IFPW FOCUS IFPW

Vol. 28, No. 2 International Federation of Pharmaceutical Wholesalers January 21, 2021

Highlights from JP Morgan's Virtual 2021 Healthcare Conference

(Source: Articles by Scrip Intelligence)

JP Morgan wrapped up its annual Healthcare Conference despite the limitations of the COVID pandemic. The three-day virtual event featured updates from industry leaders and healthcare stakeholders from around the world, giving their insights and perspectives on the upcoming year.

Day 1 Highlights

Executives from Amgen, Vertex, Anlymin, Biomarin, Gilead, Pfizer/BioNTech, and Merck KGaA shared their visions surrounding future business development and challenges/opportunities related to the COVID pandemic.

Amgen's CEO, Bob Bradway, spoke to pressures on the company to generate new drugs and engagement in business development aimed toward substantial revenue growth. He elaborated on the fact that the company was focused on finding opportunities for investment both internally and externally that are a "good fit" for the company.

Pharma manufacturer **Vertex** will direct its focus to business development in 2021, according to its CEO Reshma Kewalraman. The company boasted US$6.3 billion in cash at the end of Q3 with no debt. One of its business development priorities involves the launch of its triple combination drug for cystic fibrosis, *Trikafta* (which can treat up to 90% of CF patients.) Vertex is also pivoting to new therapeutics in several treatment areas.

Biomarin Pharmaceuticals CEO Jean-Jacques Bienaime is confident that there could be enough data to support approval by the U.S. FDA of its hemophilia A gene therapy, *valoctocogene rosaparvovec,* and said Biomarin hopes to meet with the FDA as soon as possible to review data so that determinations can be made regarding next steps. The company plans to file the data with European regulators as well.

Alnylam Pharmaceutcals has set its sights on being one of the top biopharma companies worldwide by 2025 through its by focusing on RNA-interference drugs. Their new business development plan, named Alynylam P 5x25, was unveiled at the conference and aims to have more than half a million patients taking the company's drugs worldwide, as well as at least six approved products and ten pipeline candidates in late-stage development.

Gilead raised sales guidance by about US$1 billion, driven by increased sales of *Veklury (remdesevir)* for the treatment of COVID-19. It also predicts an upward trend of its top-selling HIV therapy *Biktarvy*, according to CEO Daniel O'Day. While 2020 was not a year O'Day wished to repeat, he said he was proud of how Gilead addressed the pandemic and acted on its other priorities, including its US$21 billion acquisition of Immunomedics, Inc.

Pfizer and **BioNTech SE** will be able to supply 2 billion doses of their COVID-19 vaccine worldwide in 2021, up from 1.3 billion doses. This puts them ahead of Moderna, which is predicting shipping 600 million to 1 billion doses. The raised forecast is

(continued on page 2)

In Brief...

- **Walgreens Boots Alliance** beat analysts' expectations for first quarter earnings while reporting a 5.7% increase in overall revenue and solid growth in its American retail pharmacy operations, which had sales of US$27.2 billion (+3.9% year-over-year). WBA reported sales totaling US$36.3 billion for the quarter and a net loss of US$308 million, which resulted from a US$1.5 billion charge from its equity earnings in AmerisourceBergen. "Our first quarter results exceeded expectations as we continue to deliver on our strategic priorities, WBA executive vice chairman and CEO, *Stefano Pessina* said. "As announced yesterday, we have taken a major step forward in our transformation; we are divesting our pharmaceutical wholesale business with plans to use the proceeds to accelerate our investment in healthcare."
- **CureVac** will enlist fellow German company **Bayer** to help provide resources needed to bring its mRNA-based vaccine candidate, *CVnCoV*, to market. The financial terms of the deal were not disclosed but will involve Bayer's support of CureVac with country operations in the EU and other select markets. The partnership also gives Bayer an option to market the vaccine in other territories.
- Pharma manufacturer **Johnson & Johnson (J&J)** plans to announce Phase III results of its single-dose COVID-19 vaccine *JNJ-78436735*, a possible gamechanger in the fight against COVID-19. J&J's single dose vaccine would help simplify immunization programs around the world, and potentially help

(continued on page 2)

Expect More Biopharma Deals in 2021 According to EY

(Sources: EY Firepower for 2021 Report, and an article by Joseph Haas for Drug Store News)

EY released its latest Firepower report and sees a significant rebound in the biopharma industry's M&A activity. The report, released January 11, 2021 in conjunction with the JP Morgan Healthcare Conference, notes that there was US$159 billion of life sciences M&A activity in 2020, down from 2019's record-setting US$306 billion.

