

## Drugs recently approved or pending approval

### APIDRA

The US Food and Drug Administration (FDA) has given approval to sanofi-aventis (Bridgewater, NJ) to market Apidra (insulin glulisine [rDNA origin] injection) to improve glycemic control in children (age  $\geq 4$  yr) with diabetes mellitus. Apidra was evaluated in a 26-week, randomized, open-label, active-controlled, noninferiority study involving 572 patients (aged, 4–17 yr) with type 1 diabetes. Patients were randomized to Apidra or insulin lispro administered subcutaneously within 15 minutes before a meal. Patients also received insulin glargine once daily in the evening or neutral protamine Hagedorn insulin twice daily. Prior to randomization, there was a 4-week run-in period with insulin lispro and insulin glargine or neutral protamine Hagedorn. The primary endpoint was change in glycemic control from baseline, as measured by glycated hemoglobin. Glycemic control was comparable between the 2 treatment arms. The adjusted mean changes in glycated hemoglobin from baseline for Apidra and insulin lispro were 0.1% and 0.2%, respectively (mean treatment difference,  $-0.1\%$  [95% confidence interval,  $-0.2$  to  $0.1$ ]). The most common adverse effect was hypoglycemia.

### TOVIAZ

The FDA has given approval to Pfizer Inc. (New York, NY) to market Toviaz (fesoterodine fumarate) extended-release tablets for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Toviaz was evaluated in two phase 3, randomized, double-blind, placebo-controlled, 12-week studies involving 1964 patients with overactive bladder. Patients with overactive bladder for 6 months' duration or more, at least 8 micturitions per day, and at least 6 urinary urgency episodes or 3 urge incontinence episodes per 3-day diary period were randomized to a fixed dose of Toviaz (4 or 8 mg/day) or placebo. In 1 study, 290 patients were randomized to an active control arm (an oral antimuscarinic agent). The primary efficacy endpoints were the mean changes in the number of urge urinary incontinence episodes and micturitions (frequency) per 24 hours. In both studies, Toviaz 4 and 8 mg/day was more effective in reducing the number of urge incontinence episodes per 24 hours as compared with placebo (study 1,  $-2.06$  and  $-2.27$  versus  $-1.2$ ; study 2,  $-1.77$  and  $-2.42$  versus  $-1.0$ , respectively). Toviaz-treated patients experienced a greater reduction in the number of micturitions per 24 hours, as compared with placebo-treated patients (study 1,  $-1.74$  and  $-1.94$  versus  $-1.02$ ;

study 2,  $-1.86$  and  $-1.94$  versus  $-1.02$ ). The most common adverse effects were dry mouth and constipation.

### TRILIPIX

Abbott Laboratories (North Chicago, IL) has received FDA approval to market Trilipix (fenofibric acid) as an adjunct to diet to be coadministered with a statin drug to reduce triglycerides and low-density lipoprotein cholesterol (LDL-C) and increase high-density lipoprotein cholesterol (HDL-C) in patients with mixed dyslipidemia. Trilipix in combination with statins was evaluated in 3 multicenter, randomized, 12-week, double-blind, controlled phase 3 studies involving 2698 patients (studies 1–3) and one 52-week, long-term, open-label extension study involving 1895 patients (study 4). Patients with an LDL-C level of 130 mg/dL or more, triglyceride level of 150 mg/dL or more, and HDL-C

level less than 40 mg/dL (males) or less than 50 mg/dL (females) were randomized to Trilipix 135 mg coadministered with 10 or 20 mg rosuvastatin (study 1), 20 or 40 mg simvastatin (study 2), or 20 or 40 mg atorvastatin (study 3) or Trilipix and statin monotherapy. The primary efficacy endpoints for all 3 studies were mean percent changes from baseline in HDL-C, triglyceride, and LDL-C levels. In a pooled analysis of the 3 studies,

Trilipix in combination with low- and moderate-dose statins was associated with significantly greater mean percent increases in HDL-C (18.1% and 17.5%) and decreases in triglycerides ( $-43.9\%$  and  $-42.0\%$ ) as compared with statin monotherapy (7.4% and 8.7% for HDL-C;  $-16.8\%$  and  $-23.7\%$  for triglycerides). Also, Trilipix combination therapy showed greater mean percent decreases in LDL-C as compared with Trilipix monotherapy ( $-33.1\%$  and  $-34.6\%$  versus  $-5.1\%$ ). In study 4, patients received Trilipix with the moderate dose of the statin that had been used in the study in which they were previously enrolled. For patients who completed 52 weeks of treatment, mean percent change from baseline was  $-38.2\%$  for LDL-C, 24.0% for HDL-C, and  $-47.6\%$  for triglycerides. The most common adverse effects were headache, nausea, and upper respiratory tract infection.



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