

Sanofi Pasteur launches FluQuadri® - India's first Four-Strain Influenza Vaccine for population above 3 years of age

- * Quadrivalent influenza vaccines are the latest innovative prevention tools to provide broader protection against influenza
- * FluQuadri® will be India's first quadrivalent vaccine that will provide broader protection against all four strains of influenza viruses
- * WHO has recommended the inclusion of the quadrivalent vaccine for 2018-19
- * Made in Swiftwater, USA, the vaccine is available in 26 countries in the world

MUMBAI – July 23, 2018 – Sanofi Pasteur, the vaccine division of [Sanofi](#), announced today the launch of its 4-strain influenza vaccine FluQuadri® in India. FluQuadri® will be India's first quadrivalent vaccine to provide broader protection against influenza to population above 3 years of age.

Currently, the majority of seasonal influenza vaccines are trivalent, meaning that they protect against: two A strains and one single B lineage (B/Victoria or B/Yamagata) of Influenza virus. However, over the recent flu seasons, co-circulation of both B lineages has been consistently observed, making it difficult for the World Health Organization (WHO) to recommend which B strain should be incorporated in trivalent influenza vaccines. Given the change in epidemiology, quadrivalent vaccination represent the next logical step to an advanced level of protection. The WHO includes quadrivalent influenza vaccines in its recommendations, stating *"Quadrivalent influenza vaccines that could potentially provide wider protection against influenza B viruses are becoming available and recommendations should not be limited to trivalent vaccine."*

Dr. Vijay Yewale, Director & Consultant Pediatrician, Dr.Yewale's Multispecialty Hospital, Navi Mumbai; and Head, ICH, Apollo Hospitals, Navi Mumbai said, "There are 2 different subtypes of influenza type B causing disease in human. The vaccine available until now includes only one of the influenza B subtypes and thus protects against only against the one included in the vaccine. The influenza vaccine is freshly prepared twice in a year and influenza viruses types, both A and B are included in

the vaccine based on the scientific prediction made about the types likely to circulate in the year. In the decade between 2000 and 2010, 50 % of the times in Europe and USA the disease causing B subtype in circulation was different from the one included in the vaccine. This would leave vaccinated individuals unprotected against the subtype that's not included in the vaccine. A quadrivalent vaccine offers protection against all four subtypes – two Influenza B and the two Influenza A subtypes. This protects them against all the circulating subtypes.”

India has also seen circulation of type B influenza strains. The IDSP (Integrated Disease Surveillance Program) annual report 2017 stated that in the wake of high number of influenza deaths and cases in Gujarat, an expert committee noted that one of the main reasons of flu epidemic in Gujrat was that during last year, the H3N2 and B subtypes of influenza virus were circulating, but not H1N1, leading to a build-up of the susceptible population. As a result, the committee has suggested that in future, in all IEC (Information Education Communication) material the words “swine flu” to be replaced by the words “seasonal flu” and all references to H1N1 be omitted. In another instance, a surveillance project for acute febrile illnesses, anchored at the Manipal Centre for Virus Research in Karnataka, found that influenza accounts for nearly 20% of fevers across rural areas in 10 Indian States and during the years when the H1N1 burden is low in these regions, H3N2 and Influenza B circulation tends to spike.

“Sanofi Pasteur remains at the forefront of innovation to fight the underestimated burden of influenza. Our 60+ years of expertise in influenza prevention inspires us to pursue better vaccine solutions to combat the burden of the disease. We are proud to bring this innovation to India, which has seen quite a few influenza epidemics in the past decade. By making FluQuadri® available to the Indian population, we aim to provide broader protection for people 3 years of age and older against this severe disease and its potentially life-threatening complications”, said **Jean-Pierre Baylet, Country Head – Sanofi Pasteur South Asia.**

About Influenza

Seasonal influenza or “Flu” is an acute viral infection caused by influenza viruses, spreading easily from person to person and circulating year-round worldwide. Seasonal influenza is characterized by a sudden onset of fever, cough (usually dry), headache, muscle and joint pain, severe malaise (feeling unwell), sore throat and a runny nose. The cough can be severe and can last 2 or more weeks. Most people recover from fever and other symptoms within a week without requiring medical attention. But influenza can cause severe illness or death especially in people at high risk. The highest risk of complications occur among pregnant

women, children aged 6–59 months, the elderly, individuals with specific chronic medical conditions such as HIV/AIDS, asthma, and chronic heart or lung diseases, and health-care workers.¹

According to the World Health Organization's (WHO) estimates, the influenza annual global attack rates are estimated at 5-10% in adults and 20–30% in children². Worldwide, annual influenza epidemics result in three to five million cases of severe illness, and 291,000 to 646,000 deaths, not including deaths during pandemics and from condition exacerbated by the flu such as diabetes, asthma, and heart disease.³ According to the Government's Integrated Disease Surveillance Project (IDSP), since 2010, ~115,000+ cases of influenza and 8000+ deaths due to influenza have been recorded. However, this number is limited to influenza caused due to one strain i.e. H1N1 only. In a study done from 2009-2013, 14% of the 44,127 ILI/SARI cases were found positive for influenza virus. Of those positive for influenza, 69% were influenza type A and 31% influenza B.⁴ Various other studies have indicated that the burden is far higher than what is being reported. For instance, one study noted that during 2009 pandemic, annual incidence of influenza hospitalization in rural area was about 47/10,000 and during post-pandemic period 40.5/ 10,000 population.⁵

**ILI/SARI- Influenza Like Illness/Severe Acute Respiratory Infection*

About Sanofi Pasteur

Sanofi Pasteur is the world's largest manufacturer of influenza vaccines. In 2016, Sanofi Pasteur confirmed its leadership by completing a production of 200 million doses of seasonal influenza vaccine, i.e. approximately 40% of influenza vaccines distributed worldwide. Sanofi Pasteur produces vaccines against seasonal influenza on its four sites: Swiftwater (Pennsylvania, United States), Val de Reuil (France), Ocoyoacac (Mexico City, Mexico) and Shenzhen (China).

Sanofi Pasteur, the vaccines division of Sanofi, provides more than 1 billion doses of vaccine each year, making it possible to immunize more than 500 million people across the globe. A world leader in the vaccine industry, Sanofi Pasteur produces a portfolio of high quality vaccines that matches its areas of expertise and meets public-health demand. The company's heritage, to create vaccines that protect life, dates back more than a century.

1 WHO fact sheet dated Nov. 2016 - <http://www.who.int/mediacentre/factsheets/fs211/en/>

2 WHO. Weekly epidemiological record - Vaccines against influenza WHO position paper, 87, No. 47 p461–476. November 23, 2012. Available at: <http://www.who.int/wer/2012/wer8747/en/>

3 [http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(17\)33293-2.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(17)33293-2.pdf)

4 M Chadha et al from 2009-2013(<https://doi.org/10.1371/journal.pone.0124122>)

5 Chadha et al. 2013 PLOS One paper

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2016. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.
