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## ▶ GLOBAL NEWS

### 1.1. **New Tuberculosis Vaccine developed at McMaster University**

Oct 06, 2013

- A tuberculosis vaccine developed at McMaster University offers new hopes for the global fight against tuberculosis. Researchers at McMaster University created the tuberculosis vaccine based on a genetically modified cold virus. Phase one of the clinical trials has been published in the journal Science Translational Medicine.
- A previous tuberculosis vaccine also exists, the Bacille Calmette Guerin (BCG) vaccine. The new tuberculosis vaccine was developed to act as a booster to BCG vaccine. The new booster will reactivate immune elements that diminish over time following vaccination with the BCG vaccine.

### 1.2. **GSK gets ready To File World's First Malaria Vaccine**

Oct 08, 2013

- GlaxoSmithKline is ready to file the world's first malaria vaccine after follow-up data from a large-scale trial in Africa confirmed its ability to prevent the disease. It plans to file RTS, S - the most clinically advanced malaria vaccine candidate with the EMA in 2014, which means it could be in use by 2015 if approval is granted.

### 1.3. **Pfizer presents data on RA drug Xeljanz for Psoriasis**

Oct 10, 2013

- Pfizer has presented data which demonstrates that a high dose of tofacitinib, already marketed as Xeljanz for rheumatoid arthritis, appears to be an effective treatment for psoriasis, but a lower dose seems to be less so.
- Tofacitinib is sold for RA in the USA as Xeljanz but it is only approved for the 5mg dose. This summer advisors to the European Medicines Agency again rejected the drug for RA due to "outstanding concerns on safety, including serious infections".

### 1.4. **NICE draft "yes" for Astellas' Prostate Cancer drug**

Oct 18, 2013

- The National Institute for Health and Care Excellence (NICE) has issued draft guidance recommending Astellas Pharma's Xtandi (enzalutamide) for treating hormone relapsed metastatic prostate cancer. Xtandi is an effective treatment and, as it can be taken orally, it allows patients to be treated at home.

## ▶ DOMESTIC NEWS

### 2.1. **Avahan AIDS initiative effective at controlling HIV infections in India**

Oct 01, 2013

- Avahan, the India AIDS Initiative, which was launched in 2003, aimed to prevent HIV transmission in the general population through a comprehensive HIV prevention programme including the promotion of condoms among the people at most risk - female sex workers, high risk men who have sex with men and intravenous drug users - in the six Indian states with the highest HIV rates. In an evaluation of the project published in Lancet Global Health, researchers estimate that it prevented more than half of the infections that would have occurred without the Avahan intervention.



## 2.2. Bharat Biotech launches Fully Indigenous Inactivated Vaccine

Oct 04, 2013

- Capping a five-year-long public-private partnership drug discovery programme, Bharat Biotech launched fully indigenous inactivated Japanese Encephalitis vaccine Jenvac that will possibly end India's dependence on China for its 10-million dose national JE control programme.
- Jenvac is a completely indigenous vaccine and an outstanding example of public private partnership (PPP), and a remarkable milestone in the emergence of our country as an innovative and self-sufficient technology hub.

## ➤ DRUGS IN DEVELOPMENT AND CLINICAL TRIALS

### 3.1. Novartis: Secukinumab Superior to Enbrel

Oct 04, 2013

- Novartis announced the results from the head-to-head Phase III FIXTURE study showing secukinumab (AIN457), an interleukin-17A (IL-17A) inhibitor, was significantly superior to Enbrel® (etanercept) in moderate-to-severe plaque psoriasis. The study of Secukinumab and Enbrel, part of largest clinical program, was completed in moderate-to-severe plaque psoriasis with more than 3,300 patients. Enbrel is a current standard-of-care anti-TNF medication approved to treat moderate-to-severe plaque psoriasis.

### 3.2. New Data show Gilenya® reduced Brain Volume Loss by one third in MS patients

Oct 07, 2013

- Novartis has announced new data indicating that continued treatment with Gilenya® (fingolimod) led to a reduction in brain volume loss in people with relapsing remitting multiple sclerosis (RRMS), and was associated with a higher proportion of people remaining free of disability progression compared to placebo. These data was presented at the 29<sup>th</sup> Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Copenhagen, Denmark.

