

Exploring Opportunities in Niche Therapies – Human Cytomegalovirus (HCMV) Infections

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Abstracts

The spectrum of diseases caused by Human Cytomegalovirus (HCMV) is diverse. Most CMV infections are “silent,” where the infected people exhibit no signs or symptoms posing no serious problems, but this infection can become a cause of morbidity /mortality in immunocompromised patients and new-borns where the immunity barrier is low. Two major areas where prevention or better treatment of CMV infection is urgently required worldwide is in Transplant (organ, bone marrow) and Congenital CMV infection. In the US alone approximately 5,000 U.S. infants develop permanent problems due to CMV, some of them severe, including deafness, blindness, and mental retardation. CMV is among the most common infections following solid-organ transplantation and hematopoietic stem cell transplant procedures, causing disease, transplant complications. Drugs with new MOA and vaccines need to be developed soon to meet the unmet needs for CMV infections. Approximately 70,000 allogeneic HCT procedures are performed annually worldwide. Currently there is no marketed CMV vaccine for these patients. In this report we discuss the recently approved therapies for CMV infections, other drugs and vaccines in the pipeline and the challenges associated with the development and commercialization

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2. DISEASE OVERVIEW

- a. Biology- Human CMV (HCMV)
 - Congenital and Neonatal HCMV Infection
 - HIV
 - Solid Organ Transplant (SOT)
 - Hematopoietic Stem Cell Transplantation (HSCT)
- b. Diagnosis
 - Laboratory Tests
 - Imaging
- c. Epidemiology

3. UNMET NEED

- a. Congenital CMV Infection – No Prophylactic Vaccine yet!
- b. Why is this Opportunity not on the “Wish List” of Major Pharma Companies?

4. MARKET OPPORTUNITY

5. TREATMENT PARADIGM FOR HCMV INFECTIONS IN TRANSPLANT AND NEWBORN

- a. Antiviral Therapies
 - Ganciclovir (9-[(1,3-dihydroxy-2-propoxy)methyl]guanine)
 - Valganciclovir (Valcyte)
 - Foscarnet/Foscavir
 - Cidofovir/Vistide
 - Letermovir/PREVMIS
 - HCMV-Specific Hyperimmune Globulin
- b. Clinical Pipeline – Small Molecules
 - Maribavir – Phase III – Shire/Viropharm
 - Intravenous brincidofovir (IV BCV, Ph1)- Chimerix
 - ATA230- Atara Therapeutics- Phase I/II
 - ANPs- Therapeutic Systems Research Laboratorie Inc (Pre-Lead)
- c. Clinical Pipeline – Vaccines

Triplex and PepVex
CyMVectin (PC / Phase I)
HB-101: Phase II

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