Oncology

Targeted cancer therapies and chemotherapeutic products are a $20 billion category. Expanding indications for marketed products and a bulging pipeline should keep this segment growing for the foreseeable future, analysts say. **Marc Iskowitz** reports

Targeted therapies command impressive sales, thanks to increased prescribing by oncologists—often in combination with chemotherapy—high price and an expanding list of indications. IMS Health puts the total US market at $20.6 billion, a 9% increase over 2008. So named because they take aim at a protein or pathway responsible for the tumor's growth, targeted drugs are expected to double in worldwide sales by 2015 to $51.2 billion, according to Decision Resources.

Targeted agents encompass monoclonal antibodies (MAbs) like Roche/Genentech's Avastin (#1, US), which treats metastatic colorectal cancer by binding to vascular endothelial growth factor (VEGF) receptors on a cell's surface, as well as small-molecule drugs like Novartis' Gleevec (#5, US), which clings to the Bcr-Abl tyrosine kinase receptor seen in chronic myeloid leukemia (CML). These drugs, along with two other Roche MAb therapies, Rituxan and Herceptin (#2-3, US), are the sales leaders (see chart). They are used as single agents or in combination with chemotherapy agents, like Sanofi-Aventis' Taxotere (#4, US), in many cancers.

Roche/Genentech's position atop the category appears secure, despite some regulatory setbacks. At press time, the FDA was set to rule on whether to rescind Avastin's accelerated approval in metastatic breast cancer after a panel voted for withdrawal of that indication. The targeted therapy is expected to enter the ovarian and gastric cancer markets next year.

Clinical benefit in some cases has been dramatic. Novartis' Gleevec, approved in 2004, has become the standard first-line therapy for patients with Philadelphia chromosome-positive CML. A long-running trial showed 86% of patients were alive at seven years. Drug resistance develops, however, and two compounds have been introduced to treat Gleevec-resistant CML, namely Bristol-Myers Squibb's Sprycel (#29, US) and Novartis' own Tasigna (#41, US). Both have shown superiority over Gleevec, which faces generic competition in the next several years.

Scientific communication is key in oncology, with presentations at medical meetings and papers in medical journals, as well as CME. As one would imagine, advertising is heavily skewed toward physicians: figures from SDI show 97% (about $23 million) of all media spend in the sector is focused on journal ads and only 3% (roughly $650,000) on DTC ads.

Michael Parisi, managing partner of ad agency Ogilvy CommonHealth Worldwide, sees that changing. "There is a tremendous shift toward the patient and communicating and engaging the cancer community," says, Parisi, who has spent his 20-year career in oncology. While there is a reticence among clients to engage cancer patients, Parisi expects more DTC investment in the next two years.

For now, says Robert Rosen, head of Bayer's global brand team oncology group (marketer of Nexavar, #43, US), his company addresses patients "by providing information to the patient advocacy groups to help educate their constituents/members about clinical trial results and milestones," in addition to issuing press releases and posting information on the web.

According to Decision Resources, 142 companies are currently developing targeted therapies. Among the most promising, says Ben Weintraub, PhD, director of research, Wolters Kluwer *in*Thought, are PARP inhibitors, agents that are most effective against one of the most deadly tumor types, triple-negative breast cancer. The most advanced PARP inhibitors are Sanofi-Aventis' BSI-201, in Phase III, and AstraZeneca's olaparib (AZD-2281), in Phase II. "There's very compelling data that as a chemotherapy sensitizer, these PARPs will be very effective," Weintraub says. Another exciting late-stage agent is BMS's ipilimumab for malignant melanoma. The FDA is set to decide on the drug by year's end, and it appears to have some benefit for patients with this so far untreatable tumor type. Perhaps more effective is a Phase III drug from Plexxikon and Roche, PLX-4032. Data showed that nearly all patients with a particular mutation experienced some melanoma tumor shrinkage. ■

MM&M's bi-monthly Therapeutic Focus series will conclude with December's Pipeline Report

