

Approval, ownership, market structure, and placement on WHO EML for 100 new cancer NMEs on NCI alpha list

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KEI research associate Paul Miano has written the following paper: Cancer: Approval, ownership, market structure, and placement on WHO Model Essential Medicines List, for 100 new molecular entities (NMEs) on the NCI alpha list of cancer drugs and vaccines. KEI Research Note 2011:1,

A full copy of the paper is available in PDF format [here](#).

The following is from the introduction (sans footnotes, which are in the PDF version):

Introduction and Summary

This research note presents data on the approval, ownership, market structure and placement on the WHO Model Lists of Essential Medicines new molecular entities (NMEs) approved by the U.S. Food and Drug Administration (FDA) for the treatment of cancer. The examined products, which include both drugs and vaccines, are those included in the U.S. National Cancer Institute (NCI) "alpha list" of cancer drugs. The July 2011 version of the alpha list includes 100 unique molecular entities, as well as a number of new formulations or combinations and chemotherapeutic regimens. Our analysis focuses on the 100 unique molecular entities.

Each of the products was approved by the FDA through one of two mechanisms. For pharmaceutical drugs, products are registered under a New Drug Application (NDA). For biologic products, registration is through a Biologic License Application (BLA).

Among our findings are the following:

1. The role of biologic products has increased

- 1.1 Of the 100 drugs and vaccines, 79 were registered under New Drug Applications (NDA) and 21 were registered under Biologic License Applications (BLA).
- 1.2 From January 1, 2000 to July 2011, 15 of 52 products were biologics, or 29 percent of the total.

- 1.3 For the 48 products registered before 2000, 6 of 48 were biologic, or 12.5 percent of the total.

2. Registrations have increased, and most cancer drugs are relatively new

- 2.1 Despite an overall decline in the registration of NME products in recent years, there has been a sharp rate of increase in the registration of NME products for the treatment of cancer.
- 2.2 In the 38 years from 1952 to 1989, there were only 21 NME on the NCI list, an average of .55 per year.
- 2.3 In the ten year period of 1990 to 1999, the list contains 27 NME cancer products - an average of 2.7 per year.
- 2.4 In the ten year period of 2000 to 2009, 45 NME cancer products were registered - an average of 4.5 per year.
- 2.5 For 2010 through the July of 2011, 7 NME products were registered, an average of 4.4 per year.
- 2.6 More than half (52 of 100) of all cancer NME products were first registered after January 1, 2000.

3. Most drugs are only available from a single supplier

- 3.1 66 of the 100 products are only available to one FDA approved supplier or a joint venture managing the same brand name, suggesting strong barriers to entry due to intellectual property rights and other factors.
- 3.2 45 of 79 pharmaceutical drugs (57 percent) do not have competitive suppliers.
- 3.3 21 of 21 biologic products (100 percent) do not have competitive suppliers.
- 3.4 For products registered between January 1 2000, and July 2011, 51 of 52 products (98 percent) do not have competitive suppliers.

4. Ownership is concentrated in six countries, and among thirteen companies

- 4.1 28 companies own or control the sale of the 66 drugs that do not have competitive suppliers.
- 4.2 13 companies control more than one cancer monopoly, including:
 - GlaxoSmithKline (9), Amgen (5), Novartis (5)
 - 4 each for Sanofi, Bristol Myers Squibb, Celgene and Roche
 - 3 each for Eisai, Merck, Astrazeneca and Eli Lilly, and
 - 2 each for Pfizer and Cephalon
- 4.3 In terms of nationality, just six countries host the companies that own and control cancer products sold as a monopoly.

- 4.4 One half (33 of the 66) monopoly products are controlled by firms located in the United States.
- 4.5 Of the remaining 33 monopoly products 12 are controlled by UK firms, 11 by firms in Switzerland, 5 by firms in Japan, 4 by firms in France and 1 by a firm in Germany.

