She’s practically bouncing out of her chair as she speaks. Dr. Diane Harper is ecstatic about the fact that a vaccine she’s been testing against human papillomavirus (HPV), which can cause cervical cancer, works. It works so well, in fact, that the Food and Drug Administration (FDA) has stepped up the approval process to get the vaccine on the market by 2006—instead of waiting until 2010, when Phase III clinical trials will be completed.

Two pharmaceutical companies, Merck and GlaxoSmithKline, have already begun manufacturing cervical cancer vaccines. Merck’s is Gardasil and Glaxo’s is Cervarix. "There has never been such a big development in women’s health in the past 50 years," says Harper. "It’s incredible!"

Types: The vaccine has the potential to greatly reduce deaths from cervical cancer, one of the leading causes of cancer death among women worldwide. It’s targeted to immunize against two different types of high-risk human papillomavirus (HPV-16 and HPV-18), which cause about 70% of cervical cancer cases, and against two viral subtypes that cause 90% of anogenital warts. HPV is transmitted by skin-to-skin contact, most often through sexual activity.

Although most cases of HPV resolve themselves through natural immunity, some progress to
cancer. About 500,000 cases of cervical cancer are diagnosed worldwide each year, and an estimated 280,000 women die from it, mostly in developing countries. In the U.S., about 20 million people are carriers of HPV, which causes more than 10,000 cases of cervical cancer and nearly 4,000 deaths a year.

Harper, an associate professor of community and family medicine, has spent 20 years researching cervical cancer. “The first discovery that HPV was even related to cervical cancer was published in 1975,” she notes. In 2004, Harper was optimistic that a cervical cancer vaccine would be available by 2010, based on the results of successful clinical trials, including one that she led between 2000 and 2003, with 1,113 women, ages 15 to 25 (see the Winter 2004 Dartmouth Medicine for the results of that trial, published in the British journal the Lancet).

Trials: But the results of three Phase III clinical trials, one of which she’s directing, have been so promising that the FDA decided to accelerate the approval process. “The very first of that data was reported and showed that the vaccine was a hundred percent effective and completely safe,” says Harper. “There were no adverse effects other than having pain in your arm from getting the shot. And that is based on a trial of 20,000 women.” Other large trials, with thousands of women all over the world, have shown results that are just as promising.

Teens: Harper anticipates that the vaccine, which is administered in a series of three shots over several months, could be ready as early as the summer. Ideally, it would be given to girls aged 10 to 13 years, before they become sexually active. HPV infection typically occurs in the late teens and early twenties. “So when you take your daughters in for their school physicals next summer, they should be asking for the vaccine at the same time,” she says.

Harper is one of the physician-researchers on Merck’s and Glaxo’s scientific advisory panels, which are responsible for the independence of the studies. She is not paid by either company but helps to design the studies, review and analyze the data, and publish the papers.

Harper shared another piece of exciting news: “The Lancet called me,” she confides in hushed tones. “They woke me up and said, ‘We want to publish your next results.’ We’re really excited about it.”

Laura Stephenson Carter