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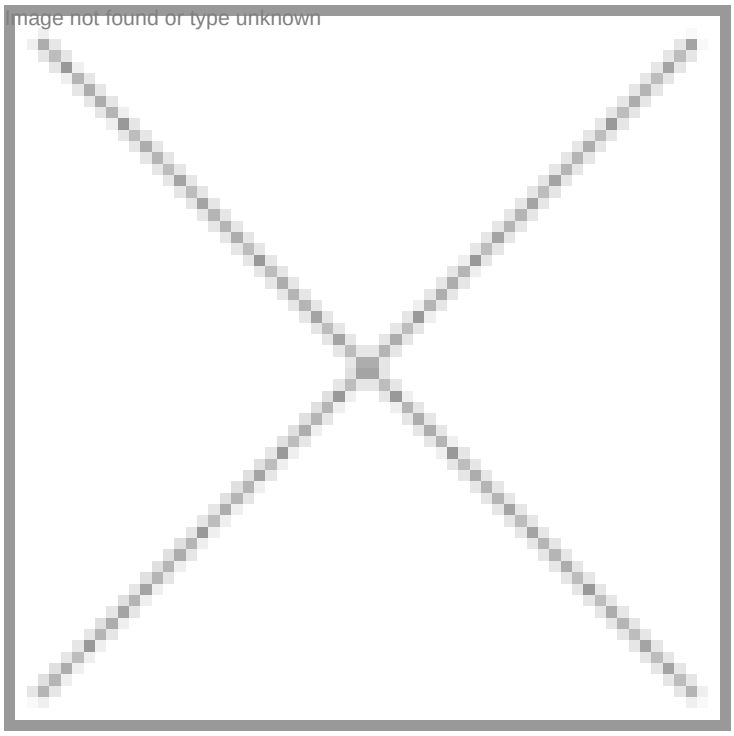

Gardasil to prevent cervical cancer

Within 10 days of its launch 10,000 doses of Gardasil were sold. In 2007, the world's first cancer vaccine is expected to contribute $40â€“$50 million in royalties from Merck, to whom CSL has licensed the technology. Many more such vaccines are on the way. Close on the heels is GSK's Cervarix, which is in the final stages of trials.

World's first cervical cancer vaccine Merck's Gardasil has been approved as the first and only vaccine in the European Union for use in children and adolescents. Earlier, this year in June, the vaccine had received approval from US Food and Drug Administration as well. Gardasil can eliminate most new cases of cervical cancer worldwide. It blocks four strains of human papilloma virus (HPV), including two that give rise to nearly 75 percent of cervical cancer cases and two other strains that cause about 50 percent of genital warts.

Set to become a blockbuster cancer therapeutic, Gardasil according to Australian analysts, will be one of the first Australian pharmaceutical successes.

The technology for the world's first cervical cancer vaccine, result of 20 years of arduous research by Brisbane-based Professor Ian Frazer, was licensed by Australia's biotech major CSL to Merck and Co. Inc., which then led basic and clinical research programs leading to development of Gardasil.

CSL markets Gardasil in New Zealand and Australia while Merck has marketing rights for the rest of the world. Within 10 days of Gardasil's launch, CSL had sold approximately 10,000 doses. Merck sales are also expected to soar in the fiscal 2007. In its recent financial statement, CSL stated that Gardasil is expected to contribute $40â€“ 50 million in royalties from Merck, the licensee, in 2007. According to estimates Merck's earnings per share will rise to $2.43 from $2.39 with an estimated $1 billion in US Gardasil sales, which are projected to reach $1.7 billion in 2010.

However, Merck's Gardasil will soon face severe competition from GlaxoSmithKline's Cervarix, which is expected to hit market soon. Cervarix is another cervical cancer vaccine being tested for the prevention of Human Papillomavirus (HPV), and is in the final stage of clinical trials.

Analysts predict that Merck's Gardasil will have global sales of $492 million by 2010, while GSK's Cervarix, expected to enter market in 2007, will have global sales of $345 million by 2010. There will be a head-on-head competition between Merck and GSK in treating this cervical cancer, which kills about 2,90,000 women worldwide each year.

Merck has also taken full financial and administrative responsibility for Stimuvax, Canada-based Biomira's lead cancer vaccine. All future development, regulatory, commercialization and marketing costs for Stimuvax will be borne exclusively by Merck KGaA. Biomira will be responsible for commercialization and marketing costs related to Canada. Merck, currently, is looking at opportunities to get this product to market as quickly as possible.

But Merck and GSK are not the only ones trying to capitalize on the cancer opportunity. Seattle-based Dendreon Corporation hopes to market its investigational immunotherapy for the treatment of advanced prostate cancer, Provenge, commercially in 2007. Dendreon is spending approximately $100 million per year for clinical trials of the vaccine. When it hits the market, it is sure to be a runaway hit for the company, doubling its investment capital. Analysts estimate it has a potential of $500 million in sales on its launch.

Worldwide cancer vaccine revenues are estimated to reach approximately $6 billion by 2010. With over 75 companies actively pursuing research in cancer vaccines, it is estimated that over the next six years, by the end of 2011, 105 cancer vaccines would reach commercialization. It is also estimated that there are 18 vaccines being actively developed in Phase III. Just to name a few, Therion's Panvac-VF is entering a Phase III study for refractory pancreatic cancer and Prostvac-VF is in Phase II study for metastatic, androgen-independent prostate cancer. Therion is also working closely with the National Cancer Institute, Aventis Pasteur, and a network of leading clinical institutions to develop treatments for other major cancer indications.

American biotechnology company, Antigenics also plans to launch its lead product candidate Oncophage (vitespen), a personalized cancer vaccine in Phase III trials and has been granted fast track and orphan drug designations by the US Food and Drug Administration for kidney cancer and melanoma.

Melanoma has high development interest among vaccine developers, with 30 vaccines manufactured by various biopharmaceutical firms in various stages from preclinical to Phase III. Other targets for the vaccine developers include lung, prostate, breast and colorectal cancers, which have 23, 22, 21 and 20 vaccines in the development stage, respectively.

According to the World Health Organization, more than 11 million people are diagnosed with cancer every year. It is estimated that there will be 16 million new cases every year by 2020. Cancer causes seven million deaths every year that is 12.5 percent of deaths worldwide.

Cancer vaccines, in addition to offering a novel treatment option also have high market potential in terms of revenues. The traditional view on vaccines as a low-growth, low-price business has changed. The cancer vaccine pipeline is growing everyday, with focus on tackling organ specific tumors. However, the wait for a possible 'universal' cancer vaccine, for an immune response against cancer cells that originate from just-about-any-tissue, continues.

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