Industry News

- Sermo, a “Yelp-like” platform which allows doctors to rate drugs for other doctors, has 655,000 ratings on more than 4,000 medications a year after launch. More than half the drugs have at least 100 reviews and 18 drugs have more than 1,000. The platform also provides the pharmaceutical industry with insight into real world experiences, effectiveness of educational messaging, and competitive situations. *(Source: FiercePharma, April 30, 2018)*

- The U.S. Supreme Court’s ruling that upheld the constitutionality of Inter Partes Review and recognized the decision to grant a patent is a matter involving public rights. The ruling is important to pharmaceutical companies who have opposed the Inter Partes Review process since it was established in 2011 as it considers patents private property which can only be revoked by court decision. Under Inter Partes Review, the U.S. Patent and Trade Board has the right to decide whether a patent is still eligible. Approximately 80 patents have been partially or totally canceled by the board’s decisions. *(Source: BioSpace, April 25, 2018)*

- After five years of declines, the number of new drug shortages rose to 39 in 2017, up from 26 in 2016 and 2015. At last count, there were 202 medications on the drug shortage list. Manufacturing problems at Pfizer contribute to some of the most troubling shortages. The company has 370 products which are depleted or in limited supply and 102 of them will not be available until 2019. *(Source: Fortune, May 22, 2018; FiercePharma, June 20, 2018)*

- The ten best-selling drugs in the U.S. by revenues in total between 1992 and 2017 were:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Manufacturer</th>
<th>Revenue</th>
<th>For treatment of...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipitor</td>
<td>Pfizer</td>
<td>$94.67 billion</td>
<td>High cholesterol</td>
</tr>
<tr>
<td>Humira</td>
<td>AbbVie</td>
<td>$75.72 billion</td>
<td>Inflammatory diseases</td>
</tr>
<tr>
<td>Nexium</td>
<td>AstraZeneca</td>
<td>$72.45 billion</td>
<td>Acid reflux, ulcers</td>
</tr>
<tr>
<td>Advair</td>
<td>GlaxoSmithKline</td>
<td>$69.08 billion</td>
<td>Asthma, COPD</td>
</tr>
<tr>
<td>Enbrel</td>
<td>Amgen</td>
<td>$67.78 billion</td>
<td>Autoimmune diseases</td>
</tr>
<tr>
<td>Epogen</td>
<td>Amgen</td>
<td>$55.63 billion</td>
<td>Anemia</td>
</tr>
<tr>
<td>Remicade</td>
<td>Johnson &amp; Johnson</td>
<td>$54.67 billion</td>
<td>Autoimmune diseases</td>
</tr>
<tr>
<td>Abilify</td>
<td>Otsuka/Bristol-Myers Squibb</td>
<td>$51.34 billion</td>
<td>Schizophrenia, bipolar disorder, other CNS indication</td>
</tr>
<tr>
<td>Neulasta</td>
<td>Amgen</td>
<td>$47.40 billion</td>
<td>Boost white blood cells during chemotherapy</td>
</tr>
<tr>
<td>Plavix</td>
<td>Sanofi/Bristol-Myers Squibb</td>
<td>$46.48 billion</td>
<td>Prevent heart attack and stroke</td>
</tr>
</tbody>
</table>

  *(Source: FiercePharma, May 14, 2018)*

- GlaxoSmithKline is forecast to lead the vaccine industry by 2024 with $10.74 billion in sales. Merck will follow with $9.40 billion. Sanofi will rise into third place with $8.13 billion trading places with Pfizer who will fall to fourth with $7.26 billion. Sanofi’s growth will be driven by Pentacel and Fluzone, which will add $1.45 billion to company revenues. *(Source: FiercePharma, June 12, 2018)*
The Food and Drug Administration wants to make drugs more affordable and accessible through the promotion of generic competition. Drug makers often prevent access to samples of their branded medications to restrict generic drug development and testing. The FDA has released a list of more than 50 instances in which companies have been blocking access to samples. It will also post a list of inquiries from generic drug companies who report having trouble obtaining samples. (Source: BioSpace, May 18, 2018)

