



Infectious Diseases

An infectious disease is a clinically evident disease resulting from the presence of pathogenic microbial agents, including viruses, bacteria, fungi, protozoa, multicellular parasites, and aberrant proteins known as prions. These pathogens are able to cause disease in animals and plants.

Infectious pathologies are usually qualified as contagious diseases (also called communicable diseases) due to their potentiality of transmission from one person or species to another. Transmission of an infectious disease may occur through one or more of diverse pathways including physical contact with infected individuals. These infecting agents may also be transmitted through liquids, food, body fluids, contaminated objects, airborne inhalation, or through vector-borne spread.

An infection however, is not synonymous with an infectious disease, as an infection may not cause important clinical symptoms or impair host function.

AIDS/HIV

Human immunodeficiency virus, or HIV, is the retrovirus that causes acquired immune deficiency syndrome (AIDS). The syndrome was first recognized in 1981. The virus weakens a person's ability to fight infections and cancer. People with HIV are said to have AIDS when they develop certain infections or cancers or when their CD4 count is less than 200. CD4 count is determined by a blood test in a doctor's office.

Having HIV does not always mean that an individual has AIDS. It can take many years for people with the virus to develop AIDS. Currently there is no cure for AIS/HIV. The first licensed agent for therapy was zidovudine in 1987. However, combination antiviral therapy (also called HAART or highly active antiretroviral therapy) has been shown to have saved over 3 million lives in the United States. Diagnosis with HIV and initialization of therapy per the US Department of Health and Human Services antiretroviral treatment guidelines has been associated with an average extension of life by approximately 30 years. An entire HIV regimen that was once complex, involving multiple agents (20 to 40 pills and capsules) taken at different times of the day is now as compact and simple as one pill, once a day. Twenty-five percent of individuals in the US with HIV do not know their status. There are over 40,000 new infections annually in the United States. The HIV positive but unaware individuals account for about 54 to 70 percent of the new infections. The Centers for Disease Control recognizes the significant benefits to an individual in terms of decreased morbidity and mortality when therapy is initiated earlier in disease, and the potential to reduce ongoing HIV transmission, now recommends that HIV testing be incorporated into routine health care for all individuals.

Indication	Company	Product	Phase
AIDS/HIV	Genentech Inc	TNX-355 (ibalizumab)	II
	Gilead Sciences Inc	GS 9137	II
	Gilead Sciences Inc	GS 9137 (elvitegravir)	II
	Gilead Sciences Inc	Tenofovir Topical Gel	II
	Presidio Pharmaceuticals Inc	MIV-310 (alovudine)	II
	Gilead Sciences Inc	Atripla (efavirenz, emtricitabine, tenofovir disoproxil)	M
	Gilead Sciences Inc	Atripla (Sustiva and Truvada)	M
	Gilead Sciences Inc	Emtriva (emtricitabine)	M
	Gilead Sciences Inc	Truvada (emtricitabine, tenofovir disoproxil fumarate)	M
	Gilead Sciences Inc	Viread (tenofovir disoproxil fumarate)	M
	Monogram Biosciences Inc	GeneSeq HIV	M
	Monogram Biosciences Inc	PhenoSense GT	M
	Monogram Biosciences Inc	PhenoSense HIV	M
	Monogram Biosciences Inc	PhenoSense HIV Entry	M
	Monogram Biosciences Inc	Trofile Assay	M
	Novartis AG	Macrolin	M

Cholera

Cholera is an acute infectious disease caused by the bacterium *Vibrio cholerae*, which lives and colonizes in the small intestine but does not destroy or invade the intestinal tissue. The major symptom of cholera is massive watery diarrhea that occurs because the bacteria's toxin stimulates the small intestine to secrete fluid. There are several strains of *V. cholerae* and the severity of the disease is based on the particular infectious strain. Cholera is not a difficult disease to treat and most people recover well with hydration. However, if the disease goes untreated, it can rapidly lead to shock, as a result of fluid and electrolyte loss, and to life-threatening complications.

