



Autoimmune & Inflammation

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

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.

Indication	Company	Product	Phase
Allergy	Dynavax Technologies Corp	Tolamba	III
	Impax Laboratories Inc	Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended Release Tablets	PA
	DEY LP	EpiPen (epinephrine)	M
	Impax Laboratories Inc	Loratadine Orally Disintegrating tablets	M
	Impax Laboratories Inc	Loratadine/Pseudoephedrine Sulfate 12-Hour Extended Release Tablets	M
	Impax Laboratories Inc	Loratadine/Pseudoephedrine Sulfate 24-Hour Extended Release Tablets	M

Carpal Tunnel Syndrome

Carpal tunnel syndrome occurs when the median nerve, which runs from the forearm into the hand, becomes pressed or squeezed at the wrist. The median nerve controls sensations to the palm side of the thumb and fingers (although not the little finger), as well as impulses to some small muscles in the hand that allow the fingers and thumb to move. The carpal tunnel - a narrow, rigid passageway of ligament and bones at the base of the hand ³/₄ houses the median nerve and tendons. Sometimes, thickening from irritated tendons or other swelling narrows the tunnel and causes the median nerve to be compressed. The result may be pain, weakness, or numbness in the hand and wrist, radiating up the arm.

Indication	Company	Product	Phase
Carpal Tunnel Syndrome	Teikoku Pharma USA Inc	Carpal tunnel tape	II

Crohn’s Disease

Crohn’s disease is a chronic inflammatory disease of the intestines. It primarily causes ulcerations (breaks in the lining) of the small and large intestines, but it can affect the digestive system anywhere from the mouth to the anus. Crohn’s Disease also contributes to Irritable Bowel Syndrome. 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.

Company	Product	Phase	Indication
ChemoCentryx Inc	Traficet-EN	II	Crohn Disease
PDL BioPharma Inc	Nuvion (visilizumab) / SMART anti-CD3 antibody	II	
Bayer HealthCare	Leukine (sargramostim)	III	
ChemoCentryx Inc	Traficet-EN	III	
Avicena Group Inc	PD-02	III	
Impax Laboratories Inc	Vadova (carbidopa, levodopa)	PA	
Impax Laboratories Inc	Carbidopa and Levodopa Extended Release Tablets	M	

Encephalitis

Encephalitis is an acute infection and inflammation of the brain itself. This is in contrast to meningitis, which is an inflammation of the layers covering the brain. Encephalitis is generally a viral illness. Viruses such as those responsible for causing cold sores, mumps, measles, and chicken pox can also cause encephalitis. The Arboviruses are spread by insects such as mosquitoes and ticks. The equine (meaning horse), West Nile, Japanese, La Crosse, and St. Louis encephalitis viruses are all mosquito-borne. Although viruses are the most common source of infection, bacteria, fungi, and parasites can also be responsible.

Company	Product	Phase	Indication
Novartis AG	Encepur	M	Encephalitis
Novartis AG	Tick-borne Encephalitis Vaccine	M	

Inflammation

Inflammation is a process by which the body's white blood cells and chemicals protect the body from infection by foreign substances, such as bacteria and viruses. In some diseases, however, the body's defense system, the immune system, triggers an inflammatory response when there are no foreign substances to fight off. In these diseases, called autoimmune diseases, the body's normally protective immune system causes damage to its own tissues. The body responds as if normal tissues are infected or somehow abnormal.

Company	Product	Phase	Indication
Genentech Inc	Rituxan (rituximab)	III	Inflammation
BioMarin Pharmaceutical Inc	Orapred ODT (prednisolone sodium phosphate)	M	
Impax Laboratories Inc	Hydrocortisone Tablets	M	
Next Pharmaceuticals Inc	Nexrutine	M	

Lupus

Lupus is a chronic, inflammatory autoimmune disorder which affects 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 known, but researchers believe it happens following an infection with an organism which 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 and may occur at any age, but appears most often in people between the ages of ten and 50 years.

Indication	Company	Product	Phase
Lupus	Genentech Inc	Rituxan (rituximab)	III
	Genelabs Technologies Inc	Prestara / Aslera (prasterone)	PA

Rheumatoid Arthritis

Rheumatoid arthritis 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 varies considerably, with infection, genes and hormones contributing to the gravity of the disease. RA commonly affects joints on both sides of the body equally, with the wrists, fingers, knees, feet and ankles of the patient primarily affected.

Indication	Company	Product	Phase
Rheumatoid Arthritis	Rigel Pharmaceuticals Inc	R406 / R788	II
	Genentech Inc	R1594 / PRO70769 (ocrelizumab)	III
	Genentech Inc	Rituxan (rituximab)	M



Founded in 2000, XDx is a molecular diagnostics company that focuses on the discovery, development and commercialization of noninvasive gene expression-based tests for the monitoring of transplant rejection and autoimmune diseases, also known as immune-mediated conditions. XDx targets immune-mediated conditions that require life-long monitoring to avoid or minimize serious complications. The first commercial offering

from XDx, AlloMap® molecular expression testing, is an objective, multi-gene molecular diagnostic test that measures the level of gene expression in a processed blood sample from a heart transplant patient. Performed at the XDx Laboratory in Brisbane, CA, results are reported as a numerical score which quantifies the probability that the heart transplant recipient is not experiencing acute cellular rejection (ACR).

AlloMap testing first became available in January 2005, and physicians in over 70 U.S. heart transplant medical centers have adopted it for monitoring their patients. Prior to the availability of AlloMap testing, physicians had to rely on endomyocardial biopsy (EMB) to detect ACR. EMB is invasive, uncomfortable for the patient, and time-consuming, and its results can be unreliable due to the build up of scar tissue, sampling error, or misreading. Although rare, patients may experience unpleasant complications from EMB such as infection, heart puncture, or valve damage. Because the AlloMap test is performed on a blood sample, potential side effects are minimal.

XDx is currently developing other gene expression-based tests, one which will monitor for acute cellular rejection in lung transplant recipients and another which will monitor for disease flares in patients affected by systemic lupus erythematosus. For more information, visit www.xdx.com.

Transplantation / Transplant Rejection

Organ and tissue transplants are risky surgeries which aim 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	Indication
XOMA Ltd	Neuprex (opebacan)	II	Allogeneic Hematopoietic Stem Cell Transplantation
PDL BioPharma Inc	Daclizumab	II	Solid Organ Transplant Maintenance
APT Pharmaceuticals Inc	Pulminiq (cyclosporine)	II	Transplant Rejection
Genentech Inc	Raptiva / Xanelim (efalizumab)	II	
XOMA Ltd	Raptiva / Xanelim (efalizumab)	II	
SuperGen Inc	Partaject Busulfan	II	Transplantation
XOMA Ltd	Neuprex (opebacan)	II	
Cerus Corporation	Intercept Blood System for Red Blood Cells	III	Inactivation of pathogens in Red Blood Cells for Transfusion
Portola Pharmaceuticals Inc	PRT054021 / Factor Xa Inhibitor	III	Prevention of Deep Vein Thrombosis and Pulmonary Embolism in Knee Replacement Surgery
Lux Biosciences Inc	LX201 (cyclosporine A)	M	Corneal Transplantation Rejection
PDL BioPharma Inc	Zenapax (daclizumab)	M	Transplant Rejection
PDL BioPharma Inc	IV Busulfex injection (busulfan)	M	Transplantation
XDx	Allo Map Molecular Expression Testing	M	Transplant Rejection