President Trump signed the “right to try” bill into law. It grants terminally ill patients access to drugs which have not been approved by the Food and Drug Administration. (Source: The Hill, May 30, 2018)

The Food and Drug Administration wants to speed up approvals of generic drugs and may also accelerate the process for new drug approvals as well. FDA Commissioner Scott Gottlieb believes companies do not want to be the fourth or fifth drug to be approved in a class and the time to approve a second market entrant is lengthening. Many pharmaceutical companies disagree with his hypothesis and say many drug markets are competitive with little lag between market entrants. Instead, health insurers and pharmacy benefit managers are the key to lowering prices. (Source: Reuters, June 3, 2018)

An annual assessment of U.S. consumer trust in different industries recorded a 13-point drop for the pharmaceutical industry, from 51 to 38. The score of 38, which places the industry in the distrusted range, may be in response to the opioid epidemic, high prices, access difficulties, and uncertainty about the Affordable Care Act. The majority of respondents agreed the industry put profits ahead of patients. Globally, the pharmaceutical industry had a score of 55. (Source: FiercePharma, June 13, 2018)

A new report predicts what the global top-selling drugs will be in 2024:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Manufacturer</th>
<th>2018 (in billions)</th>
<th>2024 (in billions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Humira</td>
<td>AbbVie</td>
<td>$18.92</td>
<td>$15.23</td>
</tr>
<tr>
<td>2) Keytruda</td>
<td>Merck</td>
<td>$3.82</td>
<td>$12.69</td>
</tr>
<tr>
<td>3) Revlimid</td>
<td>Celgene</td>
<td>$8.19</td>
<td>$11.92</td>
</tr>
<tr>
<td>4) Opdivo</td>
<td>Bristol-Myers Squibb</td>
<td>$5.73</td>
<td>$11.25</td>
</tr>
<tr>
<td>5) Eliquis</td>
<td>Bristol-Myers Squibb/ Pfizer</td>
<td>$4.87</td>
<td>$10.54</td>
</tr>
<tr>
<td>6) Imbruvica</td>
<td>AbbVie/Johnson &amp; Johnson</td>
<td>$3.2</td>
<td>$9.56</td>
</tr>
<tr>
<td>7) Ibrance</td>
<td>Pfizer</td>
<td>$3.13</td>
<td>$8.28</td>
</tr>
<tr>
<td>8) Dupixent</td>
<td>Sanofi</td>
<td>$247 million</td>
<td>$8.06</td>
</tr>
<tr>
<td>9) Eylea</td>
<td>Regeneron/Bayer</td>
<td>$6.28</td>
<td>$6.82</td>
</tr>
<tr>
<td>10) Stelara</td>
<td>Johnson &amp; Johnson</td>
<td>$4.01</td>
<td>$6.47</td>
</tr>
</tbody>
</table>

(Source: FiercePharma, June 7, 2018)

Another poll recorded a 14% decline in consumers’ perception that pharmaceutical companies will do the right thing, a 13% drop in willingness to give drug makers the benefit of the doubt, and a 3.7-point decline in overall reputation. Negative media coverage was a strong contributor to the slide in reputation. Concerns about ethics and governance were the primary drivers behind the decline in reputation. The pharma companies with the best reputations were Sanofi, Genentech, Celgene, AbbVie, and Biogen. (Source: FiercePharma, June 18, 2018)
A survey of Americans found 75% favor the idea of putting the list prices of a drug in direct-to-consumer advertisements. The results were similar regardless of political affiliation. (Medical Marketing and Media, June 27, 2018)

