

New rotavirus vaccine could be licensed this year

Henry Nicholls, BMN News



A new generation of rotavirus vaccines could receive approval from the Mexican authorities this year, says a spokesperson

for GlaxoSmithKline (GSK; <http://www.gsk.com>). This could be the beginning of a global effort to tackle a virus that kills around half a million children a year.

Protozoan parasites

Rotaviruses are common protozoan parasites that cause potentially fatal diarrhoeal illness in children.

'Something like 450,000 to 800,000 [children] die from this disease every year, primarily in the developing world,' said Roger Glass of the Centers for Disease Control in Atlanta, Georgia (<http://www.cdc.gov>). '1 in 250 [children] or so will die from this disease,' he said. 'This is a big problem.'

Both GSK and Merck (<http://www.merck.com>) have vaccines against rotavirus that are well into Phase III trials. But GSK has already filed an application to the Mexican authorities for its Rotarix® vaccine, and expects to hear whether it has been successful 'later on this year', says Beatrice De Vos, worldwide clinical project director for Rotarix.

GSK's Rotarix and Merck's ROTATEQ are not the first rotavirus vaccines to

reach the market. RotaShield, manufactured by Philadelphia-based Wyeth-Ayerst Laboratories (<http://www.wyeth-pharmaceutical.com>), was approved by the US Food and Drugs Administration (FDA) in 1998. But a year later, it was withdrawn because of a significant risk of intussusception, a potentially lethal condition where one part of the bowel telescopes into another.

A similar fate?

There is no evidence, however, that the GSK and Merck vaccines will suffer the same fate as RotaShield, says Richard Ward, Professor of Pediatrics at Cincinnati Children's Hospital in Ohio (<http://www.cincinnatichildrens.org>), who developed Rotarix and licensed it to GSK. He is also involved in the labwork from trials of Merck's ROTATEQ vaccine, which, he says, has now been tested on some 65,000 children. 'So far, to my knowledge, [Merck] have no cases of intussusception associated with their vaccine.'

This may be something to do with the type of rotavirus used to raise an immune response, he says. RotaShield was based on a strain of rotavirus from rhesus monkeys. 'The monkey virus does weird things, things that other rotaviruses don't do,' said Ward.

By contrast, Rotarix contains a single strain of human rotavirus and ROTATEQ is composed of five strains of bovine/human reassortant rotavirus that contain neutralization proteins representing dominant human serotypes.

On the market...

However, although Merck began Phase III trials of their vaccine about three years ago – earlier than did GSK – their product will probably take longer to reach the market, says Ward. 'They're only applying, to my knowledge, in the United States,' he said. 'Merck is not going to be this year, for sure.'

This estimate is supported by a statement on Merck's website. A product license application will be submitted to the FDA in the second half of 2005, they predict.

But GSK's Rotarix, which is aimed at developing countries where the disease burden is highest, could be rolled out to Mexico this year, says Rotarix clinical project director De Vos. This could help GSK tap into a market they estimate is worth more than US\$800 million in the EU and other non-US countries, with a similarly sized market in the US.

It is much more likely to receive a license in this context, admits Ward. The Mexican government is expected to come to a decision later this year, he says.

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