TOP 50 CHEMOTHERAPY & TARGETED CANCER PRODUCTS, 2009

Category leaders, ranked by 2009 US sales, and their media spend

Rank	Product	Manufacturer	US sales dollars (millions)	% change vs. prior 12 mos.	US media spend dollars (thousands)*	% change vs. prior 12 mos.	US DTC media spend dollars (thousands)	US journal spend dollars (thousands)
1	**Avastin**	Genentech/Roche	2,880.42	19.06%	4,047.87	112.5%	–	4,047.87
2	**Rituxan**	Genentech/Roche	2,521.86	8.56%	2,698.69	-61.9%	.06	2,698.63
3	**Herceptin**	Genentech/Roche	1,376.24	8.01%	1,177.26	1.7%	90.03	1,087.23
4	**Taxotere**	Sanofi-Aventis	1,182.94	9.97%	–	NA	–	–
5	**Gleevec**	Novartis	1,051.24	17.89%	688.90	-46.4%	–	688.90
6	**Eloxatin**	Sanofi-Aventis	948.76	-29.66%	–	-100.0%	–	–
7	**Arimidex**	AstraZeneca	846.57	15.82%	428.20	-96.4%	428.20	–
8	**Alimta**	Eli Lilly	810.20	48.87%	1,125.74	237.5%	–	1,125.74
9	**Gemzar**	Eli Lilly	753.13	6.80%	425.19	-2.5%	–	425.19
10	**Erbitux**	BMS/Imclone	697.58	-6.21%	780.74	-43.1%	–	780.74
11	**Femara**	Novartis	559.41	21.47%	748.00	-31.6%	58.31	689.69
12	**Tarceva**	Genentech/OSI	468.49	7.69%	552.43	-47.0%	15.61	536.82
13	**Xeloda**	Genentech/Roche	460.40	13.60%	343.11	-39.3%	7.93	335.18
14	**Velcade**	Millennium/Takeda	457.34	28.46%	84.64	54.0%	5.00	79.63
15	**Temodar**	Merck	355.95	5.94%	287.10	NA	–	287.10
16	**Oxaliplatin**	*Generic*	337.54	–	–	NA	–	–
17	**Abraxane**	Abraxis	310.33	5.12%	99.14	-75.3%	.36	98.78
18	**Sutent**	Pfizer	257.23	6.54%	1,503.49	26.0%	–	1,503.49
19	**Vidaza**	Celgene	236.64	33.48%	1,634.72	144.0%	–	1,634.72
20	**Treanda**	Cephalon	216.62	232.28%	969.41	56.4%	7.56	961.85
21	**Doxil**	Centocor Ortho Biotech	213.46	7.54%	257.94	41.20%	–	257.94
22	**Lupron Depot-3 mo.**	Abbott	196.50	4.03%	–	NA	–	–
23	**Revlimid**	Celgene	181.83	-5.43%	–	-100.0%	–	–
24	**Casodex**	AstraZeneca	180.49	-41.51%	–	NA	–	–
25	**Lupron Depot-4 mo.**	Abbott	166.81	-8.09%	–	NA	–	–
26	**Dacogen**	Eisai	164.18	7.56%	363.64	-23.3%	12.37	351.26
27	**Hycamtin**	GlaxoSmithKline	161.74	11.14%	–	-100.0%	–	–
28	**Aromasin**	Pfizer	152.69	12.30%	48.81	-96.7%	–	48.81
29	**Sprycel**	Bristol-Myers Squibb	126.46	45.48%	137.69	-58.1%	–	137.69
30	**Faslodex**	AstraZeneca	112.23	5.70%	1.18	-99.4%	1.18	–
31	**Lupron Depot**	Abbott	102.00	-4.55%	–	–	–	–
32	**Ixempra Kit**	Bristol-Myers Squibb	95.84	3.29%	444.59	-61.2%	–	444.59
33	**Vectibix**	Amgen	95.56	-14.92%	940.05	110.9%	–	940.05
34	**Megace ES**	Strativa	90.25	9.78%	–	–	–	–
35	**Tykerb**	GlaxoSmithKline	84.29	9.30%	176.55	41.5%	–	176.55
36	**Torisel**	Pfizer	83.47	7.65%	827.82	NA	18.34	809.49
37	**Eligard**	Sanofi-Aventis	78.83	2.97%	–	NA	–	–
38	**Lupron Depot-ped.**	Abbott	75.78	-1.17%	–	NA	–	–
39	**Fluorouracil**	*Generic*	74.81	9.50%	–	NA	–	–
40	**Alkeran**	GlaxoSmithKline	72.11	-5.94%	–	NA	–	–
41	**Tasigna**	Novartis	66.16	96.98%	823.47	32.5%	–	823.47
42	**Zoladex**	AstraZeneca	59.50	-21.71%	.05	NA	.05	–
43	**Nexavar**	Bayer	59.16	2.25%	241.22	-84.5%	.50	240.73
44	**Paclitaxel**	*Generic*	55.87	-13.67%	–	NA	–	–
45	**Irinotecan HCl**	*Generic*	54.13	-0.28%	4.08	-97.5%	–	4.08
46	**Cyclophosphamide**	*Generic*	50.17	70.02%	–	NA	–	–
47	**Afinitor**	Novartis	47.01	–	1,910.52	NA	7.43	1,903.09
48	**Campath**	Ilex	46.99	-23.38%	–	-100.0%	–	–
49	**Megestrol Acetate**	*Generic*	46.90	-11.05%	–	NA	–	–
50	**Methotrexate Sodium**	*Generic*	46.20	-0.89%	..	NA	..	..

*DTC/journal spend

Sources: Sales, IMS Health; media spend, SDI