SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NYSE: SNY)

FDA Approves VAXELIS™, Sanofi and MSD's Pediatric Hexavalent Combination Vaccine

PARIS and KENILWORTH, N.J. – December 26, 2018 – The U.S. Food and Drug Administration has approved VAXELIS™ (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine) for use in children from 6 weeks through 4 years of age (prior to the 5th birthday). VAXELIS was developed as part of a joint-partnership between Sanofi and MSD (NYSE: MRK), known as Merck inside the United States and Canada.

Sanofi and MSD are working to maximize production of VAXELIS to allow for a sustainable supply to meet anticipated U.S. demand. Commercial supply will not be available in the U.S. prior to 2020.

Indication for VAXELIS in the US

VAXELIS is a vaccine indicated for active immunization to prevent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and invasive disease due to *Haemophilus influenzae* type b. VAXELIS is approved for use as a 3-dose series in children 6 weeks through 4 years of age (prior to the 5th birthday).

Select Safety Information for VAXELIS

VAXELIS is contraindicated in children with a history of severe allergic reaction (e.g., anaphylaxis) to a previous dose of VAXELIS, any ingredient of VAXELIS, or any other diphtheria toxoid, tetanus toxoid, pertussis-containing vaccine, inactivated poliovirus vaccine, hepatitis B vaccine, or *H. influenzae* type b vaccine.

Do not administer VAXELIS to anyone with a history of encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), within 7 days of a pertussis-containing vaccine, that is not attributable to another identifiable cause.

Do not administer VAXELIS to anyone with a history of progressive neurologic disorder until a treatment regimen has been established and the condition has stabilized.

Vaccination with VAXELIS may not protect all individuals.

Carefully consider benefits and risks before administering VAXELIS to persons with a history of:

- fever of ≥40.5°C (≥105°F), hypotonic-hyporesponsive episode (HHE) or persistent, inconsolable crying lasting ≥3 hours within 48 hours after a previous pertussis-containing vaccine.
- seizures within 3 days after a previous pertussis-containing vaccine.

If Guillain-Barré syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following VAXELIS.

Apnea following intramuscular vaccination has been observed in some infants born prematurely. The decision about when to administer an intramuscular vaccine, including VAXELIS, to an infant born prematurely should be based on considerations of the individual infant's medical status and the potential benefits and possible risks of vaccination.

Urine antigen detection may not have definitive diagnostic value in suspected *H. influenza* type b disease following vaccination with VAXELIS.

The solicited adverse reactions following any dose were irritability (≥55%), crying (≥45%), injection site pain (≥44%), somnolence (≥40%), injection site erythema (≥25%), decreased appetite (≥23%), fever ≥38.0°C (≥19%), injection site swelling (≥18%), and vomiting (≥9%).

Please see the full Prescribing Information for VAXELIS (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine).

Dosage and Administration for VAXELIS

The 3-dose immunization series consists of a 0.5 mL intramuscular injection, administered at 2, 4, and 6 months of age.

A 3-dose series of VAXELIS does not constitute a primary immunization series against pertussis; an additional dose of pertussis-containing vaccine is needed to complete the primary series.

About VAXELIS

VAXELIS is the result of the U.S.-based joint-partnership[i] established in 1991 between Merck & Co, Inc and Sanofi Pasteur, the vaccines unit of Sanofi, and draws upon both companies' experience in the development, manufacturing and marketing of individual and combination vaccines. VAXELIS includes antigens for diphtheria, tetanus, pertussis (whooping cough), and poliomyelitis from Sanofi and antigens for *H. influenzae* type b and hepatitis B from MSD.

About MSD

For more than a century, MSD, a leading global biopharmaceutical company, known as Merck inside the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, MSD continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world – including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit www.msd.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, to complete related transactions 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, 2017. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2017 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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[i] *VAXELIS™ is the result of the U.S.-based business joint-partnership (MCM) created in 1991 between Merck & Co., Inc., Connaught Laboratories and Pasteur Mérieux Serums & Vaccins, the latter two now known as Sanofi Pasteur, the vaccines unit of Sanofi.*