

Grifols Obtains Exclusive Rights to Distribute MassBiologics' Tetanus and Diphtheria Toxoids Adsorbed (Td) Vaccine in US

Grifols is the only company in the U.S. that offers two tetanus therapies, providing patients at risk for tetanus with both passive and active immunity

RESEARCH TRIANGLE PARK, N.C., U.S., December 17, 2015 /EINPresswire.com/ -- Grifols, a global leader in the production of plasma-derived medicines, has reached an agreement with MassBiologics (MBL) of the University of Massachusetts Medical

The Grifols logo is displayed in a large, bold, blue serif font, centered within a light gray rectangular box.

School that gives Grifols exclusive rights to market and distribute MBL's tetanus and diphtheria toxoids adsorbed (Td) vaccine in the United States with the exception of Massachusetts, where MBL will continue distributing the vaccine. Grifols is already distributing the Td vaccine.

With the addition of the Td vaccine, Grifols is the only company in the U.S. that offers two tetanus therapies, forming a complete solution for patients at risk for tetanus. For tetanus-prone wounds in persons with incomplete or unknown history of tetanus immunization, Grifols HyperTET® S/D (tetanus immune globulin [human]) is the sole product on the U.S. market that provides immediate, passive immunity against tetanus; the Td vaccine is a complementary therapy that yields longer-term, active immunity for tetanus. According to the Centers for Disease Control (CDC) and the Advisory Committee on Immunization Practices (ACIP), providing at-risk patients with passive and active immunity is standard medical practice for those in need of protection from tetanus.

"It's always exciting to expand our family of important therapeutics to help healthcare providers and patients," said Bill Zabel, President, North America Sales and Commercial Operations, Grifols. "We're particularly proud to strategically expand our Hypermunes portfolio with a vaccine that is the perfect complement to our plasma heritage."

MassBiologics' Td vaccine was licensed by the U.S. Food and Drug Administration (FDA) in 1970. The vaccine is indicated for active immunization for the prevention of tetanus and diphtheria and is approved for use in people seven years of age and older.

The U.S. Centers for Disease Control and Prevention (CDC) recommends that adults 19 years of age and older with an uncertain or incomplete history of receiving the primary vaccination series of three doses of Td vaccine should begin or complete the Td primary vaccination series, and that adults who have not had a Td booster shot in 10 years or more should be vaccinated. Adults 19 years of age and older should receive a booster dose of Td vaccine every 10 years. Tdap (tetanus, diphtheria, and acellular pertussis) vaccine should replace a single dose of Td for adults aged 19 years and older

who have not received a dose of Tdap previously, to additionally help protect them against pertussis disease.

“Most people have heard of the ‘tetanus’ shot and this vaccine has been a workhorse of modern medicine for more than 80 years,” said Dr. Steve Scholand, an infectious disease specialist at Midstate Medical Center in Meriden, CT. “Everyone should have protection against tetanus with a tetanus booster shot every 10 years, or more frequently if required.”

Tetanus and diphtheria can be serious diseases

Cases of tetanus and diphtheria have been drastically reduced in the U.S. since the introduction of vaccines, but people can still be at risk for these diseases. The bacteria that cause tetanus are found in soil and can enter the body through any cut or wound. Tetanus is not spread from person to person. Because tetanus bacteria are widespread in the environment, vaccination is an important way to protect against tetanus. Almost all cases of tetanus occur in people who have never been vaccinated or who have not had a tetanus booster shot within the preceding 10 years¹.

Tetanus, sometimes called "lockjaw," is a bacterial infection affecting the nervous system. It causes severe muscle spasms that can lead to, among other things, "locking" of the jaw so a person cannot open his/her mouth or swallow. Symptoms include stiffness in the neck, rigidity of abdominal muscles, difficulty with breathing and swallowing, and muscle spasms that can cause fractures of the spine and long bones. According to the CDC, approximately 1 out of 10 cases of tetanus are fatal².

