BUSINESS BRIEFS

Dapagliflozin Goes to Japan

Dapagliflozin, a sodium-glucose cotransporter-2 inhibitor, will be developed and commercialized in Japan, AstraZeneca and Bristol-Myers Squibb announced last month. Dapagliflozin, one of two investigational drugs under joint development by the companies, is currently being studied in phase III clinical trials in several countries, including the United States, to assess its efficacy and safety as a once-daily treatment for type 2 diabetes. The two companies will jointly market the product in Japan, where the drug is currently in phase II trials, sharing all expenses and splitting profits or losses equally. "Bristol-Myers Squibb and AstraZeneca have been working together to develop dapagliflozin for type 2 diabetes for nearly 2 years, [and] this inclusion of Japan was a natural progression of our collaboration and an important strategic step in our relationship," said Lamberto Andreotti, executive vice president and chief operating officer of Bristol-Myers Squibb. "Our companies have a shared vision for these diabetes treatments, and this agreement will help ensure we can successfully launch and maximize the potential of dapagliflozin for the more than 6 million people in Japan living with type 2 diabetes."

Wyeth Buys Thiakis

Madison, N.J.–based Wyeth has agreed to pay $30 million for Thiakis, a privately held London biotech company, the two firms announced last month. Additional milestone-driven payments of up to approximately $120 million are also available to Thiakis' investors. Thiakis' portfolio includes several synthetic gastrointestinal peptides. The company launched a phase I trial of the lead candidate for appetite control, TKS1225, in March. TKS1225 is a potent, long-acting analogue of oxyntomodulin, a naturally occurring peptide hormone involved in regulating food intake. It is thought to work through the GLP-1 receptor and does not cross the blood-brain barrier, an important consideration given the suicidality risks associated with the CB-1 antagonists, another class of obesity treatments.

Bristol-Myers Signs for XL184

Exelixis has signed a deal with long-term partner Bristol-Myers Squibb for its phase III cancer drug XL184, plus an earlier-stage molecule, that will bring in $240 million in assured payments plus a major codevelopment and marketing role. XL184 is a small-molecule inhibitor of MET, VEGFR2, and RET that just entered phase III clinical trials for use in medullary thyroid cancer, for which there is no currently approved treatment. The compound is also in midstage studies for glioblastoma and is being tested for a variety of other tumor types. The second compound, XL281, is a small-molecule RAF kinase inhibitor in phase I development for advanced solid-tumor cancers. In October, GlaxoSmithKline declined to license XL184, probably because it had already licensed a similar compound, XL880, from Exelixis. Under the terms of the licensing agreement with Bristol-Myers, that company will pay Exelixis $240 million in cash upfront, $45 million of it in two installments during the first half of 2009. Exelixis plans to begin "substantial" R&D for both XL184 and XL281 in 2009 and 2010.

Novo Nordisk, VLST Sign Pact

Novo Nordisk has inked a deal with VLST Corp., a Seattle-based biotechnology company, to develop treatments for autoimmune disorders, including diabetes. Under the terms of the agreement, Novo Nordisk and VLST will jointly undertake a research program to identify collaboration targets and develop product candidates. VLST will receive an upfront payment and equity investment totaling about $12 million; the company also is eligible for payments dependent on achieving clinical and regulatory milestones across multiple disease indications, Novo Nordisk said in a statement. Novo Nordisk also will fund the salaries of VLST researchers for the next 3 years, and will provide resources to move product candidates through preclinical development, clinical development, and commercialization. The research collaboration will run for 3 years, with an option to extend the agreement. "VLST's platform technology provides a promising avenue for Novo Nordisk to continue expanding and enhancing its research and development in the field of autoimmune and inflammatory disorders," said Terje Kalland, senior vice president and head of the biopharmaceuticals research unit at Novo Nordisk. "As Novo Nordisk continues to build its presence in Seattle, the collaboration with VLST marks an important step in our overall strategy to develop therapeutics for autoimmune and inflammatory disorders."

DexCom CGM Gets European OK

DexCom has received the CE mark in the European Union for SEVEN, the company's 7-day continuous glucose monitoring system, allowing it to market the system in Europe as well as in Asian and Latin American countries that recognize the mark. "We are pleased to have CE mark approval for the SEVEN, and we look forward to working with physicians, nurses, and diabetes educators to bring this important technology to patients around the world," Terrance H. Gregg, DexCom's president and CEO, said in a statement.