Firepower, as defined by EY's life sciences business development group, refers to a company's capacity to fund transactions based on its corporate balance sheet (including cash and equivalents, existing debt, capacity to take on debt, and market capitalization.) In 2020, companies only used 12% of their aggregate firepower, compared with 20% in 2019 with mega-mergers such as Bristol Myers Squibb/Celgene Corporation and AbbVie Inc./Allergan plc.

EY's lead for its global health sciences and wellness strategy unit, Peter Behner, said, "We expected [2020] to come in lower, but possibly close to or above the US$200 billion. That to us is usually a reasonably good year, but then COVID hit hard."

(continued on page 2)

JP Morgan (cont.)...

thanks to new manufacturing capacity at its newly acquired manufacturing site in Marburg, Germany.

Merck KGaA's new incoming CEO Belén Garijo told investors she is ready for the challenges brought on by COVID-19. The company increased guidance twice in 2020, despite COVID lockdowns. She expects 2021 to be another strong year for sales with earnings growth in all three of the company's business sectors.

Day 2 Highlights

Challenges surrounding drug pricing were addressed by **Pfizer** CEO Albert Bourla. When asked about his perspective, he offered, "We have arrived in a situation that we need to reform, that needs to change. I think it has become a unanimous… concern for all of us," he continued. "If you ask any of my peers and friends, they will tell you that one of the highest concerns is that in the U.S., patients are getting their medicines [as] if they don't have insurance, although they do have it." He also noted that financial impact should be spread across industry stakeholders "The companies should contribute, the states should contribute, everybody should contribute to that," he said. "This is a must because it's not a sustainable situation."

Kenneth Frazier, CEO of **Merck & Co.**, elaborated on changes in 2021. It will spin off its Organon women's health business, biosimilars, and legacy brands. For the remainder of the company, it will rely heavily on *Keytruda*. When pushed on the possibility of larger deals, Frazier said Merck doesn't consider company size "the most important aspect" but did acknowledge that it will need to find a sizeable transaction with the loss of exclusivity of *Keytruda* in 2028.

Novartis oncology president, Susan Schaffert, explained that Novatis' deal with BeiGene will add a robust late-stage PD-1 inhibitor as a monotherapy candidate. Novartis' will focus on its four oncology pillars – targeted therapies, cell therapies, immune-oncology and radiotherapies. The addition of a licensing deal for *tislelizumab* will give Novartis the opportunity to have an approved PD-1 in the portfolio, noted Schaffert.

Sanofi head of R&D, John Reed explained that the company is now actively pursuing business development to build its capabilities in gene therapy, a hot area of drug development, but not without its challenges. "We will need partnerships to access a larger toolbox of next-generation tools so we can build the next generation of gene therapy products," he said. Reed also noted that Sanofi is prioritizing cell therapies, pointing to the acquisition of Kiadis Pharma NV and its natural killer cell platform. The "off the shelf" NK technology can be customized to attack specific kinds of cancer.

AbbVie plans to grow without additional deals. CEO Rick Gonzalez outlined how the company expects to produce high-single-digit annual revenue growth in the years after its blockbuster *Humira* loses U.S. patent protection in 2023. New growth will come from *Rinvoq, Skyrizi, Imbruvica,* and *Venclexta* and bolstered by label expansions. Those projections do not factor in any additional business development that AbbVie may initiate in the interim.

Biogen hopes to be the first to bring a disease modifying Alzheimer's drug to market in 2021. It also announced a partnership with Apple to explore the possibilities of using the

EY (cont.)...

In fact, 2020 saw one major M&A deal, AstraZeneca's December acquisition of Alexion Pharmaceuticals for US$39 billion. AstraZeneca's acquisition of Alexion afforded not just pipeline capabilities, but a substantial amount of revenue.