Patients and doctors reacted favorably to Amazon’s $1 billion acquisition of PillPack. Reasons for supporting the market-disrupting merger include increased medication adherence, opportunity to get more patient education and support programs to hard-to-reach patients, reduction in medicine costs, and trust in Amazon. Patients did express concern about how Amazon might use their personal medical information. (Source: Medical Marketing and Media, June 29, 2018)

According to the Centers for Medicare and Medicaid Services Open Payments data, makers of drugs and medical devices gave $8.4 billion to doctors and teaching hospitals in 2017, down from $8.8 billion in 2016. The 11.54 million recorded transactions included $4.7 billion in research-related grants, $2.82 billion in non-research related payments for items such as meals and travel expenses, and $927 million in investments held by physicians or family members. (Source: Healthcare Dive, July 3, 2018)

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Pharmaceutical and healthcare companies are forecast to spend $2.84 billion on digital advertising this year, a 12.7% increase. The category will represent only 2.7% of all digital ad spend this year. Spending growth is also projected to slow down to 10.6% next year. Display ads account for 56.3% of spend while search garners 37.1% of industry expenditures. (Source: FiercePharma, July 9, 2018)

The top-spending pharmaceutical brands on television advertising in June were:

1) Humira - AbbVie - $29.8 million spend in June
2) Trulicity - Eli Lilly - $19.9 million
3) Lyrica - Pfizer - $18 million
4) Xarelto - Johnson & Johnson - $14.2 million
5) Xeljanz - Pfizer - $14.16 million
6) Eliquis - Pfizer/Bristol-Myers Squibb - $14 million
7) Verzenio - Eli Lilly - $13.7 million
8) Latuda - Sunovion - $12.1 million
9) Otezia - Celgene - $11.9 million
10) Victoza - Novo Nordisk - $10.4 million

(Source: FiercePharma, July 18, 2018)

Pharmaceutical and medical devices companies funded 28% of total continuing medical education in 2017 with a total investment of $739 million. The funding contributed to 10% of 162,965 CME activities. CME is considered one of the most important marketing tools pharmaceutical companies have at their disposal. Advertising, exhibits, and in-kind support is not counted and CME without any pharmaceutical industry presence is rare. (Source: Medical Marketing and Media, July 23, 2018)

Health and Human Services estimates Medicare Part D beneficiaries could have saved more than $600 million if generics had been substituted for brand name drugs with a total savings of almost $3 billion overall. Medicare spent nearly $9 billion in 2016 on branded products through Part D even though generic equivalents were available. (Source: FDAnews Drug Daily Bulletin, July 26, 2018)
Company News

AbbVie

- AbbVie and Boehringer Ingelheim submitted an application to the Food and Drug Administration seeking approval for risankizumab for the treatment of moderate-to-severe plaque psoriasis. AbbVie will lead future development and global commercialization if the drug is approved. (Source: FirstWord, April 25, 2018)

- AbbVie’s hepatitis C virus treatments recorded $919 million in revenues during the first quarter, a 249% increase year-over-year and significantly higher than analysts’ consensus estimate of $572 million. Mavyret, a pan-genotypic treatment, drove the increase as it gained market share more rapidly than anticipated since its approval last August. (Source: FiercePharma, April 26, 2018)

- AbbVie ended a phase 1 trial of an antibody-drug conjugate for solid tumors after the risks outweighed the benefits. The trial was among patients with colorectal or gastric cancer and was designed to measure dose-limiting toxicities. AbbVie remains committed to oncology research. (Source: FierceBiotech, April 30, 2018)

- Rather than co-pay coupons, AbbVie has begun offering patients pre-paid debit cards to use towards out-of-pocket costs. The change comes after payers have banned the use of copay coupons to cover deductibles. In 2017, privately insured patients used coupons for 18% of branded prescriptions filled and 42% of specialty prescriptions. The coupons cut out-of-pocket expenses for specialty drugs by $261 on average. (Source: FiercePharma, May 18, 2018)

