

Press Release

27 October 1999 **Glaxo Wellcome voluntarily withdraws Raxar (Grepafloxacin)**

Glaxo Wellcome plc announces that it is voluntarily withdrawing its oral fluoroquinolone antibiotic, Raxar (grepafloxacin), with immediate effect, as a result of emerging safety concerns. In coming to this decision the company has recognised the need to strike a balance between the therapeutic benefits of the medicine, the potential risk of side effects, and the availability of alternative treatments.

An estimated 2.65 million patient treatments have been prescribed since Raxar was first marketed in August 1997. In line with the company's practice, Glaxo Wellcome has monitored the safety profile of Raxar since launch, and has observed a small number of severe cardiovascular events among patients. While the reported incidence of such cardiovascular events is infrequent, the company is no longer convinced that the benefits of Raxar outweigh the potential risk to patients, given the availability of alternative antibiotics.

Glaxo Wellcome has discussed the safety profile of Raxar with the appropriate regulatory authorities and cardiovascular medical specialists. The decision to withdraw the medicine has been taken on the recommendation of Glaxo Wellcome's senior medical review group, and the company is in the process of informing doctors and pharmacists of the decision in countries where Raxar is marketed.

Raxar is indicated for the treatment of a variety of infections including pneumonia, bronchitis, and some sexually transmitted infections. Glaxo Wellcome licensed Raxar from Otsuka in 1996, and currently markets the medicine in tablet form in over 30 countries, primarily in Europe, North America and Latin America. A co-marketing agreement exists between the two companies in Spain. The medicine is marketed as Raxar or Vaxar.

Glaxo Wellcome is a research-based company whose people are committed to fighting disease by bringing innovative medicines and services to patients throughout the world and to the healthcare providers who serve them.

For further information health professionals may call 1-888-825-5249 (added by MedWatch, FDA)