



IN PARTNERSHIP WITH



MEDICINES IN DEVELOPMENT: IMMUNO-ONCOLOGY

JUST THE FACTS¹

MORE THAN

1.6M

estimated new cases of cancer in 2017

ESTIMATED

600K

U.S. cancer deaths in 2017

MORE THAN

4.8%

of U.S. population are cancer survivors

87%

of cancer diagnoses in the U.S. are in people age 50 and older

MORE THAN 240 IMMUNO-ONCOLOGY TREATMENTS IN DEVELOPMENT ARE ACCELERATING PROGRESS FOR PATIENTS WITH CANCER

The rapid pace of scientific advances has helped usher in a new era of medicine for cancer patients over the last decade. Biopharmaceutical researchers' understanding of the underlying biological mechanisms that initiate and control cancer cell growth have created promising new avenues for treatment advances. Research into the role of the body's immune system in fighting cancer has yielded some of the most exciting new advances, resulting in a new wave of immunotherapies specifically targeting cancers.

Cancer immunotherapies, also known as immuno-oncology, enable the patient's own immune system to fight cancer similarly to the way it fights disease-causing viruses and bacteria. These treatments can help unleash a patient's own immune system against cancer, with the promise of lasting results. Different cancer immunotherapies work on the immune system in different ways. For example, some immunotherapies facilitate a stronger immune response to cancer, while others show the immune system what cancer looks like so that it can better identify, target and kill the cancer cells.

While immunotherapies broadly have been around for years, innovation has ushered in a new era in science that has opened the door to the next generation of discoveries. Today, biopharmaceutical companies are developing 248 immuno-oncology medicines and vaccines² in the most recognized classes of cancer immunotherapy. All of the treatments in development are in clinical trials or awaiting review by the U.S. Food and Drug Administration (FDA).

There is no single accepted definition of immuno-oncology. However, this report includes many of the most recognized classes: adoptive cell therapies (including CAR-T therapy), bi-specific antibodies, cytokines, immune checkpoint modulators, oncolytic virus therapies, and vaccines.³

In addition to the new medicines in the pipeline, researchers are also working to understand the full potential of each individual medicine,

seeking approval for new indications for many existing immunotherapies, and also new uses in combination with other cancer medicines.

While we are at a time of remarkable change in cancer care, and new drug approvals over the past several years represent significant advances for many patients across many types of cancer, we are just beginning to understand the true power of immuno-oncology treatments to help patients. There is still a great need for new cancer treatments and potential cures, as cancers continue to present some of the greatest complexities for scientists.

ADVANCES IN CANCER IMMUNOTHERAPY

Today, there are some 248 immuno-oncology therapeutics in the clinical pipeline, with many more in preclinical development. Former President Jimmy Carter was a notable recipient to immunotherapy treatment in his battle to fight metastatic melanoma. Some examples of the most recognized and exciting classes of cancer immunotherapies include:

ADOPTIVE CELL THERAPY

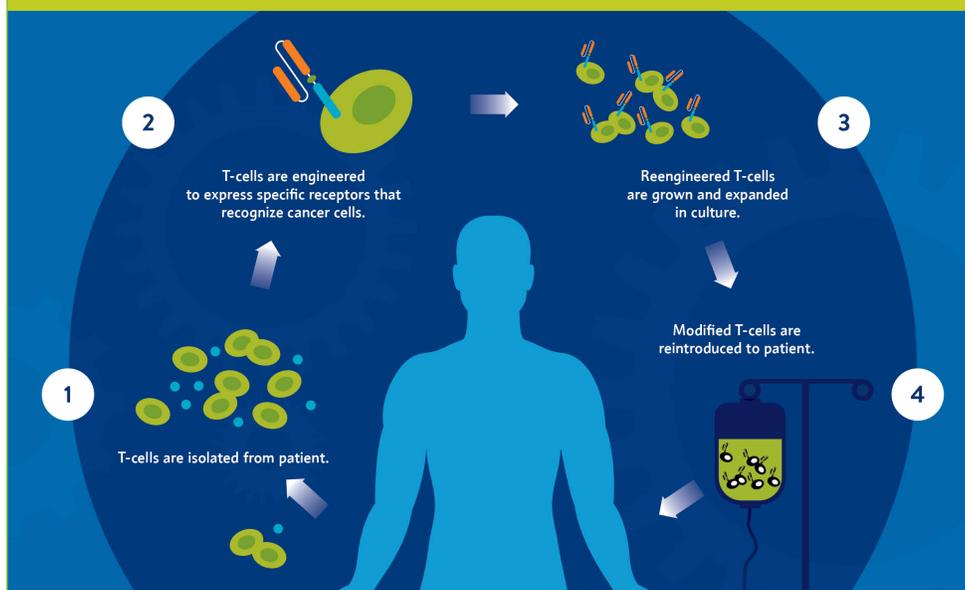
White blood cells, called T-cells, play a role in many cancer immunotherapy approaches. In healthy individuals, T-cells identify and kill infected or abnormal cells, including cancer cells. Two promising technologies in development that activate a patient's own T-cells to attack cancer cells are genetically modified chimeric antigen receptor T-cell therapy (CAR-T) and non-genetically modified T-cell receptors (TCR) therapy. Other types include tumor infiltrating -lymphocytes (TILs) and natural killer cells.

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CAR-T THERAPY DRIVING BREAKTHROUGHS FOR CANCER PATIENTS

Engineered immune T-cells can recognize, zero in on and kill cancer cells



“WE ARE IN THE MIDST OF A SEA CHANGE IN HOW WE ARE TREATING CANCER. WE’RE REALLY SEEING THE FRUITS OF MANY YEARS OF RESEARCH INTO WHAT DRIVES CANCER AND HOW IT INTERACTS WITH THE IMMUNE SYSTEM TO DEFEAT IT AND SURVIVE.”