5. The WHO Model Essential Medicines List excludes all new cancer drugs

- 5.1 The March 2011, 17th Edition of the WHO Model Essential Medicines List (EML) includes zero products from the NCI alpha list of cancer drugs on its “core” list of the minimum medicine needs for a basic health care-system.
- 5.2 The 17th Edition of the WHO Model EML includes 20 products from the NCI alpha list on its “complementary” list of “essential medicines for priority diseases.”
- 5.3 For the 2011 WHO Model EML complementary list, the newest product that is also on the NCI alpha list was registered 15 years ago, in 1996.
- 5.4 The newest cancer product on the 2002 version of the complementary WHO Model EML was first registered 19 years earlier, in 1983.

Note: These are the 100 "alpha list" drugs and vaccines included the paper:

No	INN (generic name) of products on NCI's Alpha List of cancer drugs	Originator brand name	1st FDA App No	Year 1st approval	Date 1st approval
1	Abiraterone Acetate	Zytiga	202379	2011	2011/04/28
2	Vandetanib	Vandetanib	022405	2011	2011/04/06
3	Ipilimumab	Yervoy	125377	2011	2011/03/25
4	Eribulin Mesylate	Halaven	201532	2010	2010/11/15

5	Cabazitaxel	Jevtana Kit	201023	2010	2010/06/17
6	Denosumab	Prolia (Xgeva)	125320	2010	2010/06/01
7	Sipuleucel-T	Provenge	125197	2010	2010/04/29
8	Romidepsin	Istodax	022393	2009	2009/11/05
9	Ofatumumab	Arzerra	125326	2009	2009/10/26
10	Pazopanib Hydrochloride	Votrient	022465	2009	2009/10/19
11	Recombinant HPV Bivalent Vaccine	Ceravix	125259	2009	2009/10/16
12	Pralatrexate	Folotyn	022468	2009	2009/09/24
13	Everolimus	Afinitor	022334	2009	2009/03/30
14	Degarelix	Firmagon	022201	2008	2008/12/24
15	Plerixafor	Mozobil	022311	2008	2008/12/15
16	Eltrombopag Olamine	Promacta	022291	2008	2008/11/20
17	Romiplostim	Nplate	125268	2008	2008/08/22
18	Bendamustine Hydrochloride	Treanda	022249	2008	2008/03/20
19	Nilotinib	Tasigna	022068	2007	2007/10/29
20	Ixabepilone	Ixempra	022065	2007	2007/10/16
21	Temsirolimus	Torisel	022088	2007	2007/05/30

22	Lapatinib Ditosylate	Tykerb	022059	2007	2007/03/13
23	Vorinostat	Zolinza	021991	2006	2006/10/06
24	Panitumumab	Vectibix	125147	2006	2006/09/27
25	Dasatinib	Sprycel	021986	2006	2006/06/28
26	Recombinant HPV Quadrivalent Vaccine	Gardasil	125126	2006	2006/06/08
27	Decitabine	Dacogen	021790	2006	2006/05/02
28	Sunitinib Malate	Sutent	021938	2006	2006/01/26
29	Lenalidomide	Revlimid	021880	2005	2005/12/27
30	Sorafenib Tosylate	Nexavar	021923	2005	2005/12/20
31	Nelarabine	Arranon	021877	2005	2005/10/28
32	Clofarabine	Clolar	021673	2004	2004/12/28
33	Palifermin	Kepivance	125103	2004	2004/12/15
34	Erlotinib Hydrochloride	Tarceva	021743	2004	2004/11/18
35	Azacitidine	Vidaza	050794	2004	2004/05/19
36	Bevacizumab	Avastin	125085	2004	2004/02/26
37	Cetuximab	Erbix	125084	2004	2004/02/12
38	Pemetrexed Disodium	Alimta	021462	2004	2004/02/04

