

Executive Summary

In recent years, interest in the prophylactic infectious disease vaccine market has grown significantly. While this is a large, established, and (for some segments) mature market, many changes are occurring in other segments of the market. Companies are expanding this market by developing novel vaccines to protect against diseases for which vaccines have not been available. Also, the success of Wyeth's Prevnar (a pneumococcal vaccine) has demonstrated that it is possible for a vaccine to become a blockbuster product. In addition, new technologies (such as DNA vaccines and viral vector vaccines) have been developed and are being applied to the development of new vaccines.

In addition to the traditional prophylactic vaccines, the field of therapeutic vaccines and immunotherapies is rapidly emerging as a promising area. Use of passive immunotherapy products (antibody products, either polyclonal or, more recently, usually monoclonal) is widespread. These passive immunotherapies can be used for prevention of infection following exposure or for treatment of a number of different diseases, including cancer. In addition, some nonspecific immunomodulators on the market (interferon, interleukin-2 [IL-2], and Bacillus Calmette-Guérin [BCG]) are used to treat certain cancers, and pegylated interferon combined with ribavirin is the current standard of care for treatment of chronic hepatitis C infection.

There is considerable interest in the field of cancer immunotherapies and vaccines for the novel, active specific immunotherapies and therapeutic vaccines that are being developed. No active specific immunotherapy products have yet reached the market in the United States, but we may be getting close, and one product (Antigenics' [New York, NY] Oncophage) was recently approved in Russia. Progress is also being made in the development of therapeutic vaccines and immunotherapies for treatment of chronic infectious diseases.

For many decades, it has been suggested that the immune system should also be able to recognize cancer cells as abnormal, and to destroy these cells. However, cancer cells have developed mechanisms that allow them to escape the surveillance of the immune system. If it were possible to stimulate the immune system to specifically attack cancer cells, it might be possible to develop an effective and relatively nontoxic approach for treatment of cancer. Similarly, with chronic infections such as human immunodeficiency virus (HIV) and chronic hepatitis C virus (HCV) infections, the virus is somehow able to avoid elimination by the immune system. Again, there is interest in being able to stimulate the immune system so that it can more effectively fight and clear the infection. Chapter 1 provides a brief overview of the immune system, and the potential for using this system.

Chapter 2 reviews 12 major cancers that are being targeted by companies developing cancer immunotherapies or vaccines: brain cancer, breast cancer, cervical cancer, colorectal cancer, leukemia, lung cancer, lymphoma, melanoma, ovarian cancer, pancreatic cancer, prostate cancer, and renal cancer. For each major type of cancer, information is provided on its pathology and epidemiology. This is followed by a discussion of over 20 infectious diseases.

Chapter 3 focuses primarily on pharmacological therapies for treatment of the major cancers being targeted by companies that are developing cancer immunotherapies and vaccines. In general, a large number of drugs are available today for treatment of the 12 cancers being highlighted in this report. However, as demonstrated by the survival rates discussed in Chapter 2 (and especially the poor survival rates for advanced or metastatic cancers), there is a clear need for more effective treatments for these cancers. This cancer discussion is followed by a discussion of currently available immunotherapies and vaccines, including passive immunotherapies, therapies used today for treatment of chronic infections, and currently available infectious disease vaccines. Chapter 3 concludes with a discussion of the medical needs, and the R&D challenges, for this field.

A large number of smaller biopharmaceutical companies, and a more limited number of major pharmaceutical companies, are developing immunotherapies or vaccines for treatment of cancer. These companies are developing a wide range of different approaches that can be used to try to overcome a cancer's ability to evade surveillance of the immune

system, and to stimulate the immune system to respond to and kill a patient's tumor cells. Chapter 4 discusses strategies that are being used by companies developing cancer immunotherapies and vaccines, and also the different types of infectious disease vaccines.

Chapter 5 discusses the many different product candidates that are in development for the 12 cancers targeted in this report. In addition, the concluding section of Chapter 5 includes brief information on numerous vaccines and immunotherapies in development for other cancers. Chapter 6 focuses on infectious disease, discussing novel prophylactic vaccines that are in development for prevention of a wide range of different diseases. Chapter 6 also includes a discussion of therapeutic vaccines and immunotherapies being developed for treatment of chronic infections.

Chapter 7 discusses a number of business considerations and trends in the field of infectious disease and cancer immunotherapies and vaccines. Finally, Chapter 8 includes interviews with nine experts in this area, who discuss the progress, and the challenges and hurdles, faced by researchers and companies working in this emerging field.

