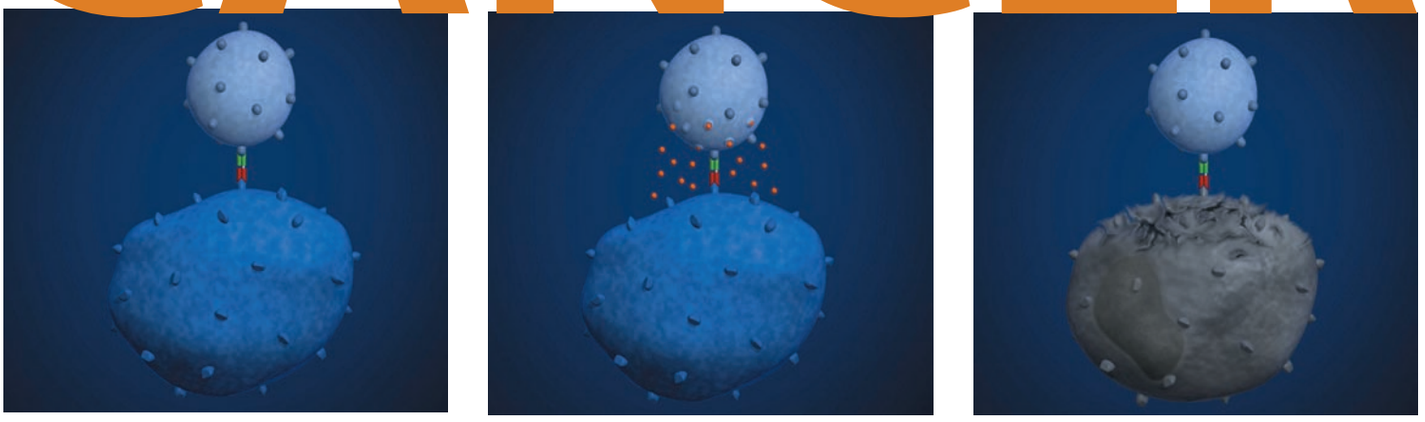
BY DENISE MYSHKO

CANCER



These pictures illustrate how Micromet's BiTE molecule links a T cell with a cancer cell (left), triggering the release of toxic particles by the T cell (middle), and the cancer cell being destroyed (right). This is one approach for employing the body's immune system to address cancer.

Harnessing the POWER of the Immune System

Cancer treatment is about to undergo a paradigm shift. Companies are making progress in using proteins, biomarkers, pathways, peptides, antigens, and other tools to trigger the body's immune system to address cancer. This approach to immunotherapy incorporates an array of strategies based upon the concept of modulating the immune system to achieve a prophylactic and/or therapeutic goal.

Current cancer treatments typically destroy healthy cells along with the cancer cells they are meant to attack. Further, they do little to stop metastasis, the often-fatal spread of the disease to remote locations in the body. In contrast, companies now are developing approaches that trigger an immune response that can eliminate tumor tissue that has spread from the treatment site (metastatic tumors).

One such company, Provectus Pharmaceuticals Inc., has a proprietary drug, Provecta, that when injected into tumor tissue, concentrates in the tumor at cytotoxic levels while quickly dissipating from healthy tissue, making it safer and more effective than conventional therapies, such as chemotherapy and radiation. Simultaneously, Provecta also can be combined with radiation, increasing the effects of radiation on tumor tissue and potentially enabling less radiation to be used, thereby subjecting patients to fewer side effects.

According to Craig Dees, Ph.D., CEO of Provectus, the use of such tools is logical as they enhance the body's own mechanisms to fight disease.

"The most successful medical products are vaccines and antibiotics," he says. "Antibiotics hold the infection but the natural system clears it. Vaccines work by enhancing the natural defenses. To combat cancer, we have to engage the natural defense system. We deliver the drug into the tumor tissue, which obliterates the tumors very quickly. At the same time, the immune system recognizes where there has been damage and the antigen presenting cells know what material they have come into contact with and choose whether T cells, B cells, or other cells are needed. In other words, the body knows how to pick the best response mechanism."

While incremental advances have been made in detecting and treating cancer, it is still the second-leading cause of death in the United States, exceeded only by heart disease.

