

World's first dengue fever vaccine cleared by Mexico (Update)

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Credit: National Cancer Institute

The world's first dengue vaccine won regulatory approval in Mexico on Wednesday, raising hopes that it could prevent more than 100 deaths there a year and eventually perhaps millions around the world.

Globally, dengue is the fastest-growing mosquito-borne disease, with as many as 400 million people infected every year, according to the World Health Organization.

The Dengvaxia vaccine is being manufactured by French pharmaceutical giant Sanofi. The company has requested regulatory approval in 20 countries across Asia and Latin America, but Mexico was the first to give it the green light.

While the price tag has yet to be decided, the vaccine has the potential to be a "blockbuster" drug and generate more than \$1 billion a year in revenue for Sanofi, said Olivier Charmeil, head of the company's vaccines division.

"It's a very important moment in the history of public health," Charmeil told AFP, describing

Dengvaxia as the "innovation of the decade."

Mexico's National Vaccination Council will meet to decide whether Dengvaxia will be among the vaccines the government distributes without cost, the head of the health regulatory agency, Mikel Arriola, told AFP.

Mexican health authorities estimate the vaccine could prevent 8,000 hospitalizations and 104 deaths per year.

"It's a great step forward," Arriola said, adding that Mexico was able to move before other countries because it was involved in the research on the vaccine, carried out since 2006.

Rapidly growing disease

Scientists have long been stumped by dengue, which has four separate strains, forcing researchers to find a drug able to fight all of them at once.

Clinical tests—carried out on 40,000 people from 15 countries—have found Dengvaxia can immunize two-thirds of people aged nine years and older, rising to 93 percent for the more severe form of the disease, dengue hemorrhagic fever.

It was also found to reduce the risk of hospitalization by 80 percent.

Dengue can trigger a crippling fever, along with muscle and joint pain. There is no known cure, and children are at particular risk.

The deadliest form of the disease kills 22,000 people per year, the WHO says.

It was once considered a disease of the tropics, endemic in only nine countries.

But globalization, urbanization, climate change and

jet travel are helping it to move into more temperate zones. It is now endemic in more than 100 countries.

The WHO says cases have risen 30-fold over the last 50 years, with more than half the world's population potentially at risk.

Sanofi to enjoy 'monopoly'

The 20 countries where Sanofi Pasteur hopes for authorization to market the vaccine have a total population of two billion people.

"We are waiting for more registrations in Asia and Latin America in the coming weeks," said Charmeil.

Several million doses of the vaccine are ready to ship, and Sanofi expects annual production to reach 100 million doses by 2017.

A stockpile for the European Union will be shipped early next year and for the United States a year later.

Sanofi's research and development work took 20 years, costing more than 1.5 billion euros (\$1.6 billion).

But the vaccine could bring the company more than \$1 billion annually starting in 2018 or 2019, analysts said.

But "it will depend on the markets, the target populations and the prices that are negotiated," said Eric Le Berrigaud, analyst at investment banking firm Bryan, Garnier & Co.

Other pharmaceutical companies are developing dengue vaccines, including US firm Merck, Japan's Takeda and Britain's GlaxoSmithKline.

But Sanofi is well ahead of the competition, said Le Berrigaud.

"Sanofi Pasteur has four years of monopoly in front of it," he said.

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