39	Palonosetron Hydrochloride	Aloxi	021372	2003	2003/07/25
40	Tositumomab (I 131 Iodine Tositumomab)	Bexxar	125011	2003	2003/06/27
41	Bortezomib	Velcade	021602	2003	2003/05/13
42	Gefitinib	Iressa	021399	2003	2003/05/05
43	Aprepitant	Emend	021549	2003	2003/03/27
44	Oxaliplatin	Eloxatin	021492	2002	2002/08/09
45	Rasburicase	Elitek	103946	2002	2002/07/12
46	Fulvestrant	Faslodex	021344	2002	2002/04/25
47	Ibritumomab Tiuxetan	Zevalin	125019	2002	2002/02/19
48	Zoledronic Acid (aka zoledronate)	Zometa	021223	2001	2001/08/20
49	Imatinib Mesylate	Gleevec	021335	2001	2001/05/10
50	Alemtuzumab	Campth	103948	2001	2001/05/07
51	Arsenic Trioxide	Trisenox	021248	2000	2000/09/25
52	Gemtuzumab Ozogamicin	Mylotarg	021174	2000	2000/05/17
53	Bexarotene	Taragretin	021055	1999	1999/12/29
54	Aminolevulinic Acid	Levulan	020965	1999	1999/12/03
55	Exemestane	Aromasin	020753	1999	1999/10/21

56	Epirubicin Hydrochloride	Ellence	050778	1999	1999/09/15
57	Temozolomide	Temodar	021029	1999	1999/08/11
58	Denileukin Diftitox	Ontak	103767	1999	1999/02/05
59	Trastuzumab	Herceptin	103792	1998	1998/09/25
60	Thalidomide	Thalomid	020785	1998	1998/07/16
61	Capecitabine	Xeloda	020896	1998	1998/04/30
62	Talc	Sclerosol	020587	1997	1997/12/24
63	Raloxifene Hydrochloride	Evista	020815	1997	1997/12/09
64	Rituximab	Rituxan	103705	1997	1997/11/26
65	Letrozole	Femara	020726	1997	1997/07/25
66	Toremifene	Fareston	020497	1997	1997/05/29
67	Imiquimod	Aldara	020723	1997	1997/02/27
68	Irinotecan Hydrochloride	Camptosar	020571	1996	1996/06/14
69	Topotecan Hydrochloride	Hycamtin	020671	1996	1996/05/28
70	Gemcitabine Hydrochloride	Gemzar	020509	1996	1996/05/15
71	Docetaxel	Taxotere	020449	1996	1996/05/14
72	Anastrozole	Arimidex	020541	1995	1995/12/27

73	Dexrazoxane Hydrochloride	Zinecard	020212	1995	1995/05/26
74	Vinorelbine Tartrate	Navelbine	020388	1994	1994/12/23
75	Pegaspargase	Oncaspar	103411	1994	1994/02/01
76	Paclitaxel	Taxol	020262	1992	1992/12/29
77	Aldesleukin	Proleukin	103293	1992	1992/05/05
78	Fludarabine Phosphate	Fludara	020038	1991	1991/04/18
79	Filgrastim	Neupogen	103353	1991	1991/02/20
80	Carboplatin	Paraplatin	019880	1989	1989/03/03
81	Ifosfamide	Ifex	019763	1988	1988/12/30
82	Mesna	Mesnex	019884	1988	1988/12/30
83	Leuprolide Acetate	Lupron	019010	1985	1985/04/09
84	Etoposide Phosphate	VePesid	018768	1983	1983/11/10
85	Daunorubicin Hydrochloride	Cerubidine	050484	1979	1979/12/19
86	Cisplatin	Platinol	018057	1978	1978/12/19
87	Tamoxifen Citrate	Nolvadex	017970	1977	1977/12/30
88	Dacarbazine	DTIC-DOME	017575	1975	1975/05/27
89	Doxorubicin Hydrochloride	Adriamycin RDF	050467	1974	1974/08/07

90	Bleomycin	Blenoxane	050443	1973	1973/07/31
91	Procarbazine Hydrochloride	Matulane	016785	1969	1969/07/22
92	Cytarabine	Cytarabine	016793	1969	1969/06/17
93	Vinblastine Sulfate	Velban	012665	1965	1965/11/05
94	Vincristine Sulfate	Oncovin	014103	1963	1963/07/20
95	Fluorouracil	Fluorouracil	012209	1962	1962/04/25
96	Cyclophosphamide	Cytoxan	012141	1959	1959/11/16
97	Chlorambucil	Leukeran	010669	1957	1957/03/18
98	Prednisone	Meticorten	009766	1955	1955/02/21
99	Methotrexate	Methotrexate sodium	008085	1953	1953/12/07
100	Leucovorin Calcium	Leucovorin calcium	008107	1952	1952/06/20

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