— LOUIS WEINER, M.D., DIRECTOR OF THE GEORGETOWN LOMBARDI COMPREHENSIVE CANCER CENTER

CAR-T therapy permanently alters a patient's T-cells to multiply in the body into an army to fight the disease. To receive the treatment, a patient's blood is filtered to remove T-cells, which are then altered in the lab by inserting a gene that targets cancer. The T-cells are then returned to the patient intravenously, where they can then identify and target cancer cells. There are 21 CAR-T cell therapies in development currently.

IMMUNE CHECKPOINT MODULATORS

The body's immune system must include many checks and balances to protect the body from invading pathogens while preventing itself from inadvertently attacking normal cells in the body. The immune system uses "checkpoint" proteins in order to either activate or prevent an immune response. Years of research have revealed that some tumors have high levels of proteins that put the brakes on the immune system, preventing it from attacking cancer cells.

Since this discovery, researchers have worked to understand the role of these checkpoint proteins and to target them in order to "release the brakes" on the immune system. Current checkpoint modulators commonly target three proteins - CTLA-4, OX40 and PD-1/PD-L1.

Long-term data has revealed tremendous survival outcomes in advanced melanoma, with 40 percent of patients receiving a checkpoint modulator in a recent study alive three years after starting treatment.⁴ Before the arrival of the first immunotherapy in 2011, survival for these patients was measured in months.

There are 45 checkpoint modulators in development.

ONCOLYTIC VIRUS THERAPY

In 2015, FDA approved the first in an entirely new class of medicines called oncolytic virus therapies for the treatment of melanoma lesions that cannot be removed by surgery or have recurred after surgery. This first-of-its-kind treatment is a genetically modified virus that, when injected directly into a cancerous lesion, replicates inside cancer cells and causes them to rupture. There are 14 oncolytic cell therapies in development today.

VACCINES

Cancer vaccines are a form of cancer immunotherapy and are considered biological response modifiers. These modifiers work by either stimulating or restoring the immune system's ability to fight infection and disease. Cancer vaccines can be either preventive, which are intended to prevent cancer from developing in healthy people, or meant to treat cancer by strengthening the body's natural immune response against the cancer. Currently available preventive vaccines for cervical cancer helps protect against strains of the human papillomavirus (which is known to cause the disease), and one therapeutic vaccine (for prostate cancer) is approved in the United States. There are currently, 96 cancer vaccines in development.



THE AMERICAN CANCER SOCIETY CANCER ACTION NETWORK: **ADVOCATING FOR CANCER RESEARCH AND PROMOTING INNOVATION IN IMMUNOTHERAPY**

In the last several decades, we have made tremendous progress in the fight against cancer. The cancer death rate has declined 25 percent since its peak in 1991, and the five year survival rate has increased by 39 percent across all cancers. Despite this progress there is still much to be done and The American Cancer Society Cancer Action Network (ACS CAN) is committed to eliminating cancer as a major health problem. Ending cancer as we know it in this country is as much a matter of public policy as it is medical science and discovery.

One of ACS CAN's long-standing priorities is increasing federal funding of cancer research through the National Institutes of Health (NIH) and National Cancer Institute (NCI). Government-funded researchers initiate important basic science that forms the foundation for work by the biopharmaceutical industry to translate complex research into new and innovative medicines for patients. NCI's contribution to our understanding of the role the immune system in cancer includes research that has yielded discoveries in cytokines, cellular and innate immunity, viral immunology and immunotherapy. Specific NCI-funded research can directly be linked to current immunotherapies, such as the initial discovery of IL-2 receptor complex that led to FDA-approved IL-2 treatment for metastatic renal cancer and melanoma.

In 2016, then-president Barack Obama announced the creation of the Cancer Moonshot Initiative. Immunotherapy research was identified as a priority and a blue-ribbon panel of experts called for the creation of both adult and childhood immunotherapy clinical trial networks designed with the needs of cancer immunotherapy research in mind. As part of the Moonshot initiative, the American Cancer Society – the largest nongovernmental funder of cancer research in the United States – also committed to a goal of doubling its own research budget to help reach the national goal of accelerating progress.

Increases in federal research funding, like those advocated for by ACS CAN, enable continued growth in our understanding of cancer immunotherapy, and allows important investments in research infrastructure such as the Moonshot-recommended immunotherapy trial network. Those federal investments in basic research provide the necessary building blocks to fuel further privately-funded innovation.

The American Cancer Society Cancer Action Network (ACS CAN) is the nonpartisan advocacy affiliate of the American Cancer Society (ACS), supporting evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem.

Sources:

1. American Cancer Society
2. Number of medicines obtained through public, government and industry sources, and the Adis "R&D Insight" database; current as of May 26, 2017
3. Some broader definitions of immuno-oncology include all monoclonal antibodies. This report focuses specifically on two types of monoclonal antibodies (immune checkpoint modulators and bi-specific antibodies) because of their action in activating and enabling the immune system. However, all monoclonal antibodies in development for cancer are included in our online appendix. When all monoclonal antibodies are included in the count there are 443 immuno-oncology medicines in development
4. American Society of Clinical Oncology, "PD-1 Inhibitor Pembrolizumab Provides Long-term Survival Benefit for Patients with Advanced Melanoma: First report of 36-month Overall Survival Data from Patients in Early-Stage Study." May 30, 2016



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Biopharmaceutical
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