IN brief

Cellulosic at the pump

For one month gasoline consumers in Canada will be buying cellulosic ethanol made from agricultural residue at their local gas stations. Iogen, of Ottawa, Ontario, and Royal Dutch Shell, of The Hague, Netherlands, are placing their cellulosic ethanol into commercial gasoline at a Shell plant in Ottawa. Since 2004, the companies have partnered on Iogen's demonstration plant, capable of producing per month 40,000 liters of cellulosic ethanol, and in July 2008 Shell increased its ownership stake in Iogen to 50%. Still, as there is not yet an established market for cellulosic ethanol, the Ottawa-based demonstration facility is churning out a product with no real buyer. To combat this, the companies are including 10% cellulosic ethanol in the gas for a month beginning June 10, and expect to sell a total of 60,000 liters of second-generation biofuel. Similar events may follow, Iogen says. But as cellulosic fuel advances, stockpiled product could plague other makers. Lignol Energy, of Vancouver, British Columbia, announced in June it had completed an end-to-end production of cellulosic ethanol in its biorefinery pilot plant in Burnaby. They might take note of Iogen's solution. Mandy Chepeka, director of communications at Iogen, says selling the fuel shows the public that "we were making this in quantities sufficient enough to be distributed," and that "we are past the point of being in a test tube or in an R&D lab." *Brady Huggett*

Plasma firms denied merger

The intended $3.1 billion acquisition of plasma product company Talecris Biotherapeutics, of Research Triangle Park, North Carolina, by rival firm CSL, of Melbourne, Australia, has come undone. First announced in August 2008, signs of trouble surfaced in October, when the US Federal Trade Commission (FTC) requested additional information on the merger, and by May this year, Australian media were speculating that the deal was in danger. CSL managing director and CEO Brian McNamee went to Washington, DC, to speak with FTC officials, but the FTC authorized a lawsuit by the end of the month challenging the buyout, saying the move was anticompetitive and violated anti-trust laws. Specifically, the FTC said the acquisition would reduce the number of competitors in the US markets for immune globulin and albumin from five to four, and US competitors for Rho-D and Alpha-1 antitrypsin would be reduced from three to two. Though there was initial opposition, the "reality was we had a break-fee date" of August 12, says McNamee. A judge's decision was not expected until September, leading both sides to "bite the bullet and end the uncertainties of the deal," he says. CSL will pay Talecris a $75 million break-up fee, though the plasma supply agreement the companies struck at the time of the merger will continue through 2013. *Brady Huggett*

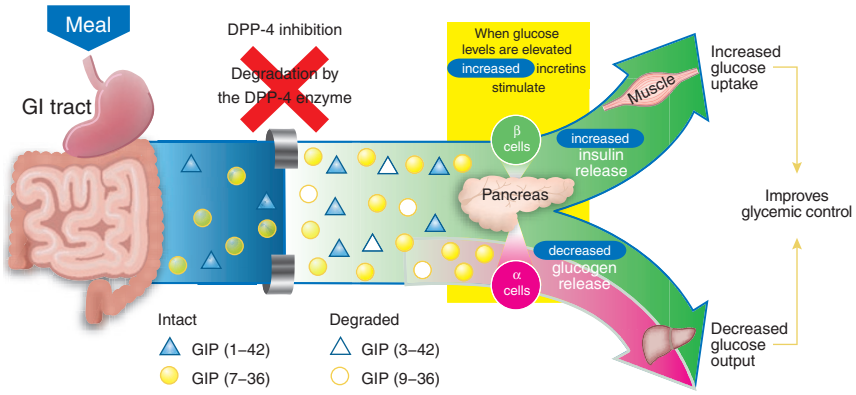

Figure 1 The role of DPP-4, GLP-1, GIP in glucose homeostasis. There has been a recent upsurge in interest in GLP-1 mimetics and DPP-4 inhibitors as potential therapies for type -2 diabetes.

If it does pass regulatory muster, analysts predict financial success for Victoza. Findlay of Frost & Sullivan says: "[Victoza] will pose a threat to Byetta. Once approved, it is expected to largely increase the market share of Novo Nordisk." Other experts agree. "If the safety concerns over GLP-1 analogs can be resolved," says Verdult, the market could be worth $2–5 billion.

The stiffest competition, however, may come from a new long-lasting formulation of Byetta—Exenatide Once Weekly. Amylin and Lilly developed this formulation using a polymer delivery technology (purified 50:50 DL polylactide coglycolide 4A polymer mixed with 5% (wt/wt) exendin-4 and 2% (wt/wt) sucrose) from Alkermes of Cambridge, Massachusetts, and filed a new drug application for this drug in July, with a PDUFA (Prescription Drug User Fee Act) date likely in the first quarter of 2010.

This sustained-release formulation could have an easier run to approval. Daniel J. Drucker, director of the Banting and Best Diabetes Center at the University of Toronto, and his colleagues showed that 77% of type-2 diabetes patients taking Exenatide Once Weekly achieved glycosylated hemoglobin values below 7.0% and lost an average of 3.7 kg of body weight (*The Lancet* **372**, 1240–1250, 2008). Also, Byetta's large patient base might influence regulatory decisions about Exenatide Once Weekly. "Byetta has been on the market for four years and used by more than one million patients with no evidence—in preclinical, clinical, or post-market analysis—of a signal for thyroid cancer," says Ken Wilhelm, an endocrinologist and senior director of medical affairs at Amylin.

The main difference between the two drugs is that Victoza is very close to natural GLP-1; thus, Victoza has 97% homology with the natural human GLP-1 peptide, whereas the lizard-derived peptide Exenatide has only ~50% homology. The modifications (mutations at Arg34 and Lys26) on Victoza (Arg34, Lys26-[*N*-ε(γ-Glu[*N*-α-hexadecanoyl])]-GLP-1[7-37]) ensure the peptide is not metabolized and cleared from

IN their words

"I don't really think Pfizer's coming or not coming really affects the success of Mission Bay."

Michael Schuppenhauer, a biotech consultant in Half Moon Bay, after Pfizer pulls out of its much-heralded Biotherapeutics and Bioinnovation Center to be housed at a building still under construction at Mission Bay. (*San Francisco Chronicle*, July 7, 2009)

"It turns out, in my view, that research is much more of an art than a science."

GlaxoSmithKline CEO Andrew Witty on the failure of large-scale genomics, proteomics and combinatorial chemistry to transform the company's R&D productivity. (*Reuters*, June 19, 2009)

"Francis is a scientists' scientist."

Tyler Jacks president of the American Association for Cancer Research explains why he is excited at the news that Francis Collins, a geneticist who led the Human Genome Project for 15 years, will be heading the National Institutes of Health. (*Medscape News*, July 9, 2009)