

Glaxo Cancer Vaccine Disappoints

By HESTER PLUMRIDGE

LONDON—In the latest of a string of drug-development setbacks, **GlaxoSmithKline** PLC on Tuesday stopped a late-stage trial of its cancer vaccine after disappointing results.

The U.K. drug company had said last month that its immunotherapy treatment didn't boost survival rates among patients with non-small-cell lung cancer, a prevalent form of the disease.

Immunotherapies are a new form of cancer treatment that use the body's own immune system to attack the cancer, rather than using traditional chemotherapies or radiotherapies.

Glaxo continued with the trial despite the poor results in the hope of finding a subset of patients who might benefit from the treatment, MAGE-A3. The company now says this will be impossible, because the vaccine didn't have a big enough impact on patients.

Another late-stage study of MAGE-A3 last year failed to extend survival in patients with melanoma. Glaxo is still hoping to identify a subset of melanoma patients in which the vaccine might work. Results are expected next year.

Despite the low probability many analysts ascribed to MAGE-A3 being successful in lung cancer, the sales opportunity was sizable given the number of patients with the disease. Melanoma is a much less common form of cancer, meaning the sales opportunity is smaller.

The failure of its cancer vaccine is a blow to Glaxo, which has missed out on a new wave of immunotherapy drugs with early evidence of efficacy that has buoyed the share prices of rivals **Roche Holding AG**, **Bristol-Myers Squibb Co.** and **Merck & Co.**

Glaxo has been struggling to offset falling sales from established drugs that are losing patent protection. Sales of its best seller, the asthma drug Advair, are being eroded by cheaper alternatives in the U.S. and Europe.

Last year Glaxo managed to secure five new drug approvals in the U.S., but investors are waiting to see if sales of new asthma and respiratory disease drugs Breo and Anoro can offset falling revenue from Advair.

Glaxo has had other disappointments. In November, it reported its heart-disease drug in development, darapladib—once one of its brightest hopes—had failed to show any meaningful effect on patients. In late

March, it withdrew a regulatory application in Europe for use of its ovarian-cancer treatment Votrient in a new group of patients with the disease.

Glaxo has also faced manufacturing and product-recall problems recently. U.S. regulators issued a warning letter to the company in March after an inspection of a Glaxo plant in Ireland found contamination of drug ingredients used in the antidepressants Paxil and Seroxat. The drug had been contaminated with material from the plant's waste tank, the letter said.

Glaxo said it is assessing the concerns and is considering a recall from wholesalers of certain batches of the drug, although it said a medical assessment concluded there was no risk of harm to patients.

Also last month, Glaxo issued a voluntary recall of all supplies of its weight-loss pill Alli in the U.S. after concerns the bottles were tampered with. Consumers in seven states reported bottles of Alli that contained capsules and tablets that didn't look like the drug or that were missing labels or seals.

Alli is a nonprescription drug that blocks the stomach from absorbing some fat from food. Analysts expected it to be a blockbuster when it was launched in 2007, but sales have disappointed.