- AbbVie abandoned a plan to raise the price of Imbruvica, its cancer drug. Early this year, AbbVie announced the 140mg dose would be discontinued and four higher dosages would be made available for $400, a 300% increase over the previous price. Public outcry and lobbying by physicians who cited concerns for patient safety lead to the reversal. (Source: FDAnews Drug Daily Bulletin, May 17, 2018)

- The Institute for Clinical and Economic Review (ICER) released a report suggesting AbbVie’s treatment for endometriosis-associated pain, elagolix, could add $5,100 to the cost per patient per year for the treatment of dysmenorrhea and $4,600 per capita to the cost for treating non-menstrual pelvic pain. The analysis used a placeholder price of $7,000. The Food and Drug Administration has not yet approved elagolix. (Source: BioSpace, May 10, 2018)

- AbbVie reported a phase 3 trial of Imbruvica in combination with Roche’s Gazyva in previously untreated patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) met its goal of significantly improving progression-free survival versus Gazyva plus chlorambucil. The combination, if approved, would be the first chemotherapy-free CD20 combination for first-line treatment of CLL. (Source: FirstWord Pharma, May 24, 2018)
AbbVie plans to submit an application to the Food and Drug Administration for approval of upadacitinib, a JAK inhibitor, for the treatment of moderate-to-severe rheumatoid arthritis after the drug met both primary and secondary endpoints in its fifth phase 3 trial. Patients treated with the drug achieved a greater measure of pain reduction than those who took methotrexate. Approximately half the patients taking upadacitinib after six months were in clinical remission compared to 18% on methotrexate. Furthermore, no new safety concerns were reported in this study with only one key adverse event among 631 patients in the trial. (Source: Biopharma Dive, June 6, 2018)

The Food and Drug Administration approved venetoclax for patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least one prior line of therapy. The combination of venetoclax and rituximab was also approved for this patient population. Genentech will commercialize the drug in the U.S. while partner AbbVie owns the rights outside the country. (Source: Seeking Alpha, June 8, 2018; Pharmaceutical Business Review, June 11, 2018)

The Food and Drug Administration criticized AbbVie for its lack of thorough investigation of five deaths linked to the drugs Humira and Venclexta that were manufactured in its North Chicago facility. Historical data on those lots of drugs shows another eight to 11 associated deaths. The company was also cited for failing to document other information related to the drugs. (Source: BioSpace, June 12, 2018)

AbbVie signed a deal with Scripps Research Institute which will give the drug maker exclusive rights for four years to the non-profit’s combination of genetically engineered immune cells and targeted drugs that track down and kill cancer cells. Clinical trials of the treatment are expected to begin next year in patients with lymphoma. (Source: San Diego Union Tribune, June 25, 2018)

AbbVie and Calico, an Alphabet company, reupped their partnership to cure age-related diseases such as cancer and neurodegenerative diseases. The partnership will contribute another $1 billion to bring total funding to $2.5 billion. AbbVie and Calico have more than two dozen early-stage research and development programs underway. (Source: CNBC, June 26, 2018)

The Food and Drug Administration granted priority review status to an application to use AbbVie and Johnson & Johnson’s drug Imbruvica in combination with Roche’s Rituxan for patients with Waldenström’s macroglobulinemia, a rare type of non-Hodgkin’s lymphoma. Imbruvica is already approved as a monotherapy for this blood cancer. The combination therapy decreased risk of disease progression and death by 80%. (Source: FiercePharma, June 26, 2018)