About 1.4 million new cancer cases are expected to be diagnosed in 2007, not including carcinoma *in situ*, and an additional 1 million people are expected to be diagnosed with basal and squamous cell skin cancers, according to the American Cancer Society. In the United States, cancer accounts for one of every four deaths.

"We haven't really made giant strides over the last couple of decades in eradicating can-

BIOPHARMACEUTICAL COMPANIES HAVE BEEN TRYING FOR SOME TIME TO USE THE BODY'S OWN IMMUNE SYSTEM TO ADDRESS CANCER.

Now, advances in research tools and enhanced knowledge of the immune system are enabling vaccines and other immunological approaches for the treatment of cancer to emerge.

cer," says Carl M. Cohen, Ph.D., chief operating officer of Biovest International Inc. "We've made incremental advances and we've improved certain types of therapies, but overall people are still dying of cancer."

The reality is that once cancer has spread, it is almost always incurable, says Alan Melcher, M.D., Ph.D., UK Senior Clinical Research Fellow and Senior Lecturer/Honorary Consultant in Clinical Oncology, St. James's University Hospital in the United Kingdom, and a lead investigator for Oncolytics Biotech Inc.

"We're getting better at pushing out the boundaries, and people are living longer and living better with their tumors, but the current treatments that we have are still woefully short of what are needed," Dr. Melcher says.

The five-year relative survival rate for all cancers diagnosed between 1996 and 2002 is 66%, an increase from 51% between 1975 and 1977.

Christian Itin, Ph.D., CEO and president of Micromet Inc., points out that today's cancer treatments are good at dealing with primary tumors but have limited success in preventing metastasis formation and treating metastases once they have formed.

"We have a hard time with those cancer cells that managed to move away from the primary tumor and have the potential to form metastasis, a process that happens very early in the disease," Dr. Itin says. "The primary tumor typically is not the cause of death for cancer patients; it's the metastatic disease that ultimately causes death."

DESIGNER VACCINES

Immunotherapy represents a paradigm shift in addressing cancer, Dr. Cohen says.

"Once the first company receives approval for a product based on the principle of immunotherapy, the industry's views will change about the utility of such drugs," he says. "These probably won't be stand-alone therapies. But if we use immunotherapeutic-based compounds in conjunction with other cancer-fighting products that have been developed, we may get to a point where patients are living with very low rates of disease."

Denis Miller, M.D., senior medical director and oncology/hematology therapeutic area leader at Parexel International, says patients may experience better results with immunotherapy if treated earlier in the course of their disease and when their tumor burden is smaller.

"A role for vaccine therapy may be in patients who have had a good — not necessarily complete — response to targeted therapy plus chemotherapy," Dr. Miller says. "Ideally, they should have minimal residual disease as it may be easier for the body's immune system when stimulated by a vaccine to attack the residual tumor cells."

The most advanced example of an immunotherapy is Dendreon Corp.'s Provenge, which has to be created for each patient using a patient's own cells. In March, the FDA's Office of Cellular, Tissue and Gene Therapies Advisory Committee concluded that there is substantial evidence of efficacy and safety of Provenge (sipuleucel-T) for the treatment of patients with asymptomatic, metastatic, hormone refractory prostate cancer. In May, Provenge received an approvable letter; upon approval, it will become the first active cellular immunotherapy and the first biologic approved to treat prostate cancer.

"There seems to be an improvement in the median survival rate in patients with hormone refractory prostate cancer who received a new prostate cancer vaccine compared with those who received placebo," Dr. Miller says.

Prostate cancer is the most common non-skin cancer in the United States and the third most common cancer worldwide. More than 1 million men in the United States have prostate cancer, with an estimated 218,890 new cases diagnosed each year. More than 27,000 men die each year of the disease.

Because key cells of the immune system are highly selective for the specific antigen they recognize, stimulating these cells creates an army designed to hone in on cancer cells while leaving healthy cells unharmed.

Dendreon also is developing lapuleucel-T, which targets HER2/neu positive cancers. HER2/neu is a growth factor receptor, and its overexpression has been associated with a number of cancers, including breast, ovarian, colon, and lung.

