



Autoimmune and Inflammation

Our immune system serves as our body's defense against bacteria, viruses, and other potential illness causing agents. It is composed of a complex system of cells, organs, and tissues arranged in an elaborate network designed to optimize our body's response against invasion by the many pathogens we come in contact with every day. The immune system is able to detect invaders (such as bacteria) and then figure out how to go about destroying or disabling the threat. The body uses three basic strategies to protect itself from infections. It first creates and maintains a barrier designed to keep bacteria and viruses out of the body (skin, mucus). If a foreign invader manages to get in, the immune system kicks in and specialized cells detect and eliminate the pathogen. The body continues to fight the invader until it has been destroyed and eliminated from the body.

Inflammation is generally the body's first immune response to infection and irritation and is often referred to as the innate cascade. It is characterized by redness, heat, swelling, pain, and the dysfunction of those organs involved.

We would like to be able to think that our immune system could recognize our own body, with all the cells and tissues involved. Unfortunately, this is not always the case and sometimes our immune system attacks our own cells, causing a host of medical problems. After transplants, our immune response sometimes attacks the new tissues, threatening to cause the transplant to fail. On a much lighter scale, sometimes the smallest triggers such as pollen and dust can cause an active immune response, causing allergy symptoms to be an annoyance for millions of people.

Allergic Rhinitis (Hay Fever)

Allergic rhinitis is a collection of symptoms, such as runny nose and itchy eyes, caused by particles of dust, dander, or plant pollens in people who are allergic to these substances. When pollens are the cause of the reaction, the allergies are commonly referred to as “hay fever.” Hay fever is one of the most common seasonal allergies, varying from region to region due to the types and amounts of flora and fauna present. Allergies are caused by an overactive immune response to substances, known as allergens, which are generally harmless to most people. According to the American Academy of Allergy, Asthma, and Immunology, allergies affect as many as 50 million people in the United States, or more than 20 percent of the U.S. population.

	COMPANY	PRODUCT	PHASE
Allergy	Dynavax Technologies Corp.	Tolamba	III
	Impax Laboratories, Inc.	Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended Release Tablets	PA
	Impax Laboratories, Inc.	Alavert D-24 (loratadine/pseudoephedrine sulfate) Extended Release Tablets	A
	Impax Laboratories, Inc.	Alavert D-12 (loratadine/pseudoephedrine sulfate) Extended Release Tablets	M
	Dey L.P.	EpiPen (epinephrine)	M
	Impax Laboratories, Inc.	Loratadine Orally Disintegrating tablets	M

Crohn's Disease

Autoimmune disorders occur when the immune system attacks the body's own cells, in this case, those of the gastrointestinal tract. Also commonly known as inflammatory bowel disease (IBD), Crohn's Disease is a chronic autoimmune disease that results in inflammation of the intestinal walls, causing the walls to thicken and deep ulcers to form. Crohn's may also cause other bowel abnormalities as well as affect other organs, contributing to skin rashes, fistulas, liver inflammation, and arthritis, among others. Young adults, those with a family history of Crohn's, and people of Jewish ancestry are at the highest risk for developing the disease. The National Institutes of Health cite that about 7 out of every 100,000 people will develop the disease.

	COMPANY	PRODUCT	PHASE
Crohn's Disease	PDL BioPharma, Inc.	Nuvion (visilizumab) / SMART anti-CD3 antibody	II
	Berlex	Leukine (sargramostim)	III
	ChemoCentryx, Inc.	Traficet-EN	III
	Nektar Therapeutics	Cimzia (certolizumab pegol) / CDP 870	PA

Graft Versus Host Disease

Graft-versus-host-disease is an acute or chronic condition that can occur after a bone marrow transplant. Transplants are performed to treat and cure cancers that have invaded the bone marrow, as well as non-malignant conditions, such as sickle cell anemia. During the transplant, the patient's own marrow is destroyed with radiation or chemotherapy and is replaced with

donor marrow, usually genetically matched from a close family member. After the surgery, drugs are given to suppress the immune system to allow the donor marrow to implant without a serious immune response. Varied degrees of graft-versus-host disease are an expected complication of marrow transplantation because tissue typing can only find close, not identical matches. Symptoms include rash, diarrhea, liver damage, and hair loss.

COMPANY	PRODUCT	PHASE	
SuperGen, Inc.	Nipent for injection (pentostatin)	II	Graft versus Host Disease

Inflammation

The inflammation of tissue is the immune system’s first response after infection or irritation and is characterized by redness, heat, swelling, pain, and dysfunction of the organs involved. White blood cells, also known as leukocytes, move from blood vessels into the inflamed tissue and pick up bacteria and cellular diseases. They may also wall off an infection and prevent its spread. Blood vessels are also dilated or constricted to prevent spread of disease and to allow the tissue to heal, causing swelling and pain in the process. This generally may result in scarring or abscess. Many available treatments aid in the reduction of swelling and pain due to inflammation.