Company	Product	Phase	Indication
Novartis AG	Cholera-Impfstoff Behring	M	Cholera

Cytomegalovirus Infection

Cytomegalovirus infection (CMV) is a viral infection that rarely causes obvious illness in patients with normal immune systems. The virus that causes CMV is part of the herpes virus family and, like other herpes viruses, may become dormant for a period of time and then be reactivated. Physicians recognize three clinical forms of CMV. These include: (1) CMV inclusion disease of the newborn, which ranges in severity from being without symptoms to being a severe disease affecting the liver, spleen and central nervous system, with possible developmental disabilities; (2) Acute acquired CMV infection, which is similar to infectious mononucleosis and characterized by fever, a feeling of being not quite right (malaise), skeletal-muscular pain and the absence of a sore throat; (3) CMV in immunocompromised persons (for instance, people who have had organ transplants or who have HIV) with increased risk for difficult eye infections (CMV retinitis), gastrointestinal CMV, and encephalitis. Therapy is available for both prevention and treatment of CMV.

Company	Product	Phase	Indication
Novartis AG	Vitravene (fomivirsen) / ISIS 2922	M	CMV Retinitis
Gilead Sciences Inc	Vistide (cidofovir injection)	M	Cytomegalovirus Infection

Diphtheria, Tetanus and Pertussis Vaccines

Diphtheria, tetanus, and pertussis (usually called "whooping cough") are all dangerous infectious diseases caused by bacteria (different bacteria are responsible for each infection).

The major symptoms of diphtheria include sore throat and swollen glands, as well as the characteristic grayish material that coats the back of the throat and may make breathing difficult. The bacteria produce toxins that damage the heart, brain, and nerves, ultimately leading to death if not treated. The bacteria responsible for tetanus also produce a toxin that affects the nerves. This can lead to muscle stiffness and spasms, especially in the face and neck muscles (which will cause "lock jaw," the condition most people associate with tetanus). Even with treatment, tetanus can be fatal.

Pertussis is better known as whooping cough. This is because the major symptom is violent coughs, followed by a “whoop” sound as the patient struggles to breathe in. The coughing spells can be so powerful that they result in broken ribs, vomiting, and broken blood vessels in the face. Whooping cough used to be the leading cause of childhood illness in the United States, and diphtheria used to be a leading cause of death in children. Tetanus was also alarmingly prevalent. Thankfully, all three diseases have become quite rare in the United States since immunization became routine.

Indication	Company	Product	Phase
Acellular Pertussis	Novartis AG	Acelluvax	M
	Novartis AG	Quatrovirelon	M
Diphtheria	Novartis AG	Dif-Tet-All	M
	Novartis AG	Quatrovirelon	M
	Novartis AG	Td-pur	M
	Novartis AG	Td-Virelon	M
Tetanus	Novartis AG	Clostet/tetanus Vaccine	M
	Novartis AG	Dif-Tet-All	M
	Novartis AG	Quatrovirelon	M
	Novartis AG	Td-pur	M
	Novartis AG	Td-Virelon	M
	Novartis AG	Tetanol	M

Epstein-Barr Virus Infection

Epstein-Barr Virus (EBV), more commonly known as Mono, is a double-stranded DNA virus in the herpes family of viruses. Infection with EBV is characterized by fatigue and general malaise. Infection with EBV is fairly common and is usually a transient and minor thing. However, in some individuals EBV can trigger chronic illness, including immune and lymphoproliferative syndromes. It is a particular danger to people with compromised immune systems, such as from AIDS. EBV was at one time believed to be the cause of the chronic fatigue syndrome, but chronic infection with this virus actually produces a separate (if similar) disorder.

Indication	Company	Product	Phase
Epstein-Barr Virus (EBV) Infection	AstraZeneca Plc	Epstein-Barr Virus Vaccine	II

Fungal Infections

Sometimes referred to as mycosis, fungal infections occur when fungi are able to pass the immune system barriers of the body and establish infections. This most often happens in individuals whose immune system functions are diminished due to other diseases or treatments. Some infections, however, occur in any individual who comes into contact with the infection-causing agent. Mycoses are usually classified according to the tissues that were initially colonized. Toenail fungus is an example of a common fungal infection.