Another one-patient-one-vaccine product is Biovest's BiovaxID, which is in late-stage development for B-cell lymphoma. This cancer immunotherapy stems from work begun in 1986 during the development of a patient-specific follicular lymphoma (FL) vaccine.

The cancer vaccine primes the immune system to recognize and eliminate cancerous lymphoma cells, while sparing normal B cells. In the vaccine's cancer target, B-cell lymphoma, the process is made possible by the presence of a hallmark surface antigen of the cancer cells that is not present in noncancerous tissue. By priming the immune system with this antigen in the form of an autologous vaccine, the vaccine induces an immune response against the cancerous cells.

There are about 65,000 new cases of non-

IDE MILLS, HealthEd

WITH IMMUNOTHERAPIES, PROFESSIONALS WILL BENEFIT GREATLY FROM EFFECTIVE COUNSELING TOOLS THAT CAN BE USED TO EDUCATE AND SUPPORT THEIR PATIENTS AND FAMILIES.

DR. CARL COHEN
Biovest International

MANY PEOPLE ARE EVALUATING THE WHOLE FIELD OF IMMUNOTHERAPY, WHICH REPRESENTS A PARADIGM SHIFT IN HOW THE INDUSTRY DEALS WITH CANCER.

DR. CRAIG DEES
Provectus Pharmaceuticals

IMMUNOTHERAPY IS THE WAVE OF THE FUTURE. THE CHALLENGE IS MAKING THE SCIENCE BROAD ENOUGH AND SIMPLE ENOUGH.

Hodgkin's lymphoma diagnosed each year in the United States with a comparable number in Europe. Depending on treatment, the median relapse time for FL patients is between three and seven years, with 50% of patients dying of a tumor-related mortality within 10 years of diagnosis.

"We start with a sample of the patient's cancerous B cells, which are easy to get because these accumulate in the patient's lymph nodes," Dr. Cohen says. "We grow these cancer cells in the laboratory, where they release unique marker proteins. Using a self-contained automated cell growth instrument that Biovest has developed called the AutovaxID, we collect the marker proteins and then we chemically modify them, by tacking on a new protein that is derived from a sea snail. The marker protein is then seen as foreign by the immune system."

While each vaccine has to be created from the patient's own cells, Biovest has automated a significant part of the process using AutovaxID.

"Eventually, we expect to have a commercial manufacturing facility with about 500 of these instruments sitting side by side producing patient-specific vaccines," he says.

Dr. Cohen predicts the company could file a BLA for BiovaxID as early as 2009.

"We continue to follow a group of 20 patients, and after almost 10 years of having been treated with BiovaxID, 95% of these patients are still alive," he says. "Historically, only half of the patients with this disease after 10 years of treatment of any type are alive."

Dr. Miller says the one-vaccine-one-patient approach, however, will have difficulties in the marketplace.

"From a drug-development perspective, although very interesting and scientifically valid, this type of approach is not going to have a role in pharmaceutical drug development because of the labor intensity, expense, and limited patients who can be treated," he says. "The general approach now is to develop a vaccine that is directed against antigen (identifying proteins) that are unique to the type of cancer. For example, renal cancer cells may express a specific antigen against which a vaccine is directed."

Dr. Cohen says from a payer perspective it's important to look at treatment as a whole.

"Analysis done in consultation with our external medical consultants indicates that from the day of diagnosis to the day of demise, the cost to the healthcare system for a patient with this disease is more than a half a million dollars," he says. "If we can sell a course of therapy of BiovaxID for a fraction of this cost, even though the treatment may appear to be more costly if it keeps patients out of the healthcare system and keeps them alive and healthy, this is a huge benefit for third-party payers."

Industry experts say there are other issues to consider as well, for example safety. According to Dr. Miller, the FDA is likely to scrutinize immunotherapies in this regard.

"Playing around with the immune system can upset its stability and could cause other difficulties, including a number of other symptoms and automimmune-related illnesses," Dr. Miller says. "A cancer vaccine could adversely affect the kidney, the skin, and other organs or tissues in the body, including the blood-forming system or the joints. Vaccine therapy could cause anemia, a low platelet count, and bleeding. An autoimmune response could cause the body to not only attack the tumor but its own tissues."

