



# The Broad-Spectrum Treatment of Biological Weapons And Emerging Pandemic Threats

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## **Summary**

Biological weapons of mass destruction and emerging pandemic threats represent a significant security and health challenge for all nations. The development and commercialization of traditional drug and vaccine countermeasures is an immense challenge requiring enormous resources. The advancement of single-target drug and vaccine therapies as the predominant strategy to address a universe of known and unknown bioterror and pandemic threats is clinically and economically unfeasible. Accordingly, the Department of Health and Human Services (HHS) of the United States has decreed that broad-spectrum therapies, able to demonstrate effectiveness in combating multiple pathogens, will become a focal point for government initiatives that encourage the development of countermeasures against bioterror and pandemic threats. This paper introduces the Aethlon Hemopurifier® as the most advanced broad-spectrum treatment platform as evidenced by a breadth of supporting *in vitro* data and human treatment experience.

## **The Hemopurifier®**

The Hemopurifier® is a therapeutic filtration device designed to act as an artificial adjunct to the immune system. The device provides a post-exposure treatment strategy to mitigate illness, suffering, and death resulting from exposure to viral pathogens,

including biological weapon or emerging pandemic threats. The Hemopurifier® delivers both an antiviral and immunotherapeutic benefit through the real-time clearance of circulating viruses and immunosuppressive proteins. The device is positioned to augment the benefit of candidate therapies procured into the strategic national stockpile (SNS) and can serve as a first-line countermeasure against drug and vaccine resistant viral threats. The Hemopurifier® also diminishes the risk of treatment resistance and addresses challenges in treating naturally occurring or genetically engineered pathogens. Thus, filling voids in the armamentarium necessary to protect against existing, evolving, and future threats.

In addition to demonstrations of safety in human studies, the Hemopurifier® has proven effective in rapidly capturing a broad-spectrum of viral threats, including some of world's deadliest known pathogens. These include: Dengue hemorrhagic fever (DHF), Ebola hemorrhagic fever (EHF), Lassa hemorrhagic fever (LHF), H5N1 avian influenza (Bird Flu), the reconstructed 1918 influenza virus (r1918), Hepatitis-C (HCV), Human Immunodeficiency Virus (HIV), West Nile virus (WNV), and Vaccinia and Monkeypox (MPV), which both serve as models for human smallpox infection.

### **Research Collaborators**

Supportive research studies demonstrating the *in vitro* effectiveness of the Hemopurifier® have been conducted with the assistance of collaborating researchers representing the following government and non-government health organizations.

**The U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)** – USAMRIID, located at Fort Detrick, Maryland, serves as the lead laboratory for the U.S. Medical Biological Defense Research Program, and plays a key role in national defense and in infectious disease research. USAMRIID operates the only laboratory in the Department of Defense (DOD) equipped to study Ebola and other highly hazardous infectious agents requiring maximum containment at bio-safety level four (BSL-4).

**The Centers for Disease Control and Prevention (CDC)** – The CDC serves as the national focus for developing and applying disease prevention and control for the people of the United States.

**The National Institute of Virology (NIV)** – The NIV is a leading infectious disease research center in India, and is designated as a collaborating laboratory of the World Health Organization (WHO). It was established in 1952 under the auspices of the Indian Council of Medical Research (ICMR) and the Rockefeller Foundation in the United States. The ICMR was established by the Government of India in 1911 and oversees medical research in the country.

**The Battelle Biomedical Research Center (BBRC)** – The BBRC is one of the largest, private, biomedical laboratories in the country. The BBRC operates as a subsidiary of Battelle, a global leader in science and technology, who manages and co-manages national labs, and oversees 20,000 staff members and conducts \$3.4 billion in annual research and development.

**The Southwest Foundation for Biomedical Research (SFBR)** – The SFBR is one of the world's leading independent research organizations. It is home to the only privately owned bio-safety level-4 (BSL-4) laboratory in the United States. This maximum containment lab allows for research on lethal pathogens for which there are no treatments or vaccines, including bioterror and emerging pandemic threats.

### **The Hemopurifier® Mechanism of Action**

The Hemopurifier® is a proprietary platform technology that provides a novel approach to address the treatment of drug and vaccine resistant viral pathogens. The primary component of the technology is a cartridge containing lectin-derived affinity agents that are covalently coupled to a solid phase matrix immobilized within the spaces between approximately 2800 porous hollow fibers that run the length of the cartridge. The technology separates viruses and immunosuppressive proteins from circulation, which are

then selectively captured by affinity attachment to glycoprotein structures both resident on and shed from the surface of infectious envelope virus species. Once blood flow is accessed in the patient, therapeutic filtration of the entire circulatory system can occur through the device every 12-15 minutes.

