BUSINESS BRIEFS

Merck, Schering to Pay Fine

Merck and Schering-Plough will pay $5.4 million to 35 states and the District of Columbia to resolve an investigation into the firms' delayed release of negative study results for the cholesterol-lowering drug Vytorin (ezetimibe and simvastatin). The agreement, which is not an admission of liability, covers the states' and Washington's investigative costs. The ENHANCE trial found Vytorin was no more effective in reducing plaque in carotid arteries than was simvastatin alone.

Amgen, GSK to Join on Denosumab

Amgen and GlaxoSmithKline have agreed to share in the commercialization of Amgen's monoclonal antibody denosumab for postmenopausal osteoporosis in Europe, Australia, New Zealand, and Mexico. Amgen will commercialize denosumab—which has not yet been approved in these countries—for osteoporosis and oncology in the United States and Canada, and for all oncology indications in Europe and specified markets. GlaxoSmithKline will register and commercialize denosumab for all indications in countries where Amgen does not currently have a commercial presence, including China, Brazil, India, and South Korea. The arrangement includes an initial payment and near-term commercial milestones to Amgen totaling $120 million, and payment of ongoing royalties. "Our collaboration with GlaxoSmith Kline will help Amgen bring the promise of denosumab to patients in Europe and other parts of the world more effectively than if we commercialized the drug globally on our own," said Amgen CEO Kevin Sharer. Andrew Witty, CEO of GlaxoSmithKline, noted that "the data for denosumab [are] very encouraging and we believe it will provide significant benefit and value to patients with postmenopausal osteoporosis and other bone disease conditions." Together with Amgen, we are committed to increasing worldwide access to this medicine."

Allergan Lap Band OKed for Diabetes

Allergan's Lap-Band AP adjustable gastric banding system for obesity intervention has received European market approval for weight loss that leads to improvement or remission of type 2 diabetes, the firm has announced. The approval, the first of its kind, was supported by results of a 2-year randomized trial that confirmed results from previous observational studies. The study showed that patients who lost weight with Lap-Band AP were more than five times more likely to achieve remission of type 2 diabetes than were patients receiving conventional diabetes therapy (73% vs. 13%). Expanded labeling for the device states that weight loss associated with the system "has been shown to improve or lead to remission of type 2 diabetes," the company said.

Sernova Gets Canadian Grant

An arm of the Canadian government, the National Research Council of Canada's Industrial Research Assistance Program, has awarded Sernova Corp. up to $486,000 to support a preclinical study of the company's Cell Pouch System for human cell transplantation. The Cell Pouch System will be used initially for treatment of insulin-dependent diabetes, and also has potential for use in other chronic diseases such as hemophilia, spinal cord injury, and Parkinson's disease. "We are grateful to NRC-IRAP for their crucial support of this important study, which will advance the development of a Canadian technology with ramifications for the treatment of insulin-dependent diabetics and other major diseases," said Philip Toleikis, Ph.D., president and CEO of Sernova, based in London, Ont. "We appreciate NRC-IRAP's thorough review of our development program and look forward to commercializing our technology into multiple disease indications and major markets worldwide." The study supported by NRC-IRAP involves implantation of Sernova's novel medical device into diabetic pigs to establish device parameters and optimize performance. The study is expected to begin this month and be completed within 12 months. The interim results from the first 3-6 months will be used to finalize the device design for the planned large animal study recommended by the Food and Drug Administration in support of a future phase I/II human clinical study. NRC-IRAP will reimburse Sernova for 100% of designated salary costs to a maximum of $262,000, and for 69% of contractor fees to a maximum of $224,000.

—From staff reports

Reporters and editors from Elsevier's "The Pink Sheet" contributed to this column.