Monoclonal Antibodies for the Treatment and Prophylaxis of Infectious Diseases: Development Opportunities for Novel Antibacterial and Antiviral Biologics

The past two decades have seen the arrival of revolutionary new biologic therapies for the treatment of numerous diseases, including inflammatory, hematologic, and malignant conditions. The majority of innovative biologics medicines have been monoclonal antibodies (MAbs), which continue to be developed for the treatment and prophylaxis of a growing variety of diseases. Despite these tremendous advances and outstanding potential, only two MAb products in the infectious disease arena, AstraZeneca/Medimmune’s Synagis, which has established itself as the standard for the prevention of respiratory syncytial virus (RSV) infections in high-risk infants, and GlaxoSmithKline’s Abthrax for the treatment and prevention of inhalation Anthrax, have reached the market. Nonetheless, MAbs hold the promise of prevention and/or treatment of a host of bacterial and viral infections, thanks to the potential for less frequent dosing, improved safety, synergistic activity with small molecule therapies, and lower selective pressure leading to the emergence of resistance. This report explores the opportunities and challenges in the quest to develop MAbs for the treatment and prevention of infectious diseases, including bacterial infections due to Clostridium difficile, Pseudomonas aeruginosa, and Staphylococcus aureus, as well as viral infections due to RSV and influenza, among other pathogens. The study evaluates the current pipeline and developers’ strategies for clinical development of MAbs in infectious diseases and makes actionable recommendations on the path forward for bringing to market new MAb therapies and prophylactic agents in this therapeutic space.

Questions Answered in This Report:

- Small-molecule antibacterials and antivirals, as well as vaccines, have dominated the infectious diseases treatment and prophylaxis markets, respectively. What are the potential advantages of MAbs over small-molecule therapies—both overall and in key infectious disease indications? What is the current pipeline for MAbs addressing infectious diseases? Why have more MAb products for infectious diseases not reached the market?

- Pharmaceutical companies have been developing MAbs for infectious diseases for decades, yet only two products have reached the market. What strategies have manufacturers employed to develop MAb-based therapies for the prevention and/or treatment of infections? What development hurdles have they encountered?
• Strong safety and efficacy performance alone will not be sufficient to generate a value proposition for MAb products targeting infections. What is the potential for commercializing novel MAb therapies in infectious diseases? How are the pricing and reimbursement landscapes likely to influence the market opportunities for novel MAb therapies?

Scope:

Market covered: Global.

Indication coverage: Treatment and/or prophylaxis of infections due to: *Bacillus anthracis*, *Clostridium botulinum*, *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), *Pseudomonas aeruginosa*, *Escherichia coli* (STEC), respiratory syncytial virus (RSV), human immunodeficiency virus (HIV), hepatitis C virus (HCV), rabies, influenza, Ebola.

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