The US$159 billion in life sciences M&A for 2020 was the lowest total since EY began circulating its annual Firepower report in 2014. However, it was not substantially out of line with 2017 and 2018 numbers. "There is ample firepower, so this is not a matter of available firepower for pharma companies," Behner said. EY estimates that the biopharma industry's firepower will increase to between US$1.2 trillion and $1.45 trillion during 2021.

EY also anticipates that 2021 will bring an abatement of the effects of the COVID pandemic, with business returning to something close to "normal" during the second half of the year. Meanwhile a positive result of the pandemic was the decline in the growth gap for biopharma companies. However, clinical trial delays and reduced sales for individual products related to the pandemic may enlarge companies' growth gaps. EY sees this leading to inorganic growth as well as M&A deals.

EY is also predicting that therapeutic focus will act as a major driver to M&A activity. Biopharma companies that derive 50% or more of their revenue from a single therapeutic area often enjoy higher revenue growth, return on capital investment, margins and capitalization than more diversified biopharmas. EY sees six therapeutic areas as deal drivers in 2021 – oncology, immunology, anti-infectives, cardiovascular, central nervous system and diabetes. Different factors may also drive alliance activities, according to analysts. Acquisitions are riskier not only due to higher valuations but also because biopharma companies are investing in higher risk areas such as cell and gene therapy.

In 2020, bioparma spent US$17.8 billion in aggregate upfront payments on alliances, amounting to 13% of the total potential value of such deals, stated Behner. These alliances were driven in part by vaccines as well as technology platforms, including R&D and manufacturing capacity. EY predicts that alliance activity will develop around emerging technologies. Cell and gene therapies, antibody-drug conjugates and anti-infective medications will also play a significant role in the coming year.

In Brief (cont.)...

with progress toward achieving all-important "herd immunity". Results of the trial are expected at the end of January, with approximately 45,000 subjects in the U.S. and Belgium.

- Reuters has reported that **Moderna's** COVID-19 vaccine is unlikely to receive Japanese regulatory approval before May, citing an official with the U.S. firm's Japanese partner **Takeda Pharmaceutical**. *Masayuki Imagawa*, head of Takeda's Japan vaccine business, said that it would take several months to finish a clinical trial in Japan, which is slated to kick off this month. A May approval would be "a best-case scenario". Takeda is responsible for the clinical trial and distribution of the Moderna vaccine in Japan.
- **CVS Health** announced that it is working with **Cancer Treatment Centers of America** to increase access to chemotherapy at home for eligible, fully insured patients. The

(continued on page 3)

JP Morgan (cont.)...

iPhone and Apple Watch to monitor cognitive performance or decline. A multi-year study will begin in 2021 and will include both young and aging adults with a range of cognitive performance measures. Its Alzheimer's drug, *aducanumab*, is pending at the U.S. FDA with an action date of March 7th.

Day 3 Highlights

Presentations from Teva, Relay Therapeutics, UCB, Ionis and Agios highlighted the agenda. **Teva Pharmaceutical** CEO Kare Schultz laid out the company's plans for single digit growth in the near term. While the company had hoped for top-line growth in 2020, COVID-19 disruption put that goal beyond reach. Schulz hopes to turn the corner in 2021, with the main drivers of Teva's improved business position being the stabilization of the U.S. generics market, cycling through the loss of *Copaxone* to generics and the launches of *Austedo* and *Ajovy*. The company continues to pay down debt and work to stabilize business.

Relay Therapeutics will jump into the competitive KRAS inhibitor race this year with a clinical trial in partnership with Roche Holding's Genentech. The trial will combine Relay's SHP2 inhibitor, *RLY-1971* with Genentech's KRAS G12C inhibitor *GDC-6036*. The study will begin in 2021, with an exact timeframe yet to be determined.

While **UCB** started its digital transformation several years ago, COVID-19 has dramatically accelerated the process, explained CEO Jean-Christophe Tellier. From research to development manufacturing and commercialization, the company is being transformed across the value chain. UCB is working with Microsoft Azure (a cloud-based platform) on a program using AI to identify molecules that counteract replication in the SARS-CoV-2 virus. The collaboration was up and running in three days. UCB also launched Nile AI, a digital health company with the ambitious goal of transforming the course of epilepsy, which historically has been the company's main area of focus.