A U.S. District Court in Philadelphia found in favor of the Federal Trade Commission’s allegations that AbbVie illegally kept a monopoly for testosterone replacement drug AndroGel. The court ordered AbbVie pay consumers who were over-charged for the drug $448 million, the largest monetary award in a litigated FTC anti-trust case. Another federal judge in Illinois ordered a new trial in another case involving AndroGel after finding the jury’s decisions contradictory. In this case, an individual plaintiff claimed AbbVie misrepresented the safety of AndroGel and the drug caused a heart attack. (Source: BioSpace, July 2, 2018; FDAnews Drug Daily Bulletin, July 10, 2018)
AbbVie and Johnson & Johnson indicated that adding their drug Imbruvica to the standard-of-care chemotherapy did not improve event-free survival in patients with diffuse large B-cell lymphoma patients who are previously untreated. Improvements were observed in a sub-population of patients and additional analysis is expected. Full results will be presented and published in the future. (Source: FiercePharma, July 11, 2018)

Mylan has signed an agreement with AbbVie which ensures Humira’s exclusivity until 2023 in the U.S. Under the patent licensing agreement, Mylan agreed to delay the launch of its Humira biosimilar and pay AbbVie royalties once the product enters the market. Previously AbbVie signed similar agreements with Amgen and Samsung Bioepis regarding their Humira biosimilars. (Source: BioPharma-Reporter, July 17, 2018)

AbbVie submitted a supplemental application to the Food and Drug Administration asking for approval of Venclexta in combination with a hypomethylating agent or low-dose cytarabine for the first-line treatment of patients with acute myeloid leukemia who are ineligible for intensive chemotherapy. This patient group accounts for roughly two-thirds of AML cases among individuals age 60 and older. (Source: Seeking Alpha, July 12, 2018)

The Food and Drug Administration approved Orlissa as a treatment for pain associated with endometriosis. The drug is expected to be available in August at a price of $845 per month. Orlissa is predicted to receive approval to treat uterine fibroids by 2020 and achieve annual sales exceeding $2 billion by 2025. (Source: FiercePharma, July 24, 2018)

AstraZeneca

AstraZeneca reported a clinical trial which combined its experimental drug tremelimumab with cancer immunotherapy Imfinzi failed to meet the endpoints of extending life or slowing disease progression among patients who have received at least two previous treatments. The study findings are not surprising given that other combinations of a CTLA-4 drug and a PD-L1 immunotherapy have shown little value. (Source: Reuters, April 24, 2018)

AstraZeneca launched a new campaign for its diabetes drug Farxiga. The campaign highlights “F-words” that help manage type 2 diabetes such as food, fitness, and Farxiga. Advertisements feature active people engaged in dancing, swimming, running, and eating out. The campaign includes television, print, digital, and social media channels. (Source: FiercePharma, April 25, 2018)

AstraZeneca’s Fasenra did not meet its primary goal in a phase 3 trial among patients with moderate to very severe chronic obstructive pulmonary disease. As compared to placebo, adding Fasenra to a dual or triple-inhaled therapy did not decrease exacerbations in COPD sufferers. AstraZeneca also reported Fasenra is exceeding sales expectations as an add-on maintenance therapy for patients with severe asthma. (Source: BioSpace, May 11, 2018)
AstraZeneca released data from two phase 3 trials evaluating Symbicort Turbuhaler as an anti-inflammatory reliever as needed in patients with mild asthma. Symbicort Turbuhaler showed superior asthma-symptom control and a 64% reduction in exacerbations versus a short-acting beta2-agonist (SABA), also used as needed. Compared to a twice-daily budesonide maintenance therapy plus SABA as needed, Symbicort Turbuhaler was found to be non-inferior. (Source: PharmaTimes, May 18, 2018)

The Food and Drug Administration approved Lokelma for the treatment of adults with hyperkalemia. The drug, formerly known as ZS-9 was rejected by the FDA in 2016 and 2017 due to deficiencies in manufacturing facilities. (Source: FirstWord, May 21, 2018)

AstraZeneca released its first advertising campaign for respiratory drug Fasenra. The commercial features potential patients watching actors portray scientists on a television answer questions about eosinophilic asthma posed by a room of scientists and doctors. The patients are then shown reacting as they go about their daily life. The ad hopes to convey that scientists are sharing important information about uncontrolled asthma and that elevated levels of eosinophils may be a potential cause of severe asthma. (Source: FiercePharma, May 21, 2018)

