to exercise. Some patients experienced a protective benefit against EIB with Singulair at 8.5 and 24 hours after administration. The results of study 1 were considered to be representative of all 3 studies. The most common adverse effect associated with Singulair was headache. Singulair has previously been approved for prophylaxis and chronic treatment of asthma in adults and pediatric patients aged 12 months and older; for the relief of seasonal allergic rhinitis in adults and pediatric patients aged 2 years and older; and for perennial allergic rhinitis in adults and pediatric patients aged 6 months and older.

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