BioSpectrum the business of Bio & Health Sciences

Sanofi outlines next wave of innovative medicines and vaccines

24 November 2014 | News | By BioSpectrum Bureau

Sanofi outlines next wave of innovative medicines and vaccines

These new launches have the potential to cumulatively generate greater than â‚¬30 billion over the first five years of sales and confirm the strong momentum of the company's R&D pipeline and ability to deliver new therapies across a range of therapeutic categories.

"These potential launches affirm Sanofi's strategy, which has been in place since 2008, and clearly demonstrate the strong momentum of Sanofi's R&D pipeline," said Mr Serge Weinberg, chairman of the Board and CEO, Sanofi. "As we move into this period of successive new product launches, we are investing in launch excellence and execution while continuing to fuel innovation to grow our existing pipeline."

Sanofi's seminar consisted of presentations on nine new medicines and vaccines:

â€¢ Rare Diseases:
o **Cerdelga** (eliglustat): The only FDA-approved, first-line oral therapy for certain adult Gaucher Disease Type 1 patients.

â€¢ Multiple Sclerosis:
o **Lemtrada** (alemtuzumab): An FDA-approved treatment for adult patients with active relapsing remitting multiple sclerosis who have had an inadequate response to two or more MS therapies.

â€¢ Cardiovascular Disease:
o **Praluent** (alirocumab): An investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9) with the potential to transform LDL-cholesterol management - developed in collaboration with Regeneron - is expected to

be submitted to U.S. and EU regulatory agencies before year-end 2014.

â€¢ Diabetes:
o **Toujeo** (insulin glargine [rDNA origin] injection, 300 U/mL): A new investigational basal insulin currently under review by the US and EU regulatory agencies.
o Afrezza (insulin human): A new, FDA-approved, rapid-acting inhaled insulin therapy for adults with type 1 and type 2 diabetes.
o **Lixilan**: An investigational fixed-ratio combination of insulin glargine, the leading basal insulin, with lixisenatide, a GLP-1 receptor agonist, in a single daily injection for the treatment of adults with type 2 diabetes.

â€¢ Vaccines:
o **Dengue Vaccine**: Sanofi Pasteur's dengue vaccine candidate with demonstrated efficacy across all dengue serotypes and a favorable safety profile in two landmark phase 3 studies, after 25 months active surveillance period. Regulatory submissions are planned in 2015.

â€¢ Immunology & Inflammation:
o **Sarilumab**: An investigational fully human monoclonal antibody targeting the IL-6 receptor (IL-6R) - developed in collaboration with Regeneron - currently being studied in patients with rheumatoid arthritis (RA).
o **Dupilumab**: An investigational fully human monoclonal antibody that blocks IL-4 and IL-13 signaling - developed in collaboration with Regeneron - entered into phase 3 in adults with moderate-to-severe atopic dermatitis. Positive results were also recently announced with dupilumab also in phase 2b in adult patients with uncontrolled, moderate-to-severe asthma and in phase 2a in chronic sinusitis with nasal polyps.

"Sanofi's global R&D teams have created an impressive dynamic that leverages internal talents and open innovation to develop an industry-leading pipeline," said Mr Elias Zerhouni, MD, president, and global R&D, Sanofi. "Sanofi has the potential to launch up to six new medicines in 2015 and approximately one new medicine every six months between 2016 and 2018. These new medicines have the potential to help address significant areas of need in rare diseases, cardiovascular care, diabetes, immunology and public health."