COMPANY	PRODUCT	PHASE	
Genentech, Inc.	Rituxan (rituximab)	III	Inflammation
Novartis AG	Encepur	M	Encephalitis
Impax Laboratories, Inc.	Hydrocortisone Tablets	M	Inflammation
BioMarin Pharmaceutical, Inc.	Orapred ODT	M	
Novartis AG	Tick-borne Encephalitis Vaccine	M	Encephalitis

Lupus

Lupus is a chronic, inflammatory autoimmune disorder that may affect the skin, joints, kidneys, and other organs. The immune system, which normally controls the body’s defenses against infection, is turned against the body’s own cells and tissues, leading to a chronic disease of the affected systems. The cause of the disease is not fully understood, but researchers believe it happens following an infection with an organism that looks similar to proteins in the body. The protein is mistakenly targeted instead of the organism. This disease can affect most organs and organ systems in the body, with most people developing arthritis, rashes, kidney problems and blood disorders. The disease affects nine times as many women as men. It may occur at any age, but appears most often in people between ages 10 and 50. People of Asian and African descent are often more susceptible to the disease. According to the Lupus Foundation of America, approximately 1.5 million Americans live with a form of lupus.

COMPANY	PRODUCT	PHASE	
Genentech, Inc.	Rituxan (rituximab)	III	Lupus
Genentech, Inc.	Rituxan (rituximab)	III	
Genelabs Technologies, Inc.	Prestara /Aslera (prasterone)	PA	

Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic disease that causes inflammation of joints and surrounding tissues, often affecting other organs. It is an autoimmune disease because the body attacks healthy tissues instead of foreign substances. The cause is unknown. The course and severity of the illness vary considerably, with infection, genes and hormones contributing to the gravity of the disease. RA commonly affects joints on both sides of the body equally, primarily the wrists, fingers, knees, feet and ankles. Symptoms include fatigue, stiffness, muscle aches, loss of appetite, weakness, and joint pain, with joint destruction occurring 1-2 years after the onset of the disease. RA can occur at any age but is more common in people between ages 25 and 55. Women are affected more often than men. The National Center for Chronic Disease Prevention and Health Promotion states that according to Census Data, in 2000, 2.1 million adults were affected by rheumatoid arthritis.

	COMPANY	PRODUCT	PHASE
Rheumatoid Arthritis	SuperGen, Inc.	Nipent (pentostatin for injection)	II
	Rigel Pharmaceuticals, Inc.	R406 / R788	II
	Johnson & Johnson	SCIO-469 (p38 kinase inhibitor)	II
	Nektar Therapeutics	Cimzia (certolizumab pegol) / CDP 870	III
	Genentech, Inc.	Rituxan (rituximab)	A
	Genentech, Inc.	Rituxan (rituximab)	M

Transplantation/Transplant Rejection

Organ and tissue transplants are major surgeries that endeavor to replace faulty or diseased organs with new, functioning organs, usually from family members or organ donors. Patients run the risk, however, of their body not accepting the new organ or tissue, causing an immune system response against the foreign body. This is commonly known as transplant rejection. Systems of rejection tend to include the improper functioning of the organ, general discomfort or illness, pain, swelling, and fever. Immunosuppressive drugs are needed to prevent organ rejection because organ and tissue transplantation almost always causes an immune response and could result in destruction of the foreign tissue.

	COMPANY	PRODUCT	PHASE
Transplantation	SuperGen, Inc.	Partaject Busulfan	II
	Novartis AG	Pulminiq (cyclosporine)	PA
	PDL BioPharma, Inc.	IV Busulfex injection (busulfan)	M
Transplant Rejection	XOMA Ltd.	Raptiva / Xanelim (efalizumab)	II
	Genentech, Inc.	Raptiva / Xanelim (efalizumab)	II
	PDL BioPharma, Inc.	Zenapax (daclizumab)	M

PDL BioPharma is a leader in the discovery, development and marketing of innovative therapies for serious or life-threatening illnesses, commercially focused on the acute care, hospital setting. Our therapeutic emphasis is on the areas of inflammation and autoimmune diseases, cardiovascular disorders and cancer.

Our roots are steeped in breakthrough antibody humanization technology — which enabled the development of some of the most innovative therapeutic advances of the past decade — including Synagis® for respiratory syncytial virus (RSV), Herceptin® for metastatic breast cancer, Avastin™ for metastatic colorectal cancer, Mylotarg® for acute myelogenous leukemia, and Xolair® for persistent asthma. In the nearly 20 years that we've been in business, we've established a strong financial foundation based on royalty revenues from licensing our technology to a variety of biotechnology and pharmaceutical partners.

In recent years, we've shifted from a royalty-driven enterprise into a commercial biopharmaceutical company. Through acquisitions and strategic partnerships, we've gained a commercial sales force and several marketed products. We've also expanded our development pipeline and focused our research capabilities, resulting in a strong pipeline of innovative therapies in Phase 2 or Phase 3 development and a strategy to continue fueling that pipeline through both internal discovery and collaboration.

Today, PDL BioPharma is leveraging its commercial presence in the acute care market, a rich pipeline, and expertise in antibody humanization to become a leading multinational biopharmaceutical company.





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