

▶ Making Strategic Alliances Work

WA'EL HASHAD, VP, U.S. Cardiovascular and Metabolic Disorders, at Boehringer Ingelheim Pharmaceuticals, talks about how an alliance with Lilly helped to bring a new product to the diabetes market.



➔ **PV:** *What challenges are encountered when developing diabetes products?*

HASHAD: Diabetes is a common disease. There are about 24 million people who have diabetes in the United States, and the population with this disease continues to grow. Therefore, diabetes products have to address a lot of different demands. One of the challenges is getting a good balance of efficacy and safety. This means the product has to deliver effective glycemic control, as well as an acceptable safety profile. Products in the past were able to deliver on effective glycemic control but some of them, unfortunately, were not able to demonstrate safety, either immediately or postmarketing.

Tradjenta, the new product we developed with Lilly, comes from a safer class of products, DPP-4. Tradjenta was approved in May to lower blood sugar in adults with type 2 diabetes as monotherapy or in combination with other medications. We have seen no major adverse events, such as weight gain, which is a very common problem with diabetes products. Additionally, the discontinuation rate was very similar to placebo, which means the drug is well-tolerated.

Another issue is cardiovascular safety. Diabetes products may cause hypoglycemia as well as edema. In our monotherapy trials, there was no incidence of hypoglycemia, and there was no evidence of edema or increased incidence of edema. Additionally, there was no reported increased incidence of cardiovascular events. We will do a post-marketing cardiovascular safety study, which the FDA often asks for.

➔ **PV:** *What challenges do you anticipate in marketing this product?*

HASHAD: The challenge with any launch, of course, is managed care access. It takes time for products to be reviewed by formulary directors, and it may take several months for Tradjenta to reach an acceptable tier-two status or a low branded copay level. To manage this process, we are providing copay savings cards. We are launching the savings card at the same time as the brand, which means that the patients who will be prescribed Tradjenta

will have a copay savings card to offset the differential between plan levels.

Another challenge is getting physicians to try the product. This is going to require a lot of education. We are investing a lot of resources into peer-to-peer education. Tradjenta is the first single-dose diabetes product approved by the FDA. This means that any patient with type 2 diabetes can take the product whether he or she has kidney or liver impairment. Diabetes comes with many different comorbidities, and this provides physicians with a simple option.

➔ **PV:** *Why did you pursue an alliance with Lilly for this product?*

HASHAD: The alliance with Lilly is the largest diabetes alliance established, and the alliance includes four products: Boehringer is contributing two oral medications and Lilly is putting forward two insulin analogues. There is also an option for a monoclonal antibody for kidney disease.

Both companies are driven by a commitment to diabetes and diabetes patients. And both companies want to make sure that we offer patients diabetes solutions the minute they are diagnosed and throughout their journey of treatment. Lilly had products that complemented Boehringer Ingelheim's pipeline and Boehringer Ingelheim had products that complemented Lilly's product pipeline. The partnership is a strategic fit from this perspective.

Lilly also has a lot of history in diabetes and was one of the first companies, if not the first, that brought diabetes products into the healthcare market. Lilly also has a long tradition in research and development and a lot of marketing capabilities that will add value to Boehringer, which has a strong tradition in primary-care products. We complement each other and have the same mission. This alliance is the biggest commitment Boehringer has; it could be a 20-year alliance, depending on the portfolio.

➔ **PV:** *What factors make for a successful strategic alliance?*

HASHAD: Every company needs to consider what it is looking to do with an alliance: what is its purpose,

is it strategic, is it to improve commercial capability, and so on. Every company will have its own situation, and it's important to find the appropriate partner that complements the end goals.

In my opinion, alliances should not be made for competitive reasons. They should be made for strategic reasons, and the alliance should complement the areas that the other company doesn't have. There also needs to be a cultural fit that makes the partnership strong. No one single partner should dominate, both need to have an equal voice. **PV**

DIABETES QUICK FACTS

- » 25.8 million children and adults in the United States — 8.3% of the population — have diabetes, including 7.0 million people who have not yet been diagnosed
- » 1.9 million new cases of diabetes were diagnosed in people 20 years and older in 2010; 215,000, or 0.26%, of all people younger than 20 have diabetes
- » In 2007, diabetes was listed as the underlying cause on 71,382 death certificates and was listed as a contributing factor on an additional 160,022 death certificates; this means that diabetes contributed to a total of 231,404 deaths
- » Adults with diabetes have heart disease death rates about two to four times higher than adults without diabetes; the risk for stroke is two to four times higher among people with diabetes
- » Diabetes is the leading cause of new cases of blindness among adults ages 20 to 74
- » Diabetes is the leading cause of kidney failure, accounting for 44% of new cases in 2008
- » Total costs associated with diagnosed diabetes in the United States in 2007: \$174 billion

Source: American Diabetes Association

UNITED STATES PATENT & TRADEMARK OFFICE

Grants TrialCard® Patent for Technology
that Optimizes Prescription Co-pay Cards



TrialCard announces the issuance of **U.S. Patent No. 7,925,531**

for technology that enables prescription Co-pay cards and coupons to adjust value based on a patient's insurance coverage.

TrialCard's **Adjusting Value™ co-pay card*** technology optimizes promotional programs that offer savings of "Pay No More Than..." or "Save Up To..." with a prescription Co-pay card.

Dave Cunningham, CEO and founder of TrialCard, says, "We are proud of our innovative technologies and look forward to continuing to provide solutions that meet the needs of our customers."

TrialCard has received a variety of patents for its solutions that improve patient access to medicines and facilitate patient reimbursement. The issuance of **U.S. Patent No. 7,925,531** is another example of TrialCard's recognized ability to provide ground-breaking solutions that meet the needs of patients and pharmaceutical marketers.

*U.S. Patent No. 7,925,531 awarded April 12, 2011

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