Hyperimmune

FACT SHEET

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emergent biosolutions®

GENERAL

What is a hyperimmune therapeutic?

- They are immune globulin therapeutics with many different types of antibodies (polyclonal antibodies) that are manufactured from plasma, a component of blood, and leverage the immune response in humans or animals
- Each dose contains a set amount of antibodies specific to a target pathogen, such as a virus, bacteria, or toxin

How do they work?

- Through passive immunity, the antibodies in hyperimmunes provide short-term, immediate protection from infection
- The antibodies in hyperimmunes bind the target pathogen, like a lock and key; since they are polyclonal, the antibodies bind many different sites on the pathogen
- When administered, antibodies circulate throughout the body and bind the pathogen and help the immune system clear it, preventing infection of cells or damage to the body

Why are they used?

- Help to provide immediate protection to people, including vulnerable populations (infants & children, elderly, immuno-compromised, and pregnant)
- Demonstrated to help protect against a wide range of pathogens
- Can be generated rapidly in an outbreak scenario
- First therapeutic use of hyperimmunes began over 100 years ago; they have a long history of being determined to be safe and effective for several target indications.
- Compatible with certain vaccines & antivirals

DIFFERENT HYPERIMMUNE PLATFORMS: HUMAN AND EQUINE

Human Hyperimmune Platform

- Purified immune globulins (IgGs) are obtained from human plasma; contain many different antibodies that bind a specific antigen or multiple antigens
- Can be made of naturally occurring antibodies in the broad population, or of antibodies generated in people following infection or vaccination

- Compared to non-human antibodies, fully human antibodies are associated with a decreased risk of a patient generating a reaction (immune response) to the hyperimmune product itself
- Certain human hyperimmunes may be used prior to exposure to a pathogen, or after potential exposure, to prevent infection; they may also be used as a therapeutic treatment in infected patients
- Other examples of human hyperimmune products include hepatitis B, anthrax, and cytomegalovirus immune globulin
- Common side effects may include headache, nausea, abdominal or back pain, malaise, myalgia, fever, chills, and fatigue

Equine Hyperimmune Platform

- Purified IgG fragments are obtained from equine (horse) plasma and contain many different antibodies that bind a specific antigen
- Horses are immunized with antigens to generate a strong antibody response to the target pathogen
- Examples of equine hyperimmunes include diphtheria and botulism anti-toxin treatments, rabies, snake anti-venoms, etc.
- Common side effects may include headache, hives or rash, itching, nausea, fever and chills; hypersensitivity or allergic reactions may occur

HYPERIMMUNE PRODUCTS AND CONVALESCENT PLASMA

Convalescent Plasma

Convalescent plasma is a source of antibodies with potential therapeutic benefit:

- It has been utilized as a disease therapy and as a starting material for the manufacture of hyperimmune products
- Convalescent plasma isolated from one patient and transfused directly into another patient offers benefits of time to availability, but often contains varying levels of target antibodies

Hyperimmunes

The potential benefits associated with hyperimmunes include:

- Higher purity and increased viral inactivation/removal and testing
- Smaller dose volume to transfer similar, or higher, amounts of antibody as in one dose of convalescent plasma. This is due to the concentrating of antibodies during the hyperimmune manufacturing process
- Increased product consistency, including standardization of potency due to a more rigorous assessment

HYPERIMMUNE PRODUCTS AND VACCINES

Vaccines

- Vaccines are used for longer-term protection; they stimulate a person's immune system to generate antibodies to a pathogen, which may take a few weeks to months, depending on the vaccine, to reach the desired protective level

Hyperimmunes

- Hyperimmunes provide shorter-term passive immunity (days to months depending on the product and disease), offering immediate protection after administration; protection does not last after the therapeutic is cleared by the body
- Hyperimmunes have been used safely with certain vaccines (hepatitis B, rabies), and have been used to provide immediate protection while individuals develop their own immune response

HYPERIMMUNE PRODUCTS AND MONOCLONAL ANTIBODIES

Polyclonal and Monoclonal Differences

Hyperimmunes are polyclonal and made up of many different antibodies, while a monoclonal antibody is one single type of antibody

- Polyclonal antibodies bind to different sites on a pathogen, which can help prevent the pathogen from changing to "escape" the antibodies
- A monoclonal antibody binds to one specific site on a pathogen and can target a certain aspect of the pathogen (for example, making a toxin inactive or preventing the pathogen from entering a cell), but it may also allow the pathogen to "escape" the antibody by changing this one particular binding site

Similar to a hyperimmune, a monoclonal antibody can be isolated from humans, or generated in animals, but they are often genetically altered and/or made recombinantly in cell lines, to be able to produce at a commercial scale