Diphtheria is rare in the U.S. due to widespread use of diphtheria-containing vaccines; however, these bacteria are still a concern. Diphtheria continues to occur in other parts of the world. Diphtheria is caused by bacteria that can be passed from an infected person to others by coughing or sneezing. Early symptoms of diphtheria include sore throat, mild fever and chills. Usually the disease causes a thick coating at the back of the throat that makes it difficult to breathe or swallow. The most common complications are inflammation of the heart that can lead to abnormal heart rhythms and inflammation of the nerves which can cause temporary paralysis of some muscles. Diphtheria bacteria not only affect the throat, but can also infect other areas of the body, such as the nose, eyes, and skin.

Important safety information for Tetanus Diphtheria Toxoids Adsorbed (Td) Vaccine

MassBiologics' Tetanus and Diphtheria Toxoids Adsorbed (Td) is a vaccine indicated for active immunization for the prevention of tetanus and diphtheria. This vaccine is approved for use in persons 7 years of age and older.

A severe allergic reaction (eg, anaphylaxis) occurring after a previous dose of this vaccine, or any other tetanus or diphtheria toxoid-containing vaccine, or any component of this vaccine is a contraindication to administration. Because of the uncertainty as to which component of the vaccine might be responsible, no further vaccination with diphtheria or tetanus components should be carried out.

More frequent administration than described in the product insert may be associated with an increased incidence and severity of adverse reactions.

Persons who experienced an Arthus-type hypersensitivity reaction following a prior dose of a tetanus toxoid-containing vaccine usually have high serum tetanus antitoxin levels and should not receive Td more frequently than every 10 years, even for tetanus prophylaxis as part of wound management.

A review by the Institute of Medicine found evidence for a causal relation between tetanus toxoid and

Guillain-Barré Syndrome. If Guillain-Barré Syndrome occurred within 6 weeks after receipt of a previous dose of tetanus toxoid-containing vaccine, the decision to give subsequent doses of this Td vaccine or any vaccine containing tetanus toxoid should be based on careful consideration of the potential benefits and possible risks.

Vaccination with MassBiologics' Td may not protect all individuals.

Epinephrine injection (1:1000) and other appropriate agents and equipment must be immediately available should an acute anaphylactic reaction occur.

Prior to the administration of MassBiologics' Td, the vaccine recipient's current health status and health history should be reviewed. This includes a review of the immunization history of the patient, the presence of any contraindications to immunization, and any adverse events after previous immunizations to allow an assessment of the benefits and risks of vaccination.

If the MassBiologics' Td is administered to immunocompromised persons (whether from disease or treatment) the expected immune response may not be obtained.

Prior to administration of MassBiologics' Td, patients, parents, or guardians should be informed by the health care provider of the benefits and risks of immunization with Td and of the importance of completing the primary immunization series or receiving recommended booster doses.

The health care provider should inform the patient, parent, or guardian of the potential for adverse reactions that have been temporally associated with MassBiologics' Td or other vaccines containing similar ingredients. Patients, parents, or guardians should be instructed to report any suspected adverse reactions to their health care provider.

Patients who are on immunosuppressive therapy, including alkylating agents, antimetabolites, cytotoxic drugs, irradiation, or corticosteroids (used in greater than physiologic doses), may have a reduced immune response to vaccines.

No safety and immunogenicity data are available on the concomitant administration of MassBiologics' Td vaccine with other U.S. licensed vaccines.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine, and may not reflect the rates observed in practice. However, the adverse reaction information from clinical trials provides a basis for identifying adverse events that appear to be related to vaccine use and for approximating rates. Data on adverse reactions following fluid and adsorbed preparations of MassBiologics' Td with various doses of the diphtheria and tetanus components have been reported in a series of studies.