Indication	Company	Product	Phase
Fungal Infections	Gilead Sciences Inc	Ambisome (amphotericin B)	M

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Hepatitis

Viral hepatitis is the inflammation of the liver caused by a virus. Hepatitis may start and resolve quickly (acute hepatitis), or cause long-term disease (chronic hepatitis). In some instances, progressive liver damage, liver failure, or even liver cancer may result. There are five identified types of viral hepatitis and each one is caused by a different virus. In the United States, hepatitis A, hepatitis B and hepatitis C are the most common types. Hepatitis A can be prevented with immunization. Hepatitis B immunization is now recommended for infants, children, health care workers, and at risk adults. Only Hepatitis B (CHB) and hepatitis C (CHC) cause ongoing chronic disease. There are 400 million individuals worldwide with CHB and 200 million with CHC. Seventy five percent of those with CHB are of Asian Pacific Islander origin. Approximately 25 to 40 percent of those with chronic disease will go on to develop end stage liver disease of hepatocellular carcinoma. There are close to 2 million in the US with CHB and 5 million with CHC. Chronic viral hepatitis accounts for the majority of liver transplants in this country. Therapy is available for both CHB and CHC. Broader screening would identify individuals earlier in the course of disease.

Company	Product	Phase	Indication
Dynavax Technologies Corp	Supervax	II	Hepatitis B
Antipodean Pharmaceuticals Inc	MitoQ (mitoquinone)	II	Hepatitis C
Intarcia Therapeutics Inc	Omega interferon	II	
SciClone Pharmaceuticals Inc	SCV-07	II	
Genelabs Technologies Inc	HEV vaccine	II	Hepatitis E
Dynavax Technologies Corp	Hepelisav	III	Hepatitis B
Gilead Sciences Inc	Emtricitabine	III	
SciClone Pharmaceuticals Inc	Zadaxin (thymalfasin)	III	Hepatitis C
Cepheid	Smart HBV Test	A	Hepatitis B
AcroMetrix	VeriSure	A	
Gilead Sciences Inc	Hepsera (adefovir dipivoxil)	M	
Monogram Biosciences Inc	GeneSeq HBV	M	
Novartis AG	Recombivax HB	M	
SciClone Pharmaceuticals Inc	Zadaxin (thymalfasin)	M	

Infection

An infection occurs when a foreign species colonizes itself in a host organism. The invader (or pathogen) uses the host’s body to multiply, which may interfere with the normal body function of the host. These pathogens can be bacteria, parasites, fungi, viruses, prions, or viroids. An infection can lead to chronic wounds, gangrene and even death. After the host body’s immune system determines that there has been an infection, an immune response kicks in and inflammation and superficial redness generally ensue. In some cases a parasitic relationship develops between the host and the parasite where the parasite benefits to the detriment of the host. There are cures for many infectious diseases; still many preventable infections cause death in developed and developing countries alike.

Indication	Company	Product	Phase
Infection	Oculus Innovative Sciences Inc	Dermacyn	II
Onychomycosis	Anacor Pharmaceuticals Inc	AN2690	II
Skin and Soft Tissue Infections	Theravance Inc	TD-1792	II
	Forest Laboratories Inc	Ceftaroline acetate	III
Bacterial Infections	Impax Laboratories Inc	Minocycline Hydrochloride	M
Complicated Skin and Skin Structure Infections	Theravance Inc	Telavancin / TD-6424	M
Infection	Impax Laboratories Inc	Demeclocycline Hydrochloride	M
	Novartis AG	DTP Vaccine	M
Infectious Diseases	Novartis AG	Quinvaxem Vaccine	M
Skin and Soft Tissue Infections	Novartis AG	Cubicin / Cidecin (daptomycin)	M
Throat Infection	Parnell Pharmaceuticals Inc	Oragesic	M
Skin and Soft Tissue Infections	Theravance Inc	Telavancin / TD-6424	PA
Methicillin-Resistant Staphylococcus Aureus	Cepheid	Xpert MRSA Test	A

Influenza

Influenza - commonly shortened to “the flu” - is an extremely contagious viral disease that appears most frequently in winter and early spring. The infection spreads through the upper respiratory tract and sometimes invades the lungs. Although both colds and influenza stem from viruses that infect the upper respiratory tract, the symptoms of influenza are more pronounced and its complications more severe.

