Sringing life to vaccine strategy...

ExpertREACT[™]

VIEW ONLY

December 1st, 2016

2016 – year of the *flavivirus* vaccine?

LONDON, UK----1st **December 2016----ExpertREACT**. As 2016 ends it's clear that Sanofi's controversial roll-out of Dengvaxia® dominated news headlines. The vaccine is now approved in 13 countries, and part of two mass vaccination campaigns (Brazil, Philippines), but how long will it hold dominance based on the >9yrs restriction (highly endemic settings)? Takeda's TAK-003 recent CAPEX decision signals competition.

Below is a list of key 2016 press releases from the major vaccine players:

January

• Sanofi signs an agreement with the Human Vaccine Project Inc

February

- Sanofi launches Zika vaccine project
- GSK announces US regulatory submission seeking expanded indication for FluLaval® Quadrivalent (Influenza Vaccine) for infants 6 mos+

<u>March</u>

 Sanofi Pasteur and Merck (Known as MSD Outside the United States and Canada) Announce Intent to End Joint Vaccines Operations in Europe, Sanofi Pasteur MSD, to Pursue Their Own Distinct Growth Strategies

<u>April</u>

- Sanofi's Dengvaxia® is used in world's first public immunization program against dengue in three highly endemic areas of the Philippines (1m school children).
- The WHO SAGE committee recommends use of Dengvaxia®

<u>May</u>

- GSK reports Phase IIIb study (V72_28) indicating new 2+1 infant schedule for meningococcal group B vaccine
- Pfizer Announces European Medicines Agency acceptance for review of marketing authorization application for TRUMENBA® (Meningococcal Group B Vaccine)
- Pfizer Presents Results from Two Phase 3 TRUMENBA® (Meningococcal Group B Vaccine) Studies at the European Society for Paediatric Infectious Diseases Meeting

June

- Merck releases systematic review of 58 publications of real-world use of Gardasil presented at EUROGIN Congress
- Pfizer Receives European Approval for New Multi-Dose Vial Presentation of Prevenar 13®
- Takeda initiates first norovirus vaccine field trial

July

- Pfizer Receives FDA Approval for Prevnar 13[®] in Adults Age 18 Through 49
- Sanofi signs research agreement for Zika vaccine project with WRAIR
- GSK publishes high efficacy Phase III (September 2016) data for Shingrix[™] in NEJM













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CONTINUED.....

August

 Sanofi's Dengvaxia® used in public vaccination program in Parana state of Brazil for 30 highly affected municipalities

September

- GSK publishes high efficacy Phase III (September 2016) data for Shingrix[™] in NEJM
- Sanofi's Dengvaxia® available in private clinics in Mexico
- BARDA grants \$43.2m to Sanofi Pasteur for Zika vaccine
- Takeda initiates Phase III (TIDES) trial for dengue candidate TAK-003
- Takeda to develop Zika vaccine with up to \$312 million from US government

October

- GSK announces US regulatory submission for Shingrix[™] (>50 yrs)
- Pfizer announces that CDC ACIP votes to recommend new dosing schedule(s) for TRUMENBA®
- Sanofi Pasteur agrees to collaborate with WRAIR and Fiocruz on Zika project

November

- GSK announces EU regulatory submission for Shingrix[™] (>50 yrs)
- GSK receives FDA approval for Flulaval QIV (> 6 months)
- Pfizer's Prevenar 13® Receives Approval For Use in Infants and Children in China
- Takeda to invest more than 100 million euros in German dengue manufacturing plant

December

TBC

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Sources: Corporate Press Releases

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