Ionis Pharmaceuticals Inc. CEO Brett Monia expressed confidence that its Phase III drug for hereditary thrasthyretin-mediated (hATTR) amyloidosis polyneuropathy will have a strong competitive edge with regard to efficacy as compared to other drugs. "I don't believe there is anything out there that will show greater efficacy than our LICA medicine," Monia said. The drug, a ligan-conjugated – or LICA - antisense medicine reduces production of the transthyretin protein.

Several weeks ago, **Agios** announced its plan to sell its oncology portfolio to Servier for US$1.8 billion so that it could focus on its drug candidates for genetic diseases (including the drug *mitapivat*) slated to hit the market in 2022 for treatment of pyruvate kinase deficiency. However, the company faced questions about *mitapivat* related to treating sickle cell disease, due to multiple potentially curative therapies and gene-editing treatments in development. Darrin Miles, senior vice president of U.S. commercial and global marketing said that the company did "a significant deep dive into the market" to assess both doctor and patient attitudes. "There's a good deal of excitement, as there should be, around gene therapy, " Miles said. However, the eligible population is limited by the procedures required around administering gene therapies. As a result of Agios' research, the company has been able to confirm that it is limited for 10-15% of the diagnosed population, leaving the vast majority of patients available for other interventions.

In Brief (cont.)...

focus of the partnership will be on minimizing patient exposure to COVID-19 from inpatient or hospital outpatient during the ongoing pandemic while ensuring treatment continuity of critical cancer care.

- **GlaxoSmithKline** and **Vir Biotechnology** announced an agreement with the UK-based *ABILE initiative* to evaluate the drug *VIR-7832d* in patients with mild to moderate COVID in a Phase1b/2a clinical trial. *VIR-7832* is a neutralizing COVID-19 antibody. Preclinical data suggests that *VIR-7832* has the enhanced ability to clear infected cells and the potential to enhance virus-specific T cell function, which could help treat and/or prevent COVID-19 infection.
- The **National Association of Chain Drug Stores (NACDS)** announced that its 2021 NACDS Annual Meeting will be held virtually on April 26-28 due to the COVID-19 pandemic. The virtual event will feature relevant business programs with presenters that include NACDS leadership and industry experts, opportunities for executive meetings between companies to foster discussion and insight, as well as recognition of NACDS' members' service to their communities and nation. Additional information on the virtual Annual Meeting will be available soon on the NACDS website (www.nacds.org).
- New research from the **USC Leonard Davis School of Gerontology** suggests that mitochondria are one of the first lines of defense against COVID-19. The research also identifies key differences in how SARS-Cov-2 interacts with mitochondrial genes when compared with other viruses. This could explain why older adults and people with metabolic dysfunction may have more severe responses to COVID-19 than other individuals. It also provides a starting point for more targeted experiment that may help identify new therapeutics. The study, published January 8th in the *Nature Journal of Scientific Reports*, expands on recent findings that COVID-19 mutes the body's innate inflammatory response by telling mitochondrial genes what to do.
- The **World Health Organization** announced that 95% of the 23.5 million doses of COVID-19 vaccines that have been administered around the world so far have been given in just 10 countries. WHO's Europe Director, *Hans Kluge*, voiced the health agency's most recurring theme of the pandemic: to effectively stop the virus, the world's vaccines must be shared equitably and include distribution in low-income and poor countries.
- Swiss biopharma company, **Debiopharm**, announced the first patient doses with a randomized phase II open-label clinical trial for its antiviral *alisporivir*. The study will be conducted to assess the efficacy and safety of the cyclophilin inhibitor in the treatment of early stage, hospitalized COVID-19 patients who do not require medical ventilation and have not exhibited signs of acute respiratory distress syndrome. This proof-of-concept trial is to evaluate the reduction of the viral load in patients treated with *alisporivir*, with a secondary objective involving the analysis of clinical and radiological efficacy, safety, and tolerability of the compound plus Standard of Care (SOC) as compared to SOC alone.

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