

WORLD MARKETS ONCOLOGY |



**GLOBAL
INSIGHT**



How are pharmaceutical companies and regulatory bodies dealing with increasing costs of—and market access barriers to—new oncology drugs? What happens when new products, generics, and/or biosimilars change the competitive landscape? What is in pipeline development that may alter the dynamics of the market?

IHS Global Insight's World Markets Oncology service, enhanced by the unique Onco-Online database, is a comprehensive online tool designed to answer precisely these kinds of questions. The service provides a clear picture of the full value proposition of any oncology product (whether in early development or fully marketed) and relates the price, cost, and specific reimbursement guidelines of new medicines with the clinical data that underpin them.

This service benefits a range of stakeholders in oncology, including strategic planners, pricing managers, business development managers, research associates, and regulatory executives.

This service enables you to instantly:

- Understand how approvals and reimbursement were secured—or not secured—based on clinical endpoints, design, and results, as well as pricing
- Compare and break down the cost of drugs in each of their approved cancer areas
- Understand the key market access barriers to new oncology drugs, including tier placements, clinical guidelines, special authority restrictions, and detailed overviews of cost-effectiveness calculations and reimbursement decisions
- Find new licensing opportunities and key areas of research and development
- Assess the risk posed by oncology drugs under development based on cancer type, drug class, and manufacturer

► **SERVICE FEATURES**

The Onco-Online Database

- Coverage of over 20,000 drugs, both approved and under development, for oncology and supportive care:
 - Global pipelines
 - Pricing, reimbursement, approval, and cost information for medicines in Australia, Canada, France, Germany, Italy, Japan, Spain, the United Kingdom, and the United States

World: Weekly Oncology Milestones Bulletin

IHS Global Insight Perspective

Significance: Clearly, the U.S. FDA's hesitation over whether to approve Centocor Ortho/PharmaMar's Yondelis—in September they requested additional data for the New Drug Application—is not shared by many other countries. This week, the European Commission approved its use in relapsed platinum-sensitive ovarian cancer. Indeed, Yondelis seems to be blazing an approval trail as of late with the approval for its use in soft-tissue sarcoma in Mexico, Chile, Uruguay, Singapore and Vietnam. In other approval news, the FDA has approved Gloucester Pharmaceuticals' ISTODAX in cutaneous T-cell lymphoma. The company plans to launch the drug in January 2010.

Implications: Just a week after the European Commission granted orphan drug designation to Clivio's CD-8326 in pancreatic cancer, two other drugs received orphan drug status in the same indication in the United States: Genzyme's TNFerade and Abraxis' abraxane. As a result of the designation, both drugs will enjoy incentives such as tax credits, reduced fees, and up to seven years of market exclusivity if approved; incentives which are likely to ease the regulatory and clinical path for both drugs, getting these drugs quickly to market will benefit those patients living with this extremely aggressive and difficult-to-treat form of cancer.

Outlook: With Eisai's announcements of positive preliminary results from the Phase III EMBRACE trial of Erlotinib in locally advanced or metastatic breast cancer a new treatment for this, the most deadly of cancers in women, may be on the near horizon. The results, which demonstrate that the primary endpoint of overall survival was met, were made even more significant that the patient population was heavily pre-treated. Based on the success of the EMBRACE trial, Eisai, after conducting a more detailed analysis, hopes to submit marketing approval applications in Japan, the United States, and Europe by year-end.