AstraZeneca announced Imfinzi demonstrated positive overall survival data in a phase 3 trial in patients with unresectable stage 3 non-small cell lung cancer and whose cancer has not progressed after platinum-based chemotherapy and radiation therapy. An Independent Data Monitoring Committee said the drug had met the second of two primary endpoints: statistically-significant overall survival benefit with clinically-meaningful improvement in patients on Imfinzi as compared to placebo. (Source: BioSpace, May 25, 2018)

AstraZeneca’s Fasenra failed to achieve its primary endpoint in a trial of patients with moderate-to-very-severe chronic obstructive pulmonary disease in a second phase 3 trial. The company will analyze the data from both trials and decide how to proceed. (Source: BioSpace, May 30, 2018)

AstraZeneca’s CEO told shareholders the drug maker plans to disclose payments to doctors in all countries where it has commercial activities, even where it is not required. The company does business in more than 100 countries. (Source: FiercePharma, June 4, 2018)

AstraZeneca reported Lynparza in combination with abiraterone delayed disease progression in metastatic castration-resistant prostate cancer patients in a phase 2 trial. Abiraterone is the standard-of-care treatment for this cancer type. The patients in the combination arm had a median radiologic progression-free survival of 13.8 months versus 8.2 months in the abiraterone monotherapy arm. (Source: Pharmaceutical Business Review, June 5, 2018)

AstraZeneca and Eli Lilly decided to stop two late stage trials of an Alzheimer’s drug after an independent data monitoring committee determined the drug would not meet its goals. The companies will continue to jointly develop another experimental Alzheimer’s drug currently in an early-stage trial. (Source: The Wall Street Journal, June 12, 2018)
A phase 3 trial of Lynparza as a first-line maintenance therapy for women with BRCA-mutated advanced ovarian cancer demonstrated a significant improvement in progression-free survival compared to placebo. The drug, jointly developed by AstraZeneca and Merck, is the only PARP inhibitor to show significant activity in this setting. The study included patients who were in clinical complete or partial response following platinum-based chemotherapy. (Source: FirstWord Pharma, June 27, 2018)

AstraZeneca has entered into a research and development collaboration with 4D molecular Therapeutics to develop a gene therapy for patients with chronic lung disease. (Source: BioPharma-Reporter, July 13, 2018)

AstraZeneca and Immunomedics are collaborating on studying the combination of AstraZeneca’s Imfinzi and Immunomedics’ sacituzumab govitecan as a frontline treatment for patients with triple-negative breast cancer and urothelial cancer. (Source: Pharmaceutical Business Review, July 24, 2018)

AstraZeneca announced selumetinib failed to meet its primary endpoint in a trial as a treatment for thyroid cancer. It previously failed in trials for KRAS mutation-positive non-small cell lung cancer and metastatic uveal melanoma. Selumetinib has been “removed from phase 3” per the drug maker though it is still in trials for the treatment of neurofibromatosis type 1. (Source: FierceBiotech, July 26, 2018)

Bayer News

Bayer has scheduled appearances at 50 events across the U.S. to raise awareness of colorectal cancer. An inflatable giant, interactive colon will make stops at community fairs, medical centers, and 5K races. The tour is in partnership with patient advocacy organization Colorectal Cancer Alliance. Bayer’s Stivarga is approved to treat the disease. (Source: FiercePharma, May 10, 2018)

The U.S. Department of Justice’s Antitrust Division approved Bayer’s acquisition of Monsanto after it agreed to sell $9 billion in assets. The deal is expected to close by the end of June and will result in the world’s largest agriculture supplies business. (Source: Reuters, May 29, 2018)

German media reports Bayer is reviewing its pharmaceutical research and development locations and that up to 1,000 positions could be eliminated as part of the review. (Source: FirstWord Pharma, May 31, 2018)

