

METABOLIC

The number of people with diabetes is on the rise, and so is revenue for metabolic products.

Marc Iskowitz examines drugmakers' efforts to control this public health issue, the marketing of diabetes and why drug development for one of its leading causes, obesity, has stumbled

Nearly two million new cases of diabetes were diagnosed in patients aged 20 and older in 2010, according to the American Diabetes Association. As the number of those with the disease rises (to 26 million people—or 8% of the population), so have sales of metabolic products. Revenue for the drugs climbed 11% last year to \$21.7 billion, according to US wholesale acquisition cost (WAC) sales data from Wolters Kluwer Pharma Solutions.

Their ascent looks set to continue. The annual growth rate is around 8%, notes Barclays Capital managing director and senior pharma analyst Tony Butler, PhD.

Type 1 diabetes treatment is largely insulin-based, and type 2 (90% of cases) is diagnosed and driven by pill sales initially, with the majority of patients staying on orals. “Fifty percent of people go on a generic [like metformin, #5] right off the bat...and then most

Sanofi-Aventis launched physician- and patient-focused educational campaigns designed to provide more information about insulin therapy, devoting \$46 million to awareness of Lantus SoloStar. “There are still a lot of myths and misperceptions out there,” says Angela Moskow, VP of diabetes marketing, Sanofi-Aventis US.

Novo Nordisk rolled out a \$10-million consumer campaign for the 2010 Victoza launch and has mostly hewed to professional channels to advertise its insulins, including top-selling fast actor NovoLog (#3). That may change. “Novo Nordisk may be looking to expand its DTC campaign for its FlexPen delivery devices after testing a TV commercial in the New York region,” says Camille Lee, VP, diabetes marketing.

Butler foresees an increased demand for long-acting basal insulins, like the Lantus family and Novo’s Levemir (#9). Novo is shepherd-



often they have to move to a TZD or DPP-IV,” the analyst notes, referring to oral drugs like Takeda’s Actos (#1) and GlaxoSmith-Kline’s Avandia (#15) and, somewhat less potent, Merck’s Januvia (#4) and AstraZeneca/Bristol-Myers Squibb’s Onglyza (#29).

TZD demand has slackened, following the brouhaha over Avandia’s heart effects and new FDA restrictions limiting use. And Teva, Mylan, Watson and Ranbaxy have been authorized to sell licensed Actos copies starting in August 2012.

Pills will continue to move higher as new diabetics get put on drugs. On the other hand, Butler says, “Despite the fact that diabetes can be best managed with insulin, people are very hesitant to take insulin, or insulin analogs or GLP-1s.”

Companies hope to change that through easier dosing schedules and novel devices. Novo Nordisk’s Victoza (#20) is a once-daily anti-diabetic agent that’s designed to unseat Lilly/Amylin’s twice-daily GLP-1 Byetta (#11). The top-selling brand in the diabetes space is also an injectable—Sanofi-Aventis’ Lantus long-acting insulin franchise, which includes the vial/syringe version (#2) and Lantus SoloStar (#7), a pen-based delivery device. From 2009-10,

ing a basal through late-stage testing, degludec, which may shave the number of insulin injections patients need per week.

The newer GLP-1s, like Victoza (liraglutide), are associated with less hypoglycemia, as well as weight loss. Novo is testing liraglutide for obesity among pre-diabetics. These drugs are also being used for increasing durations. To wit: Lilly/Amylin’s investigational GLP-1 Bydureon aims to drive patient compliance via once-weekly dosing but has experienced setbacks, including two FDA rejections and, in March, data showing the drug failed to match efficacy in a head-to-head trial vs. Victoza.

Further up the metabolic pipeline are products for obesity, one of the leading causes of type 2 diabetes. Due to side effects, three promising new compounds have been rejected by the FDA in the last 12 months. Abbott also withdrew Meridia from the US market last year because of heart concerns. With regulators cautious, says Butler: “Anything in weight loss will require years of work.” ■

The next installment of MM&M’s bi-monthly series examining therapeutic categories will be June’s focus on rheumatology products

TOP 50 METABOLIC PRODUCTS, 2010

Category leaders, ranked by full-year 2010 US sales, and their media spend for the 12 months ending November 30