—Joyce Frieden

Reporters and editors from the Elsevier publication "The Pink Sheet" contributed to this column.

Daschle's Dual Role Lifts Hopes for Health Reform

BY MARY ELLEN SCHNEIDER
New York Bureau

Early signals from the incoming Obama administration have many physician groups thinking about the prospects for comprehensive health care reform.

"There are a lot of unknowns," said Dr. Jonathan Leffert, chair of the American Association of Clinical Endocrinologists' (AACE) legislative and regulatory committee. "Anyone knows that with these reforms come a lot of potential changes. But we're going to be involved … and hopefully there at the table," he said. "I am optimistic about what we can do."

For the AACE, most of its legislative goals for 2009 are similar to those of 2008, including repealing the sustainable growth rate (SGR), which ties Medicare physician payments to the gross domestic product, and ensuring fair reimbursement for in-office DXA scans.

But now that a health care overhaul looks likely, Dr. Leffert said that having a voice in the shape that reform takes also is crucial.

"As endocrinologists, we want to be able to be there with our ideas related to chronic diseases like diabetes," said Dr. Leffert. "We want to be able to put forward our thoughts and ideas as to what might be the best way to take care of a chronic disease and make that a model for chronic diseases in the reform package."

Endocrinologists also have a thing or two to say about preventive medicine, continued Dr. Leffert. "[President Barack] Obama has discussed the issue of prevention and how important that is, and we are always trying to [convince] people to make lifestyle changes, to decrease our country's big problem with obesity. So we as an organization are going to be in the forefront of trying to give guidance to the federal government about what the priorities should be."

The economy is one reason that health reform may have a greater chance for success now than it did during the Clinton administration, said Dr. Nancy H. Nielsen, president of the American Medical Association. As more Americans lose their jobs, they are also losing their health insurance, she said, driving policy makers to address the issue of the uninsured. "There may be more tension for change now than there has been in the past," she said.

President Obama addressed that tension head-on during a press conference last month to announce former Sen. Tom Daschle (D-S.D.) as his choice for Health and Human Services secretary, who Dr. Leffert called "a very energetic and enthusiastic individual."

Sen. Daschle's experience as Senate majority leader will no doubt be an asset in his new post, added Dr. Leffert. "That [experience] in and of itself will be very useful in trying to move something as big and unwieldy as health care reform through the halls of Congress."

The current state of health care in the United States—with rising premiums and the large number of uninsured Americans—is having a direct and negative impact on the U.S. economy, President Obama said. "If we want to overcome our economic challenges, we must also finally address our health care challenge."

In a move that many agree signals how serious Mr. Obama is about health reform, he tapped Sen. Daschle for not one, but two posts. In addition to serving as HHS secretary, Sen. Daschle is slated to serve as director for a new White House Office on Health Care Reform. Jeanne M. Lambrew, Ph.D., a health policy expert who coauthored the health care book "Critical: What We Can Do About the Health-Care Crisis" with Sen. Daschle, was chosen as deputy director of the new White House office.

Sen. Daschle's HHS position has to be confirmed by the Senate; however, the health care czar position does not.

In another example of the focus on health care reform, Mr. Obama and congressional Democrats have signaled their interest in including health information technology incentives as part of an economic stimulus package, said Robert Doherty, senior vice president of governmental affairs and public policy at the American College of Physicians. "I think the signals are positive."

The Obama transition team appears to be learning from some of the mistakes made during the Clinton administration's attempt at health reform, Mr. Doherty said. For instance, there has been a much greater effort by the Obama staff members to be open about their process and to gather input from the physician community.

Physician societies are making their priorities known to the new administration, emphasizing the need for physician payment reform to be a part of any reform package.

The AMA is pushing Congress and the administration to enact permanent Medicare physician payment reform by eliminating the SGR. Without congressional action on the payment formula within the next year, physicians will be faced with a projected 21% cut in Medicare payments starting in 2010, Dr. Nielsen said.

If Congress chooses to throw out the SGR formula, they likely will need to authorize some fast-track pilot projects to test some of the most promising models for new payment systems such as global and bundled payments, said ACP's Mr. Doherty.

ACP officials are hoping that the Obama health reform proposal will include some of their top priorities—coverage of the uninsured and improving access to primary care physicians. ■

Associate Editor Denise Napoli contributed to this story.