Influenza occurs most commonly in school-age children, but it’s most severe effects are felt by infants, the elderly and people with chronic ailments. Despite advances in prevention and treatment, influenza and its complications are still fatal to about 36,000 people in the U.S. annually. Specific strains of the disease can be prevented by a flu vaccine, or taking one of several types of medications. Some of these medications may also reduce the severity and the duration of the illness if started within the first 48 hours of symptoms. One licensed oral agent is active against all strains of seasonal influenza A and B and the current avian strain (H5N1) and is being stockpiled world-wide by

countries and the WHO for use in pandemic influenza. Go to pandemicflu.gov and influenza-info.org for more information.

Company	Product	Phase	Indication
AstraZeneca Plc	CAIV-T (cold adapted intranasal influenza vaccine-trivalent)	A	Influenza
AstraZeneca Plc	FluMist	M	
Gilead Sciences Inc	Tamiflu (oseltamivir phosphate)	M	
Impax Laboratories Inc	Rimantadine Hydrochloride	M	
Novartis AG	Begrivac	M	
Novartis AG	Fluad	M	
Novartis AG	Fluvirin/flu Vaccine	M	
Novartis AG	PedvaxHIB	M	
Novartis AG	Vaxem-Hib	M	
Novartis AG	Agrippal-S1	M	
Novartis AG	Triacelluvax	M	
SciClone Pharmaceuticals Inc	Zadaxin (thymalfasin)	M	

Malaria

Malaria is an infection of the blood that is carried from person to person by mosquitoes. The disease has been recognized for thousands of years and once was found almost everywhere except in the most northern areas of the world. Malaria has been significantly reduced in North America, Western Europe, and Russia. It remains a serious problem in much of the tropical and subtropical world, however. Millions of people continue to be infected every year, and resulting in up to 1 million deaths.

Company	Product	Phase	Indication
Impax Laboratories Inc	Chloroquine Phosphate Tablets	M	Malaria

Measles

Measles is a highly contagious viral infection. It is also called rubeola or red measles. The disease is extremely rare in the United States because of widespread immunization programs. Measles is transmitted when an infected person coughs or sneezes. The virus is most often spread when people first become ill and before they know they have the disease. A person is contagious from approximately four days before the rash breaks out to four days after the rash appears.

Company	Product	Phase	Indication
Novartis AG	M-M Rvax	M	Measles
Novartis AG	Morbilvax	M	
Novartis AG	Morubel	M	

Meningococcal Infection

Meningococcal meningitis is caused by a specific bacterium known as *Neisseria meningitidis*. Meningitis is characterized by inflammation of the membranes around the brain or spinal cord. This inflammation can begin suddenly or develop gradually. Symptoms may include fever, headache, and a stiff neck, sometimes with aching muscles. Nausea, vomiting and other symptoms may also occur. Skin rashes occur in about half of all individuals with meningococcal meningitis.

Indication	Company	Product	Phase
Meningitis	SuperGen Inc	Partaject Busulfan	II
	Novartis AG	MenACWY vaccine	III
Meningococcal Infections	XOMA Ltd	Neuprex (opebecan)	III
Meningitis	Gilead Sciences Inc	Ambisome (amphotericin B)	M
Meningococcal Infections	Novartis AG	Menjugate	M
	Novartis AG	Menpovax A + C	M

Mumps

Mumps is a contagious viral infection that can cause painful swelling of the parotid glands, which are the salivary glands located between the ear and the jaw. Mumps can affect many body systems and cause flu-like symptoms, abdominal pain, swollen cheeks, and swollen and painful testicles. However, up to 20 percent of people who are infected with the mumps virus do not have any symptoms. Mumps is spread when an infected person coughs or sneezes, as well as through contact with recently contaminated items such as tissues, drinking glasses, and dirty hands.

Indication	Company	Product	Phase
Mumps	Novartis AG	M-M Rvax	M
	Novartis AG	Vaxipar	M

Pneumonia

Pneumonia is frequently but not always due to infection, causing one or both lungs to become inflamed. The infection may be bacterial, viral, fungal or parasitic. Symptoms may include fever, chills, cough, chest pain, and shortness of breath. Community-based pneumonia can be contracted in daily life, such as at school or work. Hospital-based pneumonia is contracted in a hospital or nursing home and is often more severe because the person is already ill.

