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Human Papillomavirus Infections Vaccine Pipeline Analysis

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Abstracts

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Currently there is significant amount of research being undertaken to study the process of HPV infection causing precancerous changes in normal cells. Also, methods to prevent and manage this situation are also being analyzed. A majority of these studies were previously focusing on cervical cells in women. But in recent years, the realm of research has been extended to other tissues also in which HPV may cause cancer, such as the oropharynx and anus. Also, many organizations are analyzing the use of second-generation preventive vaccines along with therapeutic HPV vaccines, which could possibly prevent the development of cancer among women previously infected with HPV. Such an “ideal” vaccine strategy would combine a preventive and therapeutic vaccine, which would help in a major way.

The mechanism of the HPV vaccines is similar to the other immunizations which help in protecting against viral infections. It has been observed and analyzed that the unique surface components of HPV have the capability to create an antibody response which could possibly protect the human body against infection. These components could thus be used as a basis of the vaccine. There are only 2 HPV vaccines which are currently marketed across the globe. Both these vaccines are prepared using the recombinant technology, which is taken from purified L1 structural proteins which self assemble to form HPV type-specific empty shells or virus-like particles (VLPs).

Since there are no therapeutic HPV vaccines available at present which have proved their efficiency in the clinical trials, there is still a lot of work which is required in this field, thus opening a large window of opportunities. There have been some technological advancements in the past 4-5 years. The future is also likely to continue to

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witness similar technological and medical success in terms of new drugs and efficient vaccines, with the help of adequate funding. Certain developments like a new treatment to reduce transmissibility in drug users and new efforts to strengthen the immune system have the potential to develop further and provide better healthcare services to the patients in the future. Thus, there needs to be more focus being given to increasing the knowledge and awareness about HPV infections and the ways and methods to treat it, either through drugs or through vaccines.

“Human Papillomavirus Infections Vaccine Pipeline Analysis” Report Highlights:

Human Papillomavirus Vaccine Market Overview

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Drug Class

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About

A group of more than 150 viruses which are related to each other are collectively known as Human papillomaviruses (HPVs). This group is referred to as papillomaviruses mainly because certain types of viruses could cause warts, or papillomas, which are generally benign or noncancerous growths. There are some types of HPV which are associated with certain types of cancer and are called "high-risk," oncogenic, or carcinogenic HPVs.

Amongst the 150 types of HPV, 40 or more types could be transmitted from one person to another through sexual contact. Close to xx million new HPV infection cases occur in the United States every year. The HPV infection is observed to be a major risk factorand a cause for cervical cancer. It has also been observed that while almost all women tend to develop an HPV infection at some point, very few women out of them become victims of cervical cancer. In most common cases, the immune system generally tends to suppress or eliminate HPVs.

Other diseases cause by the HPV infection include some specific cancers of the oropharynx, vulva, vagina, and penis, head and neck cancers, anogenital warts and recurrent respiratory papillomatosis.

The mechanism of the HPV vaccines is similar to the other immunizations which help in protecting against viral infections. It has been observed and analyzed that the unique surface components of HPV have the capability to create an antibody response which could possibly protect the human body against infection. These components could thus be used as a basis of the vaccine.

There are only 2 HPV vaccines which are currently marketed across the globe. Both these vaccines are prepared using the recombinant technology, which is taken from purified L1 structural proteins which self assemble to form HPV type-specific empty shells or virus-like particles (VLPs).

The HPV vaccines have been designed only for prophylactic use. Hence, they are uncapable of clearing existing HPV infection or treat HPV-related disease. Though the mechanisms by which these vaccines induce protection have not been fully defined, it has been observed that both these involve cellular immunity and neutralizing immunoglobulin G antibodies.

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There are close to xx million people in the USA who have been diagnosed with HPV infection currently. Annually about xx million people are being newly infected. Globally, close to half a million women tend to be diagnosed with cervical cancer annually, and more than a quarter of a million tend to die due to it.

Though anal cancer is uncommon, it has been estimated that more than 5,000 people, both men and women, were diagnosed with this disease in the USA. Other health problems related to HPV include genital warts, due to which close to 360,000 people were affected and cervica cancer, which affected more than 10,000 women in the USA.

The global prophylactic human papillomavirus (HPV) vaccine market value was worth approximately USD xx billion in 2012. The pharma industry has come to recognize both the role of HPV in other non-cervical cancers and the benefits of herd immunity. This trend has led to a more significant level of interests on vaccinating both males and females. There has been a shift from a sole focus on cervical cancer in women to other diseases in men also, which has led to an increasing popularity and demand for HPV vaccines. These factors are expected to push the industry at a CAGR of xx% to reach close to USD xx billion by 2022.

In the global pie, there are xx major markets including the US, Canada, France, Germany, Italy, Spain, the UK, Japan and Australia. The sales of HPV vaccine in Canada and Australia alone are likely to record a growth rate of close to xx% in the next 6-8 years horizon. This significant growth rate is expected to be driven mainly by the launch of Merck's V503 vaccine coupled with the inclusion of males in routine HPV vaccine recommendations.

It is expected that V503, launched by Merck has the potential to generate significant revenues in the future, with its sales forecast to reach close to USD 1.5 billion in the US alone by 2022. This would account for a significant 95% market share.

There has been stiff competition between pharma giants GlaxoSmithKline (GSK) and Merck in the HPV vaccination market, mainly because the countries choose their sides in their programs for cervical cancer vaccination. These companies are continuously striving to increase their market share and have a strong presence.

There are 2 vaccines called Gardsil and Cervarix have been approved till now by the US Food and Drug Administration (FDA) in order to prevent HPV infection. Both these vaccines are considered to be highly effective in preventing infections with HPV

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types 16 and 18. These are the 2 high-risk HPVs which tend to cause about 70 percent of cervical and anal cancers. Gardasil has also been used to prevent infection with HPV types 6 and 11, which are known to cause 90% of genital warts. The Gardasil vaccine is produced by Merck & Co., Inc. It is also called a quadrivalent vaccine as it protects against four HPV types: 6, 11, 16, and 18.

GlaxoSmithKline (GSK) is the manufacturer of the Cervarix vaccine. This vaccine is also called as a bivalent vaccine because it targets two HPV types: 16 and 18. This vaccine has been approved by the US FDA to be used in women in the age group of 9 to 25 in three doses over a 6-month period. Inspite of Cervarix being approved in Europe in 2007 itself, it was given approval in the US only in 2009. This situation provided a monopoly status to competiting brand Gardsil in the US during this period. The approval of use of Gradsil has now been extended to prevent genital warts and anal cancer caused due to human papillomavirus infection. This extension of approval has provided additional strength to the drug against competing products.

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