OPPI

Daily News Monitor

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1. **Scientists hunt 'anti-evolution' drugs in new cancer fight – Reuters**

   Scientists are opening a new front in the war on cancer with plans to develop "anti-evolution" drugs to stop tumor cells from developing resistance to treatment. Britain's Institute of Cancer Research (ICR), one of the world's top cancer centers, said on Friday its initiative was the first to have at its heart the target of overcoming cancer evolution and drug resistance.

2. **Roche CEO fears hit to UK drug research from Brexit vote – Reuters**

   Britain's decision to leave the European Union threatens to undermine its position as a center for drug research and UK patients could fall behind others in Europe in getting access to new drugs, Roche's chief executive said. Currently, new drugs are approved by the European Medicines Agency, but in future Britain may have to set up its own drug approval system and the country could move to the back of the queue for new medicines, industry executives say.

3. **Roche beats forecasts on new drugs and one-off gain – Reuters**

   Switzerland's Roche beat market expectations for adjusted net income in the first six months of the year, helped by cancer drug sales but also inflated by a one-off gain from its pensions scheme. Core earnings per share, adjusted for certain items, rose 7 percent to 7.74 Swiss francs ($7.86), where analysts had expected 7.52 francs on average. The company also made a one-off accounting adjustment to its pension plan that boosted earnings by 426 million francs but that effect will be offset over time because it expects its pensioners to live longer and returns on its pension investments to remain depressed because of low interest rates.

4. **BRIEF-Merck provides regulatory update on Biologics application – Reuters**
   FDA has requested submission of new data and analyses from modify I and modify II clinical trials previously submitted
   * Merck provides regulatory update on Biologics licensing application for investigational agent Bezlotoxumab
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   * New Bezlotoxumab PDUFA date will be Oct. 23, 2016.

5. **BRIEF-Allergan, Amgen collaborating on development, commercialization of four oncology biosimilars – Reuters**
   In neoadjuvant phase of study, which included chemotherapy, there were more serious adverse events reported in ABP 980 group:
   * Allergan Plc says Amgen and Allergan are collaborating on development and commercialization of four oncology biosimilars
   * Amgen and Allergan announce top-line results from phase 3 study evaluating ABP 980 compared with Trastuzumab in patients with human epidermal growth factor receptor 2-positive early breast cancer
   * Results ruled out inferiority compared to Trastuzumab but could not rule out superiority based on its primary efficacy endpoint
   * Overall results also showed comparable immunogenicity
   * In adjuvant phase of study, which did not include chemotherapy, serious adverse events were comparable between treatment groups.

6. **Capping stent prices will halt new launches, says industry – The Economic Times**
   The government move to cap prices of coronary stents seems to have pushed some multinational medical device makers to rethink their India strategy and even hold back plans to roll out new generation stents, industry experts said. "With price controls, margins of all players including manufacturers will be impacted. Global stent makers may scale back introducing their top-of-the-line brands and launch value products instead," said Rana Mehta, Leader-Healthcare at PwC India.

7. **Drug approvals in India near record despite FDA inspection blitz – Mint**
   The US Food and Drug Administration (FDA) has become something of a bogeyman for India’s stock market. An inspection blitz on Indian drug factories that supply to the US helped push the broader index of Indian healthcare stocks down by as much as 20% earlier this year from its all-time high in 2015 after some top firms received warning letters for failing to meet the regulator’s standards.

8. **Wockhardt gets EIR with observations from USFDA for 3 plants – Mint**
   Drug maker Wockhardt Ltd on Thursday said it had received an establishment inspection report (EIR) with observations from the US Food and Drug Administration (USFDA) on three of its facilities in Maharashtra. “We have to inform you that the company’s three units L-1 Chikalthana, H-14/2 Waluj and B-15/2 Waluj in Maharashtra have received establishment inspection report with observations,” the company said in a statement to stock exchanges.