### 3.3. MannKind files Inhaled Insulin Product with FDA again

Oct 16, 2013

- MannKind Corp has once again resubmitted its inhaled insulin Afrezza with the US FDA and a number of observers believe it could be third time lucky. Afrezza (insulin human [rDNA origin]) has been refiled to improve glycaemic control in adults with type 1 or type 2 diabetes based on the entire data set from the extensive Afrezza clinical development programme and particularly the positive results from two recent Phase II trials.

### 3.4. FDA Grants Lilly's Ramucirumab Priority Review

Oct 23, 2013

- FDA Grants Lilly's Ramucirumab Priority Review as a Potential Single-Agent Treatment for Advanced Gastric Cancer. Eli Lilly announced that the U.S. FDA has assigned Priority Review to the regulatory submission for ramucirumab (IMC-1121B) as a single-agent treatment for advanced gastric cancer following disease progression after initial chemotherapy.



**3.5. Zydus announces US FDA approval for initiating Phase I**

Oct 23, 2013

- Close on the heels of launching Lipaglyn, the breakthrough therapy to treat diabetic dyslipidemia and India's first NCE to reach the market, the Zydus group announced the Phase I clinical trial approval from the USFDA for ZYDPLA1 - a Next Generation, long-acting DPP-4 Inhibitor.

**3.6. J&J wins FDA panel blessing for Hep C blockbuster hopeful**

Oct 24, 2013

- Johnson & Johnson's much-hyped simeprevir picked up the unanimous support of FDA advisers, moving the potential hepatitis C blockbuster one step closer to market as a who's who of drug developers advances next-generation therapies. The agency's Antiviral Drugs Advisory Committee voted 19-0 in favor of approving simeprevir, an NS3/4A protease inhibitor that promises to treat the most common genotype of chronic hepatitis C, standing out amid a new class of combo treatments angling for entry into the huge market.

**3.7. BD launches shortest ever insulin syringe needle in Hyderabad**

Oct 24, 2013

- Becton, Dickinson and Company (BD), a leading global medical technology company, has launched BD Glide 6mm needle, the smallest ever insulin syringe needle developed with TBL technology for the first time in India. The needle has been designed to improve patient comfort. Compared to present needle size, 80 per cent patients have preferred this new needle.

**MERGER, ACQUISITIONS AND COLLABORATIONS**

**4.1. Zydus Cadila signs biologics pact with Pieris**

Oct 16, 2013

- India's Zydus Cadila has linked up with Pieris of Germany to develop the latter's therapeutic proteins called anticalins. Under the terms of agreement, the financials for which have not been disclosed, Zydus has been granted exclusive marketing rights in India and several other emerging markets. Pieris will retain them in key developed markets.

**4.2. Amgen to buy Roche's filgrastim franchise rights**

Oct 23, 2013

- Amgen has entered into a definitive agreement with F. Hoffmann-La Roche (Roche) to acquire Roche's rights to filgrastim and pegfilgrastim in approximately 100 markets, effective January 1, 2014. Roche has held the rights to filgrastim and pegfilgrastim under license from Kirin-Amgen, Inc. (a joint venture between Amgen and Kirin Holdings Co. Limited, of Japan) in Eastern Europe, Latin America, Asia, the Middle East and Africa since 1989. The franchise generated approximately \$200 million in sales in these territories in 2012.



## ▶ TECHNOLOGY NEWS

### 5.1. **Liquid Biopsy: New Device Could Help Doctors Diagnose And Treat Cancers** Oct 02, 2013

- A micro fluidic chip developed at the University of Michigan is among the best at capturing elusive circulating tumor cells from blood-and it can support the cells' growth for further analysis. The device, believed to be the first to pair these functions, uses the advanced electronics material graphene oxide. In clinics, such a device could one day help doctors diagnose cancers, give more accurate prognoses and test treatment options on cultured cells without subjecting patients to traditional biopsies.

### 5.2. **PET scan shows promise in predicting patients with inoperable lung cancer** Oct 08, 2013

- Advanced imaging with Positron Emission Tomography (PET) scan shows great promise in predicting which patients with inoperable lung cancer have more aggressive tumors and need additional treatment following standard chemotherapy/radiation therapy, according to new research recently published online in the Journal of Clinical Oncology.