

Pfizer Statement on Washington Post Clinical Trial Series

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NEW YORK, Dec. 17 /PRNewswire/ -- Pfizer said today that it strongly disagrees with The Washington Post series of articles about clinical trials conducted by pharmaceutical companies in the developing world.

The company said it particularly objected to the Post's mischaracterization of the company's 1996 clinical trial of its antibiotic trovafloxacin in Nigeria, West Africa.

Epidemic meningococcal meningitis does not occur in the U.S. but does occur in impoverished areas, such as regions of West Africa. In this regard, Nigeria was an appropriate location for this clinical trial.

Pfizer strongly believes that the trovafloxacin trial in Nigeria played an important role in investigating a potential breakthrough oral therapy for this terrible epidemic. The company emphasized that other therapies require injections, which present serious public health problems, such as the spread of hepatitis or HIV, due to inadvertent needle-stick injuries.

Pfizer stated that it has fully cooperated with The Post in providing requested materials. The company provided extensive responses to several inquiries from The Post over the past two months, provided positions on Pfizer clinical work in Europe, Central and South America, and Nigeria, and ensured that The Post had access to physicians who led the Nigeria trial.

From The Post's initial inquiry, it was clear to Pfizer that The Post reporting team had already formed a viewpoint about clinical trials in the developing world and the trovafloxacin trial. Because Pfizer believes this view distorted the company's position, Pfizer is posting its correspondence with The Washington Post on the Pfizer website: <http://www.pfizer.com> [<http://www.pfizer.com>].

The Nigerian trovafloxacin trial was an important clinical investigation and Pfizer is proud of the way the trial was conducted, in the midst of a deadly meningococcal meningitis epidemic among Nigerian children.

The trial was part of a broad series of studies of Trovan for the treatment of many serious infections. Trial results showed that Trovan benefited the majority of the children participating in the study. In that trial, patients who received trovafloxacin did as well as patients who received the comparator drug, ceftriaxone, considered to be the gold standard treatment for epidemic meningococcal meningitis. Fatality rates in the study -- for both trovafloxacin and the control drug ceftriaxone -- were lower than recently published results from advanced Western medical centers, and lower than the existing fatality rate for this epidemic.

Pfizer has been active in advancing health care throughout Africa. It is donating millions of dollars of Zithromax for the treatment of trachoma in five African countries. In South Africa, the company has launched a partnership program with the South African Health Ministry to make Diflucan available at no charge for the treatment of cryptococcal meningitis and esophageal candidiasis in AIDS patients. As Pfizer told The Post, the company would have likely made Trovan available free-of-charge for use during the cyclical epidemics in developing nations, in a manner similar to the Diflucan and Zithromax programs.

Pfizer currently supports and participates in an important global initiative, underway by all sectors of the biomedical community, to globalize clinical trials and raise worldwide health standards. This effort, the company said, is critical to 1) help regulators, drug developers, physicians, and health care professionals gain a clearer understanding of how new medicines work in people of diverse medical and cultural backgrounds; 2) expand development of medicines to treat diseases that are only found in countries outside the U.S.; and 3) include full participation of the medical community around the world in the development of innovative medicines.

Pfizer believes that globalization of clinical trials is key to establishing a worldwide standard of excellence in clinical trials and expanding access of novel medicines to patients around the world.

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