To counter these safety issues and complicated side effects, companies will have to have a very good way of measuring whether there is a specific and strong response against tumor cells, rather than normal tissues, Dr. Miller says.

"TICKLING" T CELLS

Another company researching B-cell lymphoma is Micromet, which is conducting Phase I trials of an immunotherapy for end-stage non-Hodgkin's lymphoma. The company is developing this product in collaboration with MedImmune Inc., which has North American rights.

Micromet's BiTE molecules mark tumor cells for recognition by the patient's own killer T cells. BiTE molecules represent a novel class of drugs that function as bispecific T cell engagers. They enable the body's killer T cells to recognize and attack tumor cells, leaving normal cells unharmed.

"The T cell, in its natural way, kills the cancer cells, which then go through apoptosis," Dr. Itin says. "This is a very clean and targeted way of taking out tumor cells."

The company's first product candidate using this platform is a BiTE molecule targeting CD19, which is found on non-Hodgkin's lymphoma cells. Recent clinical data with this BiTE molecule in patients with relapsed non-Hodgkins lymphoma showed clinical respons-

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GARNETT DEZEMBER
The Navicor Group

THE TARGETED NATURE OF IMMUNOTHERAPIES DICTATES THAT THERE HAS TO BE A CERTAIN CUSTOMIZATION OF TREATMENT, WHICH IS UNLIKE CURRENT THERAPIES.

DR. VAFA SHAHABI, Advaxis

IMMUNOTHERAPIES HAVE TREMENDOUS BENEFITS COMPARED WITH OTHER THERAPEUTIC MODALITIES. THE QUESTION BECOMES: CAN THE INDUSTRY MAKE AN IMMUNOTHERAPY THAT IS SAFE AND EFFECTIVE?

es and a reduction or complete disappearance of lymphoma cells from bone marrow following treatment. The data was presented in December 2006.

Micromet's next potential product candidate is an antigen found on solid, epithelial tumors such as colorectal, gastric, breast, pancreatic, etc., called EpCAM, which is one of the most frequently and intensely expressed tumor-associated antigens known.

Dr. Itin says this candidate is expected to be in the clinic in the second half of this year.

The company also is working with MedImmune on two other programs against subsets of solid tumors.

BACTERIA AND VIRUSES

Other companies are using bacteria to trigger an immune response. For example, Advaxis' technology forces the body to recognize tumor-associated or tumor-specific antigens as foreign, creating the immune response needed to attack the cancer. This process is done by combining elements from all immune pathways, including the stimulation of both innate and adoptive immunity by using the biologic characteristics of a common bacterium, Listeria monocytogenes.

"Listeria engenders a cell-mediated immunity, and cell-mediated immunity kills cancer," says Vafa Shahabi, Ph.D., director of research and development at Advaxis. "During its life cycle, Listeria does many things within the cellular mediated framework, and as such it is a very powerful stimulator of the body's cells to seek out invaders to kill them. We have modified Listeria in such a way that the cell-mediated response it engenders is directed against a specific cell of our choosing. Rather than just adding a cancer antigen, we have engineered Listeria to secrete what we call an antigen fusion protein; this is an antigen fused with another element that creates a larger immune response than the antigen would alone."

Listeria is an environmental bacterium with which humans have an existing immune relationship. Found primarily in dairy products, ingestion of excessive quantities of Listeria, such as might be found in spoiled milk, can result in disease.

When Listeria enters the body, it is seen as foreign by the antigen-processing cells and is ingested into cellular compartments called lysosomes, whose destructive enzymes kill most of the bacteria. But some of the Listeria is capable of escaping and can carry proteins into the intracellular compartment. These antigens are then presented to the immune system by two different pathways.

Advaxis is conducting Phase I/II trials of Lovaxin C in cervical and head and neck cancers, and the company expects to complete these trials sometime this summer.

The company also is conducting preclinical work in other solid tumors, such as breast, lung, prostate, and ovarian cancers.

Other companies, such as Oncolytics Biotech, are using viruses to trigger the immune system.

Oncolytics Biotech's Reolysin is based on reovirus technology. Late in 2006, Dr. Melcher hypothesized that reovirus activation of dendritic cells, which are key to early detection of infection — through the innate immune response — may "instruct" cells belonging to the adaptive immune response, namely natural killer cells and T cells, to attack the tumor even after the virus no longer remains in the body.

