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TOKYO 2020

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## Is a Booster Vaccine Necessary to Fight Variants?

(Source: An article by Andrew McConaghie for Scrip Intelligence)

As many countries make plans for possible COVID-19 vaccine booster programs this fall, the U.S. Food and Drug Administration and the U.S. Centers for Disease Control have pushed back at the suggestion from Pfizer and BioNTech that the extra shots are necessary in the U.S. – at least for now.

Companies with COVID-19 vaccines have reported data showing that a third dose of their vaccine produces greater efficacy, including against the newer Delta variant of the virus.

On July 8th, Pfizer/BioNTech announced their plans to file for emergency use authorization (EUA) for a booster shot of their products, *Comirnaty (BNT 162b2)* in the U.S., EU and other countries in the coming weeks. The partners cited “encouraging data” from a study using a third dose of the current version of *Comirnaty* and expects to publish more definitive data shortly.

The companies believe booster shots are likely to be necessary for two reasons: real world data from Israel has shown that immunity provided by the initial prime-boost vaccinations wanes within six months of the completion of a prime-boost schedule; and secondly, variants, most notably the Delta variant (now the dominant strain in India and the U.K.), are spreading at a rapid pace worldwide.

However, the U.S. FDA and the U.S. CDC put out a joint statement on July 8th that states “Americans who have been fully vaccinated do not need a booster shot at this time.” They also did not rule out booster programs in the future but indicated that they were not seen as a current priority. This is in stark contrast to some countries that have already instituted a booster program, notably Indonesia where healthcare professionals are already underway due to “breakthrough” infections in individuals who have received a full dose of the COVID vaccine. The U.K.’s Joint Committee on Vaccination and Immunisation (JCVI) has said that a booster program targeting the country’s most vulnerable populations could begin as soon as September.

The reason for the U.S. FDA and U.S. CDC’s hesitancy over a booster program is due to the substantial number of people who have still not had an initial vaccination. At present, approximately 54% of the U.S. adults have received at least one shot. Vaccination coverage also varies greatly across the U.S., providing the opportunity for large outbreaks to take place where vaccination rates are low.

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## In Brief...

- ◆ **McKesson Corporation** announced that it has agreed to sell its European businesses in France, Italy, Ireland, Portugal, Belgium, and Slovenia to the **PHOENIX group**. This transaction includes McKesson’s German-based AG headquarters in Stuttgart, **Recucare GmbH**, its German wound-care business, its shared services center in Lithuania, and its 45% ownership stake in Netherlands joint venture **Brocacef**. The transaction is expected to close in 2022, subject to customary closing conditions, including receipt of required regulatory approvals.

- ◆ **Walgreens Boots Alliance** beat expectations with its Q3 results, with strong growth internationally from its German joint venture and solid sales growth in its U.S. and U.K. pharmacy operations. Sales grew by 12.1% year over year to US\$34 billion; earnings per share were \$1.27, compared with a loss of \$2.05 per share a year ago. WBA also completed its divestiture of Alliance Healthcare to AmerisourceBergen for US\$6.5 billion, the proceeds from which were used to pay off US\$3.3 billion in debt and invest in its retail pharmacy and healthcare businesses.

- ◆ **DP World** will buy South African company **Imperial Logistics Ltd.** for US\$890 million. Imperial’s business will be a strong addition to DP World and its existing footprint in Africa and Europe. The announcement comes one week after DP World said it acquired American logistics company **Syncreon Holding** for US\$1.2 billion.

- ◆ **Sanofi** will invest US\$472.4 million in a mRNA vaccine technology Center of Excellence as it seeks to position itself at the forefront of the next generation of candidates. While Sanofi did not lead in the R&D for the COVID-19 vaccines, it is determined to accelerate end-to-end R&D of next generation vaccines through resource reallocation.

- ◆ The quick rollout of the COVID-19 vaccine in the U.S. saved an estimated 279,000 lives and prevented 1.25 million hospitalizations according to a new study. However, surges

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## Top 15 Drugs Approaching the Patent Cliff

(Source: An article by Noah Higgins-Dunn for FiercePharma)

Over the next decade, some of the biggest drugs in the industry fall off the patent cliff, putting pharma manufacturers under pressure to come up with their next blockbuster. The biggest names set to face generic pressure in the coming years include the top four of the industry’s best-selling drugs in 2020: *Humira*, *Keytruda*, *Revlimid* and *Eliquis*.

In all, nine of the industry’s top 20 drugs by sales are set to lose exclusivity over the coming years, according to a report by Moody’s. While it is not easy to predict exactly when competition will start heating up since there may be numerous patents protecting these medicines it is also unclear whether some companies may be able to evade generic competition

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## Booster Vaccine (cont.)...

The pushback also reasserts that the FDA will not rush into authorizing vaccines without strong evidence that it is beneficial. Currently, the agencies are working with the National Institutes of Health (NIH) on a “science-based, rigorous process” so that a decision may be reached as to whether a booster may be necessary. The process will take into account lab data, clinical trials and real-world evidence, as well as filing from pharma companies.

Pfizer/BioNTech asserts that a third dose will boost antibodies even higher, similar to performance against the Beta variant. Both preclinical and clinical tests are underway. The companies also expect to enter clinical studies in August with a modified vaccine to target the Delta variant, subject to regulatory approvals.