### **Implementation of the Hemopurifier®**

The Hemopurifier® is designed for widespread implementation as a post-exposure treatment against viral pathogens deemed high priority category A, B, and C bioterror and pandemic threats. To initiate treatment with the Hemopurifier®, blood circulation is established into the filtration device via a catheter or other blood access device. Once blood flow has been established and directed through the Hemopurifier®, infectious viruses and immunosuppressive proteins are selectively cleared from circulation prior to the occurrence of cell and organ infection. The Hemopurifier® incorporates the use of industry standard connectors and blood tubing, thus allowing the continuous circulation of patient blood to be maintained with portable blood pumps or apheresis and dialysis machines. Such flexibility allows for the Hemopurifier® to deliver therapeutic benefit in field locations, mobile military hospitals, quarantine treatment centers, and within the established network of dialysis machines already located in civilian and military hospitals and clinics.

### **Human Treatment Experience**

The Hemopurifier® is an advanced stage therapeutic candidate. Multi-site human safety studies of the Hemopurifier® have been conducted at the Apollo and Fortis Hospitals, both located in Delhi, India. To date, device safety has been observed in 43 human treatment experiences. The studies also provided the opportunity to observe robust viral load reductions in Hepatitis-C (HCV) infected patients who were enrolled and tested in the studies. Further studies of HCV and HIV infected patients are expected to begin in India this month. Aethlon has submitted an Investigational Device Exemption (IDE) to the U.S. Food and Drug Administration (FDA) requesting permission to initiate a 10-patient human safety study in the United States. The goal of this clinical program is to

validate the Hemopurifier® as a safe and innovative strategy to improve public health emergency preparedness against bioterror and pandemic threats.

### **The Broad-Spectrum Application of the Hemopurifier®**

Most pathogens considered to be material bioterror or pandemic threats remain untreatable with traditional drug and vaccine therapies. Effective treatments are either non-existent, of limited usefulness, or vulnerable to both naturally emerging and intentionally engineered pathogens. Highly pathogenic viral threats often remain unknown and do not become characterized until after the occurrence of widespread host-to-host infections in humans. The Hemopurifier® offers the potential to improve public health emergency preparedness against **Traditional**, **Enhanced**, **Emerging**, and **Advanced Agents**, which represent the entire biological and pandemic threat spectrum.

I. **Traditional Agents** – Traditional agents are known naturally occurring viral pathogens classified as high-consequence threats with potential to cause mass casualties upon dissemination. Examples include Ebola and Smallpox viruses.

*The Hemopurifier® serves as an adjunct therapy to augment the benefit of approved or available therapies for traditional agents.*

*The Hemopurifier® serves as first-line countermeasure against drug and vaccine resistant traditional agents.*

II. **Enhanced Agents** – Enhanced agents are traditional agents that have been genetically modified to enhance their ability to harm human populations or circumvent traditional drug and vaccine therapies.

*The Hemopurifier® is a first-line countermeasure against enhanced agents created to be drug and vaccine resistant.*

*The Hemopurifier® serves as a combination therapy to strengthen the benefit of candidate therapies proven safe but unable to previously demonstrate treatment effectiveness against unknown enhanced agents.*

☑ *The Hemopurifier® assists in the initial identification of enhanced agents through the concentration and capture of genetically modified viral pathogens from the entire circulatory system.*

III. **Emerging Agents** – Emerging agents are previously unrecognized pathogens that might be naturally occurring and present a serious risk to human population, such as Severe Acute Respiratory Syndrome (SARS) or future strains of pandemic influenza. Tools to detect and treat these threats may be limited or not exist.

☑ *The Hemopurifier® is a first-line countermeasure against emerging agents.*

☑ *The Hemopurifier® serves as a combination therapy to strengthen the benefit of candidate therapies proven safe but unable to previously demonstrate treatment effectiveness against unknown emerging agents.*

☑ *The Hemopurifier® assists in the initial identification of emerging agents through the concentration and capture of unidentified viral pathogens from the entire circulatory system.*

IV. **Advanced Agents** – Advanced agents are novel pathogens that have been artificially engineered in the laboratory to bypass traditional countermeasures or produce a more severe or otherwise enhanced spectrum of disease.

☑ *The Hemopurifier® is a first-line countermeasure against advanced agents.*

☑ *The Hemopurifier® assists in the initial identification of advanced agents through the concentration and capture of artificially engineered pathogens from the entire circulatory system.*

In addition to broad-spectrum attributes against bioterror and pandemic threat agents, the Hemopurifier® may address the needs of immunocompromised and at-risk populations, including children, pregnant women, and senior citizens for whom the administration of traditional bioterror and pandemic threat drugs or vaccines may be medically contraindicated.

## **Conclusion**

By acting as an artificial adjunct to the immune system, the Hemopurifier® holds promise to be an integral post-exposure treatment strategy to mitigate illness, suffering, and death resulting from exposure to biological weapon and emerging pandemic threats. The device has been demonstrated safe in initial human studies and proven effective in capturing many of the worlds deadliest pathogen during *in vitro* studies performed at leading government and non-government research centers. In conclusion, the unprecedented broad-spectrum capabilities of the Hemopurifier® offer to beneficially impact the state of preparedness for the United States and ally nations.

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