Rank	Product	Manufacturer	US sales dollars (millions)*	% change vs. prior 12 mos.	TRx count (thousands)**	TRx % change vs. prior 12 mos.	US media spend dollars (thousands)**	Media spend % change vs. prior 12 mos.
1	Actos	Takeda	\$3,335.7	5.3%	12,875.1	-3.7%	\$40,662.9	>999.9%
2	Lantus	Sanofi-Aventis	\$2,199.2	6.2%	9,832.1	-5.3%	\$5,609.6	-26.2%
3	NovoLog	Novo Nordisk	\$1,736.9	23.4%	5,103.3	10.5%	0 [†]	N/A
4	Januvia	Merck	\$1,689.1	13.6%	6,858.3	4.9%	\$63,833.1	103.4%
5	Metformin HCL	Generic	\$1,285.9	12.2%	52,851.3	6.1%	\$281.3	N/A
6	Humalog	Eli Lilly	\$1,267.8	14.0%	4,685.3	1.7%	0 ^{††}	N/A
7	Lantus SoloStar	Sanofi-Aventis	\$1,151.6	50.8%	4,620.0	37.5%	\$46,435.5	>999.9%
8	Synthroid	Abbott	\$805.0	4.9%	26,157.1	-3.0%	0	N/A
9	Levemir	Novo Nordisk	\$710.3	41.9%	2,793.1	26.9%	\$42.71 ^{†††}	-92.2%
10	Janumet	Merck	\$618.2	25.5%	2,804.8	14.4%	\$1,105.1	-58.1%
11	Byetta	Lilly/Amylin	\$613.6	-15.6%	1,967.0	-21.1%	\$3,285.1	-3.6%
12	NovoLog mix 70-30	Novo Nordisk	\$533.9	18.8%	1,690.8	5.9%	\$172.8	N/A
13	Levothyroxine sodium	Generic	\$528.6	12.5%	71,316.7	7.0%	0	N/A
14	ACTOplus Met	Takeda	\$463.1	5.6%	1,931.6	-2.6%	0	N/A
15	Avandia	GlaxoSmithKline	\$360.2	-33.5%	1,552.4	-39.8%	\$46.7	>999.9%
16	Humalog mix 75-25	Eli Lilly	\$300.5	4.9%	1,003.6	-7.2%	0	N/A
17	Novolin 70-30	Novo Nordisk	\$281.4	9.2%	1,065.0	-10.2%	0	N/A
18	Metformin HCL ER	Generic	\$232.4	9.0%	9,971.7	8.2%	0	N/A
19	Novolin N	Novo Nordisk	\$229.7	12.3%	669.6	-2.8%	0	N/A
20	Victoza	Novo Nordisk	\$216.8	N/A	595.7	N/A	\$10,544.6	>999.9%
21	Humulin 70-30	Eli Lilly	\$204.5	6.8%	1,589.0	-9.8%	0	N/A
22	Prandin	Novo Nordisk	\$202.8	-1.0%	869.5	-10.9%	0	N/A
23	Humulin N	Eli Lilly	\$202.7	12.0%	1,971.8	-1.7%	\$184.1	N/A
24	Novolin R	Novo Nordisk	\$195.2	3.2%	442.6	-2.8%	0	N/A
25	Glyburide	Generic	\$194.4	10.6%	8,636.9	-3.6%	0	N/A
26	Avandamet	GlaxoSmithKline	\$180.5	-22.2%	825.6	-29.6%	\$5.2	N/A
27	Glimepiride	Generic	\$156.7	6.3%	11.1	6.1%	0	N/A
28	Humulin R	Eli Lilly	\$154.8	26.1%	986.4	-4.4%	\$392.22	619.1%
29	Onglyza	AstraZeneca/BMS	\$150.0	>999.9%	717.1	>999.9%	\$41,962.5	>999.9%
30	Glyburide-metformin HCL	Generic	\$139.5	-19.0%	4,261.5	-9.1%	0	N/A
31	Phentermine HCL	Generic	\$129.5	2.1%	7,302.9	7.0%	0	N/A
32	Levoxyl	King	\$125.1	2.6%	6,859.3	-1.0%	0	N/A
33	Glipizide	Generic	\$99.5	-1.3%	9,049.5	4.3%	0	N/A
34	Fortamet	Andrx	\$79.1	14.0%	286.9	-14.3%	0	N/A
35	Glipizide ER	Generic	\$72.8	-2.0%	4,665.8	-4.5	0	N/A
36	Glipizide XL	Generic	\$63.6	-9.4%	3,215.1	-7.2%	0	N/A
37	Apidra	Sanofi-Aventis	\$63.6	-10.6%	255.1	-14.6%	0	N/A ^{††††}
38	SymlinPen 120	Amylin	\$60.3	24.4%	107.1	5.6%	\$22.6	N/A
39	Glumetza	Santarus/Depomed	\$51.6	33.1%	299.7	1.0%	0	N/A
40	Humalog mix 50-50	Eli Lilly	\$46.6	54.9%	125.1	40.2%	0	N/A
41	Nateglinide	Generic	\$41.5	352.8%	463.6	367.9%	0	N/A
42	Xenical	Genentech	\$41.5	-14.3%	100.8	-37.0%	0	N/A
43	Avandaryl	GlaxoSmithKline	\$39.3	-25.8%	190.2	-33.8%	0	N/A
44	Liothyronine sodium	Generic	\$38.5	120.6%	1,337.8	137.0%	0	N/A
45	Duetact	Takeda	\$37.6	-3.3%	152.4	-12.4%	0	N/A
46	Apidra SoloStar	Sanofi-Aventis	\$33.9	254.1%	136.1	240.4%	0	N/A
47	Symlin	Amylin	\$31.7	-17.1%	45.7	-40.3%	0	N/A
48	Starlix	Novartis	\$30.7	-68.5%	174.0	-72.0	0	N/A
49	Methimazole	Generic	\$27.6	3.8%	1,596.2	7.0%	0	N/A
50	Armour Thyroid	Forest	\$26.0	-40.0%	2,100.5	-42.0%	0	N/A

*Integrated wholesale acquisition cost (WAC) sales, full year

**DTC/journal spend between 12/10-11/11 inclusive. Sources: Sales/TRx, Wolters Kluwer Pharma Solutions; media spend, SDI & Kantar Media. TRx count includes retail only.

[†]Media spend for NovoLog family, \$3.12 million

^{††}Media spend for Humalog family, \$15.07 million

^{†††}Media spend for Levemir family, \$4.68 million

^{††††}Media spend % change for Apidra family, -100%