

Frost & Sullivan Releases Drug Launch and Phase 3 Watch List



According to an industry report released by Frost & Sullivan, the top therapeutic areas of investment in 2015 will include oncology, cardiovascular, autoimmune/anti-inflammatories and infectious diseases. The report also projects an increase in spending on personalised medicine beyond oncology and into areas such as virology and cardiology.

Pharmaceutical companies are expected to invest in in-vitro diagnostics such as biomarker, molecular, tissue, companion diagnostics, predisposition disease and predictive testing. This will be driven by an expected increase in drugs with companion diagnostics and an increased focus on cardiology and inflammatory diseases.

Frost & Sullivan's therapeutics watch list for 2015 includes:

- Puma Biotechnology's tyrosine kinase inhibitor, **neratinib**, for breast cancer adjuvant therapy. The drug is in its Phase 3 trial and has demonstrated higher disease-free survival rates compared to placebo after adjuvant therapy with trastuzumab for early-stage HER2-positive breast cancer. The drug is expected to be approved by the FDA in the second quarter of 2015.
- Bristol-Myers Squibb's PD-1 immune checkpoint inhibitor, **nivolumab**, for previously treated advanced melanoma patients. This drug is also in its Phase 3 trial. One-year survival rate with the drug was 73 percent as compared to 42 percent for the chemotherapy, dacarbazine (DTIC) in patients with treatment-naïve BRAF wild-type advanced melanoma. The drug is expected to be approved by the FDA by March, 2015.
- Novartis' selective IL-17A inhibitor, **secukinumab**, for the treatment of plaque psoriasis: Also in Phase 3 trial, the drug has proven to be more effective in clearing skin lesions as compared to Enbrel. The drug is expected to be launched in the first quarter of 2015.
- Novartis' angiotensin receptor neprilysin inhibitor (ARNi), **LCZ696**, for the treatment of heart failure: The drug is expected to be introduced in the second quarter of 2015 and has shown significantly better results as compared to enalapril.
- AbbVie's ABT-450/ritonavir co-formulated with ombitasvir (ABT-267), and dasabuvir (ABT-333) with or without ribavirin for the treatment of hepatitis C: This **interferon-free, all oral regimen** is supported by six Phase 3 clinical trials and is expected to be launched in the first quarter of 2015.
- GlaxoSmithKline's **RTS,S vaccine** is expected to be the first malaria vaccine in the market and is expected to be launched in 2015.
- Sanofi Pasteur's **Dengue Vaccine** is also expected to have a first-mover advantage, with FDA approval expected in 2015.
- **Ebola virus vaccines** consisting of cAd3-ZEBOV by GlaxoSmithKline, PSC-1001 by Newlink Genetics Corporation, and potentially an unnamed vaccine developed by Johnson & Johnson are anticipated to be entering Phase 3 trials in 2015.

In addition to the above mentioned drugs, Frost & Sullivan projects excellent growth opportunities for generic and biosimilar drugs since the

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patents of several blockbuster drugs are expected to expire in 2015. These include Ablify (anti-psychotic), Copaxone (relapse-remitting multiple sclerosis), Gleevac (chronic myeloid leukaemia), Namenda (Alzheimer's disease), Zyvox (anti-viral) and Avodart (benign prostatic hyperplasia).

Source: Frost & Sullivan

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