Indication	Company	Product	Phase
Pneumonia	Nektar Therapeutics	NKTR-061 (inhaled amikacin)	II
Hospital-Acquired Pneumonia	Theravance Inc	Telavancin / TD-6424	III
Pneumonia	Forest Laboratories Inc	Ceftaroline acetate	III
	Theravance Inc	Telavancin / TD-6424	III
	Novartis AG	Pneumopur	M

Polio

Polio (poliomyelitis) is a viral illness that damages nerves that control muscles, resulting in muscle weakness. In severe illnesses, a person can lose the ability to move both arms and legs (paralysis) and may be unable to breathe without help. Symptoms of polio include: headache, sudden fever, sore throat, neck and back stiffness, muscle weakness and pain. Polio is now rare in developed countries because most children receive immunization against the virus.

Company	Product	Phase	Indication
Novartis AG	IPV-Virelon	M	Polio
Novartis AG	Polio vaccine	M	
Novartis AG	Polioral	M	
Novartis AG	Quatrovirelon	M	
Novartis AG	Td-Virelon	M	

Rabies

Rabies is a disease caused by a virus that can affect the central nervous system (brain and spinal cord) of any kind of mammal, including humans. Rabid animals can spread the disease through their saliva or brain matter. People who get rabies are almost always exposed from a bite from a rabid animal. Because of widespread animal vaccination programs, people in the United States rarely get rabies: it is more common in developing nations.

Company	Product	Phase	Indication
Novartis AG	RabAvert	M	Rabies

Rubella

Rubella, also called German measles or three-day measles, is a disease caused by the rubella virus. Rubella is generally a mild illness that does not result in long-term problems. The rubella virus is most often spread through droplets of fluid from the mucous membranes that contain the virus. An infected person can spread these droplets by coughing, sneezing, talking, or sharing food and drinks. One can become infected by touching a surface contaminated with the droplets and then touching the eyes, nose, or mouth.

Company	Product	Phase	Indication
Novartis AG	Gunevax	M	Rubella
Novartis AG	M-M-Rvax	M	
Novartis AG	Morubel	M	
Novartis AG	Rubellovac	M	

Tuberculosis

Tuberculosis (TB) is a bacterial infection caused by *Mycobacterium tuberculosis*, slow-growing bacteria that thrive in areas of the body that are rich in blood and oxygen, such as the lungs, but it can spread to other parts of the body. TB in the lungs is easily spread to other people through coughing or laughing. Treatment is often successful, though the process is long. Treatment times average between six and nine months.

Indication	Company	Product	Phase
Tuberculosis	SciClone Pharmaceuticals Inc	SCV-07	II

Typhoid

An acute illness with fever caused by infection with the *Salmonella typhi* bacteria, typhoid fever is contracted from contaminated water and food. The disease has an insidious onset characterized by fever, headache, constipation, malaise, chills, and muscle pain. Confusion, delirium, intestinal perforation, and death may occur in severe cases. Without therapy, the illness may last for three to four weeks and death rates range between 12 percent and 30 percent.

Indication	Company	Product	Phase
Typhoid	Novartis AG	Typhoral L	M

Urinary Tract Infections

An infection in the urinary system begins when microorganisms cling to the opening of the urethra (the canal from the bladder) and begin to multiply. A urinary tract infection is mostly due to one type of bacteria - *E. coli*. The infection can be prevented by drinking plenty of fluids and practicing good hygiene, especially after sexual intercourse.

Indication	Company	Product	Phase
Urinary Tract Infections	Osel Inc	Lactin-V	II
	Depomed Inc	Proquin XR (ciprofloxacin hydrochloride)	M
	Impax Laboratories Inc	Flavoxate Hydrochloride Tablets	M

Yellow Fever

An acute systemic illness caused by a virus called a Flavivirus, yellow fever in severe cases causes a high fever, bleeding into the skin, and necrosis (death) of cells in the kidney and liver. The damage done to the liver from the virus results in severe jaundice, which yellows the skin. In urban settings, yellow fever may be transmitted from person to person by the *Aedes aegypti* mosquito. In the jungle, yellow fever is transmitted from monkeys to people by mosquitoes that breed in tree-holes in the rainforests.

Indication	Company	Product	Phase
Yellow Fever	Novartis AG	Arilvax	PA

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