The Food and Drug Administration awarded priority review status to larotrectinib, a cancer drug developed by Bayer and Loxo Oncology, for patients with tumors that share a rare mutation. If approved, the drug is forecast to achieve annual sales of $500 million to $1 billion. (Source: FDAnews Drug Daily Bulletin, May 31, 2018)
Bayer launched a new corporate campaign to connect its branded products in pharmaceuticals, consumer health, animal health, and agriculture to the parent name. The ad covers Bayer’s history and thanks the audience for trusting in the company then and now. The campaign will encompass print, digital, social, radio, and television media. (Source: FiercePharma, July 18, 2018)

Bayer is teaming up with MIT’s Broad Institute and Harvard to launch the Precision Cardiology Laboratory. The new collaboration will focus on developing new therapies for heart failure through scientific insights about the heart. The Broad Institute and Bayer have previously partnered on an oncology program. (Source: Pharmaceutical Business Review, July 2, 2018)

Bayer introduced myMentor, a peer-to-peer support group for patients with pulmonary arterial hypertension (PAH) or chronic thromboembolic pulmonary hypertension (CTEPH). Through a dedicated website, patients can identify a mentor and schedule a confidential call with a longtime patient to ask questions. The website shows photos of the mentors and provides information about their gender, age, condition, and when they were first diagnosed. Bayer markets Adempas, a drug approved to treat both conditions. Sales of Adempas increased 11% year over year in the first quarter of 2018. (Source: FiercePharma, July 13, 2018)

**Bristol-Myers Squibb News**

Bristol-Myers Squibb has halted two phase 3 clinical trials of an IDO1 inhibitor it acquired through license from Flexus Biosciences. The decision was made after Incyte’s rival IDO drug in combination with Merck’s Keytruda failed to meet its primary endpoint in a trial. BMS says the drug may be evaluated at a later date once scientists have a better understanding of why Incyte’s drug failed. (Source: FierceBiotech, May 1, 2018; FirstWord Pharma, May 1, 2018)

Bristol-Myers Squibb expanded their relationship with Flatiron Health to include the formation of a joint scientific advisory board focused on using real-world evidence in regulatory submissions. BMS would like to use real-world data in its oncology research. The three-year deal includes broader access to Flatiron and Foundation Medicine’s joint database of de-identified clinical and genomic data which has been gathered from approximately 20,000 patients across many tumor types. (Source: FierceBiotech, May 2, 2018)

In a recent survey, Bristol-Myers Squibb was ranked as the most trusted drug maker among those physicians who had recent digital interaction with the company. Ninety-one percent of qualified respondents agreed BMS was a trusted partner and 82% agreed it provides the most up-to-date information and services online. (Source: FiercePharma, May 9, 2018)

Bristol-Myers Squibb is teaming up with Gritstone Oncology to test Opdivo and Yervoy in combination with personalized tumor-specific neoantigens among patients with solid tumors such as non-small cell lung, gastroesophageal, bladder, and colorectal cancers. (Source: FierceBiotech, July 19, 2018)
Bristol-Myers Squibb announced the combination of Empliciti, pomalidomide, and low-dose dexamethasone in patients with relapsed/refractory multiple myeloma achieved its primary endpoint in a phase 2 study. The trial data showed an improvement in progression-free survival for patients treated with all three drugs as compared to pomalidomide and dexamethasone alone. The patients had received at least two prior therapies. (Source: Pharmaceutical Business Review, June 18, 2018)

In a clinical trial, Bristol-Myers Squibb segmented a group of patients whose tumors do not have the PD-L1 biomarker to determine if the combination of Opdivo and Yervoy and Opdivo and chemotherapy worked better in patients with high levels of tumor mutational burden (TMB). The data may help understand which patient populations respond best to different combinations and save patients from ineffective treatments. (Source: FiercePharma, June 4, 2018)