The following adverse events have been identified during post-approval use of MassBiologics' Td. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequencies or to establish a causal relationship to vaccination. The following adverse events were included because of seriousness or frequency of reporting:

- General Disorders and Administration Site Conditions: Injection site reactions, including pain, tenderness, erythema, induration, pruritis, swelling and warmth; peripheral oedema, pyrexia, malaise
- Nervous System Disorders: Dizziness, headache, convulsions
- Musculoskeletal and Connective Tissue Disorders: Myalgia, musculoskeletal stiffness or pain, arthralgia
- Skin and Subcutaneous Tissue Disorders: Rash

- Gastrointestinal Disorders: Nausea
- Infections and Infestations: Cellulitis

To report SUSPECTED ADVERSE REACTIONS, contact MassBiologics at 1-800-457-4626 or Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or www.vaers.hhs.gov.

Please click here for Tetanus and Diphtheria Toxoids Adsorbed (Td) full Prescribing Information for complete prescribing details.

Important safety information for HyperTET® S/D (tetanus immune globulin [human])

HyperTET® S/D (tetanus immune globulin [human]) is indicated for prophylaxis against tetanus following injury in patients whose immunization is incomplete or uncertain.

HyperTET S/D should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations.

In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, HyperTET S/D should be given only if the expected benefits outweigh the risks.

Slight soreness at the site of injection and slight temperature elevation may be noted at times. Sensitization to repeated injections of human immunoglobulin is extremely rare. In the course of routine injections of large numbers of persons with immunoglobulin, there have been a few isolated occurrences of angioneurotic edema, nephrotic syndrome, and anaphylactic shock after injection. Administration of live virus vaccines (eg, MMR) should be deferred for approximately 3 months after tetanus immune globulin (human) administration.

HyperTET S/D is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses and theoretically, the Creutzfeldt-Jakob disease (CJD) agent that can cause disease. There is also the possibility that unknown infectious agents may be present in such products.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <http://www.fda.gov/medwatch>, or call 1-800-FDA-1088.

Please click here for HyperTET S/D full Prescribing Information for complete prescribing details.

About Grifols, 75th Anniversary of improving people's health

Grifols is a global healthcare company founded in 1940. In 2015, Grifols celebrates its 75th Anniversary of improving people's health and well being through the development of plasma medicines, diagnostics systems, and hospital pharmacy products.

The company is present in more than 100 countries worldwide and is headquartered in Barcelona, Spain. Grifols is a leader in plasma collection with a network of more than 150 plasma donor centers in the U.S., and a leading producer of plasma-derived biological medicines. The company also provides a comprehensive range of transfusion medicine, hemostasis, and immunoassay solutions for clinical laboratories, blood banks and transfusion centers, and is a recognized leader in transfusion medicine.

In 2014, sales exceeded Euro 3.3 billion (\$4.4 billion) with a headcount close to 14,000 employees.

Grifols demonstrates its commitment to advancing healthcare by allocating a significant portion of its annual income to R&D.

The company's class A shares are listed on the Spanish Stock Exchange, where they are part of the Ibex-35 (MCE:GRF). Its non-voting class B shares are listed on the Mercado Continuo (MCE:GRF.P) and on the U.S. NASDAQ via ADRs (NASDAQ: GRFS). For more information, visit www.grifols.com.

About MassBiologics

MassBiologics is the only non-profit FDA-licensed manufacturer of vaccines and other biologic products in the United States and produces tetanus-diphtheria vaccine. MassBiologics traces its roots to 1894, and since then has maintained a mission to improve public health through applied research, development and production of biologic products. MassBiologics has been a part of the University of Massachusetts Medical School since 1997.

About the University of Massachusetts Medical School

The University of Massachusetts Medical School, one of the fastest growing academic health centers in the country, has built a reputation as a world-class research institution, consistently producing noteworthy advances in clinical and basic research. The Medical School attracts more than \$240 million in research funding annually, 80 percent of which comes from federal funding sources. The mission of the Medical School is to advance the health and well-being of the people of the commonwealth and the world through pioneering education, research, public service and health care delivery with its clinical partner, UMass Memorial Health Care. For more information, visit www.umassmed.edu.

References:

1. Epidemiology and Prevention of Vaccine-Preventable Diseases: The Pink Book: Course Textbook - 13th Edition (2015), Chapter 21
2. CDC Vaccine Information Statement, 2/24/15

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