Other COVID vaccine manufacturers are working on follow-up strategies. Pfizer/BioNTech rival Moderna has opted to prioritize tweaked versions of its vaccine to target new variants, rather than booster studies of the existing shot.

## Top 15 (cont.)...

through court, or when imitators will score regulatory approval.

But this list provides a snapshot of some of the world's billion-dollar drugs that are inching toward generic or biosimilar competition, which will undoubtedly pressure their drugmakers into looking toward their R&D programs, or other companies, for future blockbuster opportunities.

At the top of many minds will be AbbVie's *Humira*. The world's top drug by sales will start facing U.S. copycats in 2023, with Amgen calling first dibs. For years, AbbVie has faced scrutiny over how it shrouded *Humira* with hundreds of patents that date out into the next decade. In all, the Chicago-based pharma has struck at least eight biosimilar settlements for *Humira*.

Next up is Merck's *Keytruda*. Top executives have long been pressed on what Merck has in store for life after the PD-1 king loses its market exclusivity in 2028. With Merck's recent Organon spinoff, the company is even more reliant on *Keytruda*, but it also has US\$9 billion in new cash to scout for deals.

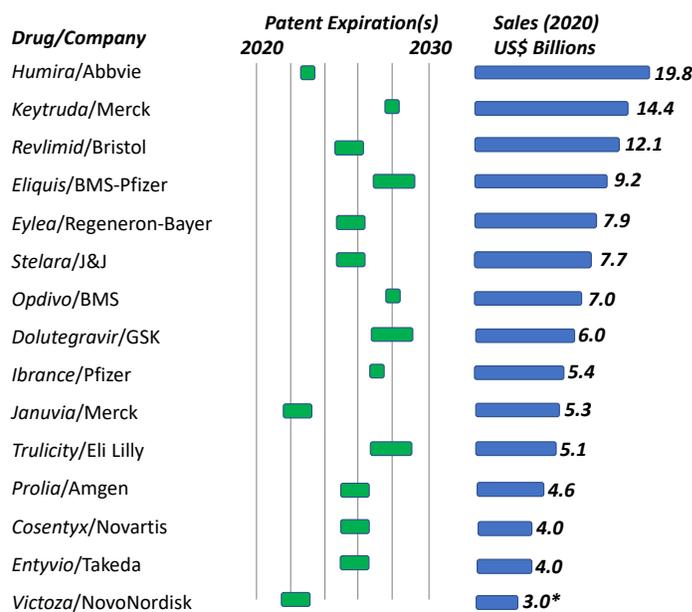
Just how important are those meds for the companies? *Humira* generated around 43% of AbbVie's total revenues last year, while *Keytruda* pulled in about 30% of Merck's haul. In the near term, though, Merck will have to deal with a patent cliff for its aging Type 2 diabetes drug *Januvia*, combined with its combo offshoot *Janumet*. The company is not giving up yet as it tries to score even more patents to extend exclusivity.

Bristol Myers Squibb is the drugmaker with the most drugs potentially losing exclusivity this decade as *Revlimid*, *Eliquis* and *Opdivo* face down the competition. But BMS, expected to be among the most active M&A dealmakers in years to come, has been hard at work shopping around for its next blockbusters, even after its US\$74 billion megadeal for Celgene in 2019 and its US\$13.1 billion buyout of MyoKardia last year.

There are no more mega M&A moves like BMS' Celgene deal in the imminent future. Analysts predict many deals will land in the US\$5 to US\$20 billion range over the next 12 to 18 months. Among the hottest markets will be oncology, immunology and gene therapy given the unmet needs for highly effective treatments and rapidly evolving technology.

The 15 top selling drugs facing expirations totaled more than US\$100 billion in sales in 2020.

MAJOR DRUGS SET TO LOSE PATENTS IN NEXT DECADE



\*Estimated  
Source: Moody's and company filings

## In Brief (cont.)...

of new cases due to the highly transmissible Delta variant could reverse these gains. The study looked at what would have happened without the U.S. vaccination campaign that administered more than 328 million vaccine doses since July 2nd.

- ◆ **U.S. Merck's** spinoff **Organon** is pushing forward as a company dedicated to women's health. This focus will apply to its Japanese business as well, according to company officials. Until the company can build its pipeline in the field, however, Organon will turn to primary care and legacy products for steady cash flow until the women's health franchise takes off, along with its number two business biosimilars.

- ◆ **Moderna** is developing a vaccine to improve upon the annual flu shot. The company has dosed the first patient in a phase 1/2 clinical trial for a new seasonal influenza vaccine. Moderna is developing *mRNA-1010* to protect against common flu strains as recommended by the **World Health Organization** and hopes to improve on traditional flu shots which are typically about 40% to 60% effective.

- ◆ A new study from **CVS Health** is examining the lasting impact of COVID-19 on consumers' healthcare preferences. The "*2021 Health Care Insights Study*" also takes a look at the ways the overall healthcare system has changed to bring about a more individualized healthcare experience that patients want. The study found people starting to seek new avenues of care, using the past year as an opportunity to work on health goals and reexamine priorities.

(Sources: Company Press Releases, Drug Store News, FierceBiotech, FiercePharma, Scrip Intelligence, and World Pharma News)