

US FDA Approves Merck's Gardasil®

Media Statement

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US FDA APPROVES MERCK'S GARDASIL®* THE WORLD'S FIRST AND ONLY CERVICAL CANCER VACCINE

CSL Limited today announced that its licensee, Merck & Co., Inc., has received approval from the U.S. Food and Drug Administration (FDA) of its cervical cancer vaccine GARDASIL® for vaccination of girls and women between the ages 9 and 26.

CSL's Managing Director, Dr Brian McNamee said, "It is anticipated that with FDA approval now achieved, GARDASIL will save the lives of many women. This landmark medical breakthrough for Australian science is the culmination of 15 years involvement by CSL in the development of the product beginning with a research collaboration with Professor Ian Frazer and the University of Queensland."

GARDASIL is a quadrivalent human papillomavirus recombinant vaccine designed to prevent the majority of HPV-related clinical diseases caused by HPV 6, 11, 16 and 18. HPV types 16 and 18 account for approximately 70 percent of cervical cancer cases. HPV 6 and 11 cause approximately 90 percent of genital wart cases. In the United States, approximately 10,000 women are diagnosed with cervical cancer every year and on average 10 women die each day from the disease.

Applications to approve GARDASIL are currently under review with regulatory agencies on five continents, including Australia.

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