The Food and Drug Administration accepted Bristol-Myers Squibb’s application for the use of Opdivo in combination with low-dose Yervoy in the first-line treatment of non-small cell lung cancer in patients with mutational burden at or above 10 mutations per megabase. This is the first application for a combination of two immuno-oncology drugs for lung cancer to be accepted by the FDA. (Source: Seeking Alpha, June 21, 2018)

The Food and Drug Administration approved the use of Bristol-Myers Squibb’s combination of Opdivo and Yervoy in patients with microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer. Approximately 5% of metastatic colorectal cancer patients have those biomarkers and they are less likely to benefit from conventional chemotherapy. In clinical trials, the combination therapy achieved response from 55% of patients compared to 31% of patients who only received Opdivo. (Source: FiercePharma, July 11, 2018)

Eli Lilly and Company News

Eli Lilly is buying AurKa Pharma, an oncology company, for $110 million upfront with up to $465 million in milestone payments. AurKa is developing an Aurora kinase A inhibitor which is in phase 1 clinical trials for multiple forms of solid tumors. (Source: BioSpace, May 14, 2018)

Eli Lilly announced it is purchasing ARMO BioSciences for $1.6 billion. Focused on immunotherapies, ARMO’s leading drug candidate, pegilodecakin, is designed to stimulate the survival, expansion, and tumor-killing ability of a particular type of white blood cell. It is in late state trials for pancreatic cancer which are expected to conclude in 2020. (Source: The Wall Street Journal, May 10, 2018)

Eli Lilly announced a phase 3 trial of Taltz as a treatment for Ankylosing Spondylitis met its primary and secondary endpoints. Taltz showed statistically significant improvement in systems as measured by the proportion of patients who achieved Assessment of Spondyloarthritis International Society 40 response at 16 weeks compared to placebo. (Source: BioSpace, June 28, 2018)
Eli Lilly reported mixed results for two late stage studies of galcanezumab as a treatment for cluster headaches. In the first trial with patients suffering from episodic cluster headaches, the CGRP inhibitor met its primary endpoint of significantly reducing weekly cluster headache attacks compared to placebo. In the second evaluation with patients who have chronic cluster headaches, galcanezumab failed to meet its main goal of an overall mean change from baseline in weekly cluster headache attack frequency. (Source: FirstWord Pharma, May 15, 2018)

The Food and Drug Administration approved a janus kinase 1/2 inhibitor baricitinib, developed by Eli Lilly and Incyte, for the treatment of moderate-to-severe rheumatoid arthritis in patients who had inadequate response to TNF inhibitors. However, the agency only approved the lower of two doses based on safety concerns and required a boxed warning about potentially serious side effects. Lilly will be required to conduct a long-term safety study. The drug will be sold under the brand name Olumiant when it launches in the second quarter. (Source: Biopharma Dive, June 1, 2018)

Eli Lilly presented a study using retrospective claims data which showed patients using Trulicity for diabetes stayed on their treatment longer and were better at taking the drug as directed as compared to Novo’s Victoza and AstraZeneca’s Bydureon, which are other drugs in the GLP-1 class. The research has limitations, but Lilly hopes it will help prescribers understand real world experience. (Source: FiercePharma, June 25, 2018)

Hours after being granted a patent for ixekizumab, Genentech filed a patent infringement suit against Eli Lilly for Taltz, a drug that has been on the market for two years. Genentech claims because Taltz’ active ingredient is ixekizumab, a humanized monoclonal antibody that inhibits the immunology pathway IL-17, it infringes on their patent. Genentech seeks royalties and damages from Lilly but not a permanent injunction. (Source: FDAnews Drug Daily Bulletin, July 10, 2018)

Eli Lilly currently has three next-generation oncology drugs on the market: Cyramza, Lartruvo, and Verzenio. All three are supported with marketing campaