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Sanofi Pasteur, the vaccines division of Sanofi, has announced that the Mexican authorities have granted marketing authorization to Dengvaxia, making it the first vaccine to be licensed in the world for the prevention of dengue.

The Federal Commission for the Protection against Sanitary Risks (COFEPRIS) has approved Dengvaxia, tetravalent dengue vaccine, for the prevention of disease caused by all four dengue virus serotypes in preadolescents, adolescents and adults, 9 to 45 years of age living in endemic areas.

"When Sanofi set out to develop a dengue vaccine 20 years ago together with local and global public health and scientific communities, it was with the intention of developing an innovative vaccine to tackle this global public health need," said Dr Olivier Brandicourt, CEO, Sanofi. "Today, with this first marketing authorization of Dengvaxia, we have achieved our goal of making dengue the next vaccine-preventable disease. This is a historic milestone for our company, for the global public health community and, most importantly, for half the world's population who lives at risk of dengue."

The COFEPRIS approval of Dengvaxia is based on results from an extensive clinical development program involving over 40,000 people of different ages, geographic and epidemiological settings, and ethnic and socio-economic backgrounds living in 15 countries. Dengue-endemic regions of Mexico participated in all three phases of the clinical development program for the vaccine.

Regulatory review processes for Dengvaxia are continuing in other endemic countries. Manufacturing of Dengvaxia has already started at vaccine facilities in France and first doses are already produced. Sanofi Pasteur remains committed to introducing Dengvaxia first in countries where dengue is a major public health priority.

The World Health Organization (WHO) has called for development of a dengue vaccine as an essential part of the integrated dengue prevention effort needed to significantly lower the dengue burden globally. The WHO has called on endemic countries to reduce dengue mortality by 50 percent and morbidity by 25 percent by 2020.