circulation as fast as GLP-1, contributing to its extended half-life.

But the diabetes market is already crowded with other small-molecule drugs that could thwart the rise of GLP-1 analogs to blockbuster status. Erik Gordon, associate director of the Samuel Zell & Robert H. Lurie Institute for Entrepreneurial Studies at the University of Michigan in Ann Arbor, expects Victoza and Exenatide Once Weekly to be prescribed primarily for people who cannot keep their glycemic levels under control with other drugs. "But that's not a big enough market," Gordon says. "Novo Nordisk and Amylin/Lilly will need to convert people who do have reasonably good glycemic control."

Because GLP-1 analogs are injected, patients and physicians could lean toward oral dipeptidyl peptidase-4 (DPP-4) inhibitors. DPP-4 inactivates GLP-1 by cleaving the molecule, so GLP-1 analogs and DPP-4 inhibitors are complementary approaches for tackling type-2 diabetes. De Block still expects the first line of treatment to remain lifestyle changes and metformin. He thinks that DPP-4 inhibitors would be used as a second step and GLP-1 analogs as a third.

The need to convert physicians brings in the weight-loss issue, which Gordon believes is "a big piece of the new antidiabetics coming into the market." Although the GLP-1 analog data indicate statistically significant weight loss, he points out that "it's a likely marketing claim that will be made against Merck's antidiabetic treatment Januvia [sitagliptin; a DPP-4 inhibitor], which is weight neutral." Still, Gordon doesn't see the weight loss from GLP-1 analogs as enough, by itself, to gain substantial market share. "It's not like taking these drugs will cause an obese guy to lose the needed 40 to 60 pounds," he says.

Mike May *Houston*

Genzyme's Lumizyme clears bioequivalence hurdles

Even as the US healthcare industry awaits a biogenerics pathway outlining all aspects of equivalence, US Food and Drug Administration (FDA) scrutiny has kept one biologics manufacturer from scaling up its own drug under the same name. Cambridge, Massachusetts–based Genzyme set out to boost the production process of its approved drug Myozyme (alglucosidase alfa), used to treat children with Pompe disease, from 160 to 2,000 liters, to have an adequate supply to treat adults with the disease. In early February 2009, the company was ready to file a supplemental Biologics License Application (sBLA) for material from the 2,000 liter bioreactor, rebranded as Lumizyme, for use in adults. The company had also fully enrolled a phase 3 trial in adults for the scaled-up drug. But even though Myozyme and Lumizyme are both alglucosidase alpha, produced by the same cell line, the FDA balked at the plan citing concerns about bioequivalence. The agency cited some differences in the enzymes' carbohydrate profiles, which could potentially influence binding and uptake of the drug. "That was a large focus of the discussions with FDA," notes Alex Kuta, Genzyme group vice president of regulatory affairs. Commercialization was further set back when FDA issued a 'complete response letter' and a separate 'warning letter' for Lumizyme (*Nat. Biotechnol.* **27**, 299–301, 2009).

The complete response letter called for discussions around a post-approval clinical verification study and post-marketing risk evaluation and monitoring studies, to which Genzyme has responded. The FDA has now agreed that data from Genzyme's Pompe registry, which tracks patients after treatment with Myozyme or Lumizyme as well as patients not exposed to either drug, can fulfill the requirements of a verification study.

Ironically, just two days before Genzyme received its FDA letter, European regulators approved a 4,000 liter bioreactor scale for Myozyme, which ensured supply of the drug in Europe. Genzyme had stated repeatedly—even as late as May 21, 2009, when it announced submission of all information requested by FDA for Lumizyme—that it would also file an sBLA for the drug at the 4,000 liter scale by the end of June. But it has pushed back those plans to focus on approval of the 2,000 liter scale process. The company says the delay is not related to the viral contamination discovered at the company's Allston Landing facility, where the 2,000 liter Lumizyme is produced. (see **News Brief**, p.681). "We're still in active discussions with FDA about the fastest route to approval of the 4,000 liter scale and we are working toward a second-half 2009 approval," says Kuta.

Mark Ratner

IN brief

Peru embraces biotech

Peru has held its first National Biotech Conference organized by the relatively young Peruvian Association for the Development of Biotechnology, PeruBiotec. The meeting, held last May in Lima, was supported by the Peruvian National Council of Science, Technology and Innovation (Concytec), the Ricardo Palma University, and several academic, corporate and public sector groups from Peru and abroad, including the US Department of Agriculture and AgroBio Colombia. Alexander Grobman, president and founding member of PeruBiotec, points out that their overall aim is to stimulate biotech research by sharing local developments, and to benefit from other countries' experience in fields ranging from genetically modified organisms to genomics and biosafety. PeruBiotec, a nonprofit organization, is also intent on tackling controversial issues, by setting up a public forum to discuss and provide information on biotech advances and their relevance to the country. Conference highlights included reports from Peruvian researchers in fish genomics, embryo cultures, alpaca cloning, the development of transgenic papaya resistant to ringspot virus and the first steps towards national biosafety regulation. The event also provided an opportunity for Peru's Concytec to announce that biotech will become a central issue in their national science and technology agenda, with an expected increase in public and private investment. Veronica Guerrero

Illumina's cut-price genome scan

Illumina of San Diego has become the first company to offer a whole-genome sequencing service for under $50,000. Knome of Cambridge, Massachusetts, the only other company currently marketing whole-genome scans to consumers, charges $99,500 for KnomeCOMPLETE—a considerable reduction from their original asking price of $350,000. Illumina's new Personal Genome Sequencing Service uses the company's popular Genome Analyzer system and is performed in its recently Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory. Clients will receive their entire genome sequence including information on single nucleotide polymorphisms (SNP) variations, insertions, deletions and rearrangements. "Illumina stands out because they have such a great reputation, the price is half what Knome is asking, and the other companies are just assaying a bunch of SNPs on a microarray," says Ken Rubenstein of Lion Consulting. Unlike its competitors, Illumina does not provide data interpretation as part of the service. "This service doesn't require much investment from them," Rubenstein says, " and yet it gives them a good window onto this evolving field." Consumer genomics is beset by uncertainty at this point. Several of the highest-profile companies, including Knome, 23&Me and Navigenics, have had to lower prices over the last year. Experts have argued that the true medical value of whole genome analysis is still far from being realized. *Malorye Allison*