9. **WHO, Health Ministry to hold awareness event on World Hepatitis Day – Business Standard**
   In a bid to raise awareness about hepatitis among people as well as health care providers and policymakers, the World Health Organisation (WHO), in collaboration with the Ministry of Health and Family Welfare (MoHFW), is organising an event on World Hepatitis Day in Mumbai on July 28. The theme for this year's World Hepatitis Day is "Know Hepatitis - Act Now". Ahead of World Hepatitis Day, WHO is urging countries to take rapid action to improve knowledge about the disease and to increase access to testing and treatment services.

10. **Five diabetes drugs in top-10 selling list – The Times of India**
    In perhaps a grim reminder of the growing incidence of lifestyle diseases, five out of the top 10 largest-selling drugs in the country are now anti-diabetes, with the therapy registering a robust double-digit clip year-on-year. The control of non-communicable diseases like diabetes poses one of the biggest challenges for the country's healthcare practitioners, even as the World Health Organisation for the first time highlighted recently the need to step up prevention and treatment of the disease.

11. **This drug combo helps soft-tissue cancer survival – The Times of India**
    Adding a novel monoclonal antibody therapy to traditional chemotherapy can help make people more likely to survive advanced sarcoma, a lethal soft-tissue cancer, by nearly a year, suggests a recent study. Findings from a multicenter clinical trial of the combination therapy, led by researchers at Columbia University Medical Center and New York-Presbyterian, represent the first appreciable improvement in sarcoma outcomes in decades.

12. **Modi under pressure from US: Global – Deccan Chronicle**
    According to the experts, the US has persistently pressured India to adopt US-style patent protections on pharmaceuticals for many years. Global leaders on AIDS, Thursday, accused Modi government of succumbing to the pressure from United States (US) and multinational pharmaceutical industry for changing country's patent law and policies. Calling on the Indian government to reverse the course in a series of actions that threaten to undermine the global AIDS response, global leaders on AIDS and human rights raised an alarm about the "conspiracy" at work between the government of US and India. They marched in heavy numbers to deliver the message to the Indian consulate from the International Convention centre(ICC)-the venue for the 21st International AIDS conference in Durban on Thursday morning. As the supplier of more than 80% of generic AIDS drugs used in low and middle income countries, changes to India's policies on affordable medicines-experts say-could have dire consequences for people living with HIV worldwide.

13. **Brace up to pay more for medicines GST regime – dna**
    A recent report on GST by Nomura said that pharma companies will pay 80% more taxes on average medicines in the new indirect tax regime, which will ultimately be extracted from consumers. A medicine starts its journey from active pharmaceutical ingredients (APIs) supplier to formulation manufacturer, then to the wholesaler and finally, to the consumer via the retailer. This chain includes value addition and indirect taxes like excise duty and Value Added Tax (VAT).

14. **MSF urges India to continue pushing generic drugs – dna**
    In a report presented on HIV drug pricing released at a conference in Durban on Thursday, the international medical humanitarian organisation Médecins Sans Frontières (MSF), also known as Doctors Without Borders, stressed on the need for India to encourage generic drugs. "India is under massive pressure to turn off its tap of affordable medicines, which are lifeline for millions of people not only in India, but across the developing world," said Leena Meghnany, South Asia Head of MSF's Access Campaign.

15. **Compulsory licensing is very critical to original patent holder: Dr Malathi Lakshmikumaran – Pharmabiz.com**
    Compulsory licensing is a practice critical to patent holders in pharmaceutical industry. And voluntary out-licensing of a new product can be a better option than compulsory licensing to a patent holder. But the revenue stream in a voluntary licensing scenario is likely to be stronger than that in compulsory licensing, according to Dr Malathi Lakshmikumaran, director and head industry practice: IPR, Lakshmikumaran and Sridharan Attorneys. The strategic advantage is that licensing in India, would also drastically improve odds in an enforcement action against infringers. Both licensee and patentee can show grievance due to infringement. Non-working or

insufficient patented inventions may disentitle the patentee from interim injunction in an enforcement action. “Patentee has the option of choosing licensees of varying capabilities. But there is no such choice in a compulsory license. This is because compulsory license is granted on manufacture of drugs after expiry of three years from grant of patent. Companies can file for compulsory license based on reasonable requirements of the public on a patented invention that is not available to the public at an affordable price,” she pointed out.