The reovirus can trigger the immune system in a variety of ways, Dr. Melcher says.

"We're only now beginning to explore this application," he says. "One thing we know is that the immune system is highly attuned to recognize viruses and to respond to them. On one level, the virus might trigger an immune response against that virus, which would effectively shut down the treatment. It also can trigger an immune response against itself, which is a good thing."

Reolysin is the company's proprietary formulation of the human reovirus, and it has been demonstrated to replicate specifically in tumor cells bearing an activated Ras pathway. Reolysin is in a number of Phase I and Phase II trials in the United States and the United Kingdom.

EDUCATED APPROACHES

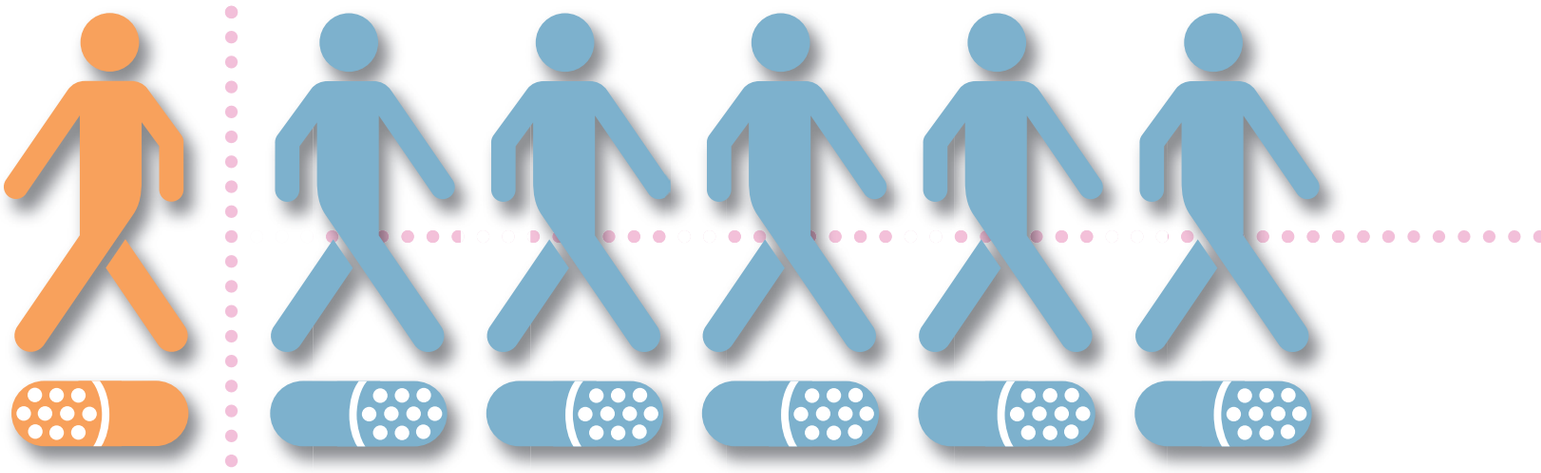
In the last five to 10 years, targeted therapies have been the buzzword in new treatment options, says Ide Mills, VP of strategic health education at HealthEd.

"Targeted therapies have extended and improved the lives of many people," she says. "Oncologists, oncology nurses, physicians, and advocacy organizations have played a significant role educating patients and their families about these medications: how they work differently from chemotherapy, what the side effects of these drugs may be, and how to effectively manage the side effects."

These professionals, she says, will benefit from effective counseling tools to educate and support their patients and families.

"While immunotherapy may be a difficult concept to understand, it is important to break down the information and explain it in a way that differentiates it from other treatment options," she says. "People with cancer need credible educational resources to inform them about the unique issues of targeted therapies and immunotherapies. Patient education that incorporates both health literacy and educational design principles is necessary for patients to understand what the treatment is, what to expect from the treatment, and how to manage any side effects. Understanding this information is at the core of adhering to the treatment plan. Ongoing patient education and communication between the patient and the treatment team is critical for optimal benefits."