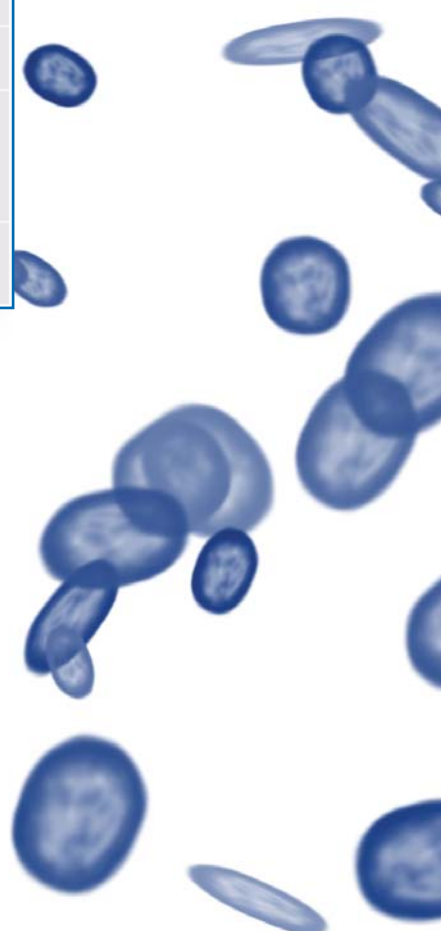
Oncology Bulletin				
Date	Drug/Target	Company/Organization	Cancer	Update
			Regulatory/P/R	
5 November	ISTODAX (romidepsin)	Gloucester (U.S.)	Cutaneous T-cell lymphoma (CTCL)	The U.S. FDA has approved ISTODAX in CTCL.
	Abraxane (paclitaxel protein-bound particles for injectable suspension)	Abraxis (U.S.)	Pancreatic cancer and melanoma	The FDA has granted orphan drug status to Abraxane in pancreatic cancer and stage IIB-IV melanoma.
4 November	Yondelis (trabectedin)	PharmaMar (Spain)	Ovarian cancer	The European Commission has authorized the commercialization of Yondelis as a combined treatment with pegylated liposomal doxorubicin for relapsed platinum-sensitive ovarian cancer.
	TNFerade	GenVec (U.S.)	Pancreatic cancer	The FDA has granted orphan drug status to TNFerade in pancreatic cancer.
	Lucanis	NovaRx	Non-Small-Cell Lung Cancer (NSCLC)	The FDA has approved a Special Protocol Assessment Protocol Amendment to the Phase III trial of Lucanis in NSCLC, which allows for, among other things, expanded patient eligibility.
3 November	-	Elektra (Sweden)	-	Elektra has announced that it has been awarded 7 out of 10 contracts for the Phase III trial of Elektra in pancreatic cancer.

- Up to 55 sets of data per drug, from Phase I through approval, including:
 - Pricing & Reimbursement:** average cost per drug in each of the approved cancer areas for any marketed drug, taking into account the price, dosing, average duration of use, and presentation; also provides ex-manufacturing prices, reimbursement restrictions, and guidelines
 - R&D:** clinical trial design, endpoints, results, and forward-looking approval information
 - Corporate:** licensing, patent, and strategic planning information

Country	Portfolio / Pipeline Status	Drug	API	Strength	Drug Class	Licensing Status	Cancer Area	Official Dosage	Aver Dur of f	US\$	
United States	II	-	PICOPLATIN, DOCETAXEL	-	Platinum	Pionard granted exclusive rights to IV picoplatin from AnorMed (now part of Genzyme)	Prostate Cancer, HRBC	-	-	US\$	-
United States	III	-	ONDANSETRON HYDROCHLORIDE	-	5-HT3 Receptor Antagonist	Stratix licensed exclusive U.S. commercialization rights to thin film technology for delivering ondansetron. SOURCE: Stratix, 24 June 2008	Supportive Care, CTRV	-	-	US\$	-
United States	I	-	PICOPLATIN	-	Platinum	Pionard granted exclusive rights to IV picoplatin from AnorMed (now part of Genzyme)	Solid Tumours	-	-	US\$	-
United States	III	-	ASOPRISINL	-	Hormone Antagonist	Abbott/Takeda joint venture TAP Pharmaceuticals dissolved. Abbott received rights to Lupron franchise; Takeda received the remaining organization and pipeline - though Abbott receives payments based on More	Myoma	-	-	US\$	-
United States	II	1019 106, RITUXAN	-	RITUXIMAB	TLR-targeted	-	Haematological Malignancy, Non-Hodgkin's Lymphoma, B-Cell Lymphoma, Follicular Lymphoma	-	-	US\$	-

Same-Day Analysis and Profiles

- Daily analysis of all key events related to the oncology market. This is supplemented with a Weekly Oncology Milestones Bulletin, summarizing the 40-60 updates made throughout the week to the database and providing an editorial perspective.
- Over 100 profiles for key cancer areas and drug classes, as well as regulatory profiles that provide an overview of the oncology environment for pricing and reimbursement, approvals, orphan drugs, and risk-sharing agreements.



▶ IHS GLOBAL INSIGHT HEALTHCARE & PHARMA SERVICES

IHS Global Insight's Healthcare & Pharma practice provides a portfolio of intelligence solutions to optimize the performance of companies and organizations across the pharmaceutical, biotech, and generics sectors. Our key focus is to provide actionable insights to support strategic decision making—particularly in the fields of market access, pricing and reimbursement (P&R), emerging markets, generics strategies, therapeutic development pathways, and general competitive intelligence. We deliver high-value subscription and consultancy services to address daily healthcare information needs, highlight important market trends and obstacles, and maximize product life cycles. These services include our Same-Day Analysis—providing the latest global analysis on fast-paced developments in the sector on a daily basis—multi-client studies, special reports, country reports, global pricing data, and market access consultancy. Our expertise is based on the unparalleled geographic and therapeutic specialties of our in-house data and specialized analysts.

For more information, please visit www.ihsglobalinsight.com/healthcare.



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