The targeted nature of newer therapies



FACT:

Committed Physicians Are up to 5 Times Less Likely to Defect from Your Brand—Dramatically Slashing Switch Risk.

FICTION:

You'd Have to Risk a Budget Increase to Win that Kind of Commitment.

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SELECTED IMMUNOTHERAPIES IN DEVELOPMENT

COMPOUND	DEVELOPER(S)	TYPE OF CANCER	STATUS	MODE OF ACTION
AE37	Antigen Express	Breast	Phase I completed	Peptide vaccine designed to stimulate an immune response against tumors that express the HER2/neu oncogene
AGS-003	Argos Therapeutics	Renal Cell	Phase I/II	RNA-loaded dendritic cell vaccine
Allovectin-7	Vical	Melanoma	Phase II	A plasmid–lipid complex that contains DNA sequences that encode for HLA and for beta2- microglobulin
Anti-GnRH vaccine	Pepscan Systems	Prostate	Phase I/II	Developing therapeutic vaccines based on the company's CLIPS technology
ANYARA (TTS)	Active Biotech	Lung	Phase II	Antibody linked to a toxin; stimulates the body's own immune system to target and kill cancer cells
BiovaxID	Biovest International	Non-Hodgkin's Lymphoma	Phase III	Patient-specific therapeutic vaccine
BrevaRex	Unither Pharmaceuticals	Pancreatic	Phase I	Immunotherapeutic monoclonal antibody that targets MUC1 and induces immune responses against MUC1 and against the tumor
CDX-1307	Celldex Therapeutics	Breast, Bladder, Pancreas	Phase I	A fusion protein composed of a mannose receptor–specific human monoclonal antibody and hCG-beta; the fusion protein delivers the tumor associated antigen (hCG-beta) to dendritic cells to induce hCG-beta–specific humoral and cellular immune responses
Collidem	IDM Pharma	Colorectal	Phase I/II	Individualized therapy using Dendritophages (dendritic cells) derived from the patient's own white blood cells
CRS-100	Cerus	Colorectal	Phase I	Attenuated Listeria vaccine; stimulates an anticancer immune response in the liver
CYT004-MelQbG10	Cytos Biotechnology	Melanoma	Phase IIa	Therapeutic vaccine consists of Melan-A/MART-1 protein coupled to QbG10
DCVax-LB	Northwest Biotherapeutics	Lung	Phase I	Personalized vaccine that combines a patient's own dendritic cells with cancer antigens to induce an immune response against the cancer; uses deactivated lung cancer cells as antigens
DCVax-Prostate	Northwest Biotherapeutics	Prostate	Phase III	Personalized vaccine that combines a patient's own DC with cancer antigens to induce an immune response
EMD 273066 (tucotuzumab celmoleukin; huKS-IL2)	Merck KgaA	Colorectal, Prostate	Phase I/II	An immunocytokine: a recombinant fusion protein created to trigger an immune response
EP-2101	IDM Pharma	Lung	Phase II	Vaccine that consists of a mixture of synthetic peptides derived from tumor antigens
FAV-201	Favrille	Non-Hodgkin's Lymphoma	Phase I/II	Patient-specific therapeutic vaccine
FavId	Favrille	Non-Hodgkin's Lymphoma	Phase III	Patient-specific therapeutic vaccine
GI-4000	GlobeImmune	Pancreatic	Phase II	Developing Tarmogens (targeted molecular immunogens) for treatment of cancer and infectious diseases
GMK	Progenics Pharmaceuticals	Melanoma	Phase III	Therapeutic vaccine that consists of purified gangliosides that have been linked to a carrier protein, together with an immune stimulant; for prevention of recurrence of melanoma following surgery
GRNVAC1	Geron	Prostate, Renal	Phase I/II	Telomerase vaccine that consists of autologous (patient-specific) dendritic cells loaded ex vivo with telomerase mRNA
GV1001	Pharmexa	Lung, Liver Pancreatic	Phase II Phase III	Peptide vaccine that targets the enzyme telomerase
GVAX immunotherapy	Cell Genesys Cell Genesys	Pancreatic Prostate	Phase II Phase III	2 pancreatic cancer cell lines that have been genetically modified to secrete GM-CSF and then irradiated
HER2 ASCI	GlaxoSmithKline	Breast	Phase I/II	GSK's ASCI approach uses recombinant protein technology and targets antigens that are expressed specifically by tumor cells and not in normal tissues
Hi-8 MEL	Oxxon Therapeutics	Melanoma and Renal Cell Carcinoma	Phase II	Therapeutic vaccine that contains 7 epitopes from 5 human melanoma antigens
IL-2/EP	Vical	Melanoma	Phase I	Delivery of plasmids that encode human IL-2, which involves direct injection of pDNA encoding IL-2 followed by electroporation
IMA901	immatics	Renal Cell	Phase I	Tumor-associated peptides (TUMAPs) for immunotherapy
IMO-2055 (IMOxine)	Idera Pharmaceuticals	Lung Renal Cell	Phase I/II Phase II	TLR9 agonist that contains a CpG dinucleotide motif and a novel DNA structure
INGN 225	Introgen Therapeutics	Breast, Small Cell Lung	Phase I/II	p53 vaccine is an immunotherapy that uses the p53 tumor suppressor gene to stimulate the patient's immune system's dendritic cells

Editor's Note: Types of cancer and modes of action have been excerpted from original report.
Source: Insight Pharma Report (formerly Advances Reports), Needham, Mass. For more information, visit insightpharmareports.com.

COMPOUND	DEVELOPER(S)	TYPE OF CANCER	STATUS	MODE OF ACTION
Insegia	Receptor BioLogix	Advanced Stomach and/or Esophageal Pancreatic	Phase II Phase III	A synthetic peptide derived from the hormone gastrin (G17) that is bound to an inactive form of the diphtheria toxin (DT) as a monotherapy and in combination with gemcitabine
Ipilimumab	Medarex and Bristol-Myers Squibb	Breast, Renal Cell, Prostate Melanoma	Phase II Phase III	An anti-CTLA4 antibody on T cells
Lapuleucel-T	Dendreon	Breast	Phase I completed	Active cellular immunotherapy product that targets Her2/neu positive cancers
Lovaxin C	Advaxis	Cervical, Head & Neck	Phase I/II	Made from attenuated Listeria, it stimulates the innate immune system priming the adaptive immune system to better respond to specific antigens
Lucanix	NovaRx	Glioma	Phase II/III (2008)	Individualized therapy using Dendritophages (dendritic cells) derived from the patient's own white blood cells
	NovaRx	Lung	Phase III	Based on AC Vaccine Immunotherapy technology
L-Vax	AVAX Technologies	Lung	Phase I/II	GSK's ASCI approach uses recombinant protein
MAGE-A3 ASCI	GlaxoSmithKline	Lung	Phase II	technology
M-Vax Phase	AVAX Technologies	Melanoma	Phase I/II	AC Vaccine Technology
MyVax Personalized Immunotherapy	Genitope	B-cell NHL and B-cell CLL Non-Hodgkin's Lymphoma	Phase II Phase III	Personalized immunotherapy
Norelin	YM Biosciences	Prostate	Phase I/II	Therapeutic vaccine that stimulates production of antibodies against GnRH
Oncophage	Antigenics	NSCLC, Glioma Metastatic Kidney Melanoma, Nonmetastatic kidney	Phase I/II Phase II Phase III	Personalized vaccine, an autologous vaccine based on proprietary heat shock protein gp96
OncoVAX	Intracel	Melanoma, Renal Cell Colorectal, Lung	Phase I/II Phase III	Autologous vaccine made from the patient's cancer cells
OncoVEXGM-CSF	BioVex	Head and Neck Colorectal, Melanoma	Phase I/II Phase II	Oncolytic virus based on HSV; the virus is genetically engineered to carry the gene for GM-CSF
Onyvax-P	Onyvax	Prostate	Phase IIb	Developing cell vaccines based on inactivated tumor cell lines from proprietary cell banks
P501 antigenspecific cancer immunotherapeutic	GlaxoSmithKline	Prostate	Phase I	GSK's ASCI approach uses recombinant protein technology and targets antigens that are expressed specifically by tumor cells and not in normal tissues
Pentrys	Avantogen	Prostate	Phase II	Anti-idiotype vaccine that targets p53 and causes the immune system to see mutated p53 gene products as foreign
PF-3512676	Pfizer and Coley Pharmaceutical	Lung	Phase III	TLR9 agonist
Prostate cancer vaccine	Progenics Pharmaceuticals	Prostate	Phase I	Therapeutic recombinant protein vaccine
Provenge	Dendreon	Prostate	Recommended for approval by FDA advisory committee	Active cellular immunotherapy product; the patient's own antigen-presenting cells are modified and returned to the patient to stimulate the patient's immune system to attack and kill prostate cancer cells that express PAP
Stimuvax	Merck KgaA and Biomira	Lung	Phase III	Synthetic MUC1 peptide vaccine
TG 1042	Transgene	Non-Hodgkin's Lymphoma	Phase II	Immune enhancement gene therapy that consists of an adenovirus with a nucleotide sequence encoding IFN-gamma
TG 4010	Transgene	Prostate Lung	Phase II Phase IIb	Vaccine based on the MVA, an attenuated vaccinia virus that expresses the MUC1 antigen
Ticilimumab	Pfizer	Melanoma	Phase III	Monoclonal antibody targeted to CTLA4 that enhances the immune system to better fight cancer cells
TNFerade	GenVec	Colorectal, Metastatic Melanoma Pancreatic	Phase II Phase II/III	An adenovirus vector with the gene for TNF-alpha for rectal cancer
TroVax	Oxford BioMedica	Breast, Renal cell, Colorectal, and Prostate	Phase II	A gene therapy that uses a pox virus vector to deliver the tumor-associated antigen 5T4
Uvidem	IDM Pharma and Sanofi-Aventis	Melanoma	Phase II	Individualized therapy using Dendritophages (dendritic cells) derived from the patient's own white blood cells
V930	Merck	Breast	Phase I	DNA cancer vaccine that is based on DNA gene-delivery technology that was licensed from Vical; it uses pDNA encoding (HER2) and CEA for cancers that express HER2 and/or CEA, such as breast, colorectal, ovarian, or nonsmall-cell lung cancers
Virulizin	Lorus Therapeutics	Pancreatic	Phase II	An immunomodulator that recruits human macrophages and monocytes, and stimulates release of TNF-alpha

DR. ALAN MELCHER
St. James's University Hospital

THE GOAL IS TO TARGET THE VIRUS TO KILL THE CANCER CELLS AND USE THAT VIRUS TO TRIGGER AN IMMUNE RESPONSE AGAINST THE CANCER CELLS AS WELL.

results in customization of treatment unlike anything the industry has witnessed before. This means there will be more segmentation in the marketplace, says Garnett Dezember, president of The Navicor Group.

"Even now we are seeing subsets of patients who respond to therapy better than the general treatment population," he says. "Consequently, education is going to play a critical role in identifying patients who have the best opportunities with the therapies. There also will be more education associated with the diagnostics for those therapies."

Mr. Dezember says education around compliance and adherence is going to be equally important as disease control becomes an increasingly viable treatment objective.

"In the past, there were relatively short spans of treatment to eradicate the disease as much as possible," he says. "Going forward, there may be more oral therapies and longer-term treatments, which will create a need for more consistent reinforcement for patients to remain compliant with their therapy."

Ms. Mills says in addition to patient advocacy groups and the pharmaceutical companies, the Internet is playing a key role in informing patients, their families, and their caregivers about cancer, from treatment options to coping with the day-to-day issues.

"There are many reputable sites providing invaluable information, resources, and support," she says. "In addition, there has been an influx of consumer-focused magazines dedicated to people with cancer and even specific types of cancer."

Mr. Dezember says, in general, there is a better understanding about treatment behaviors these days.

"Comprehending patient attitudes about their treatments allows us to target our messages and channels to physicians, patients, and caregivers with opt-in programs so everyone involved can more actively participate in treatment approaches," he says.✦

DR. DENIS MILLER, Parexel

CANCER CELLS ARE VERY TRICKY. THEY'RE LIKE STEALTH BOMBERS THAT FLY UNDER THE RADAR OF THE IMMUNE SYSTEM AND SO THE BODY'S NATURAL DEFENSES DON'T RECOGNIZE THE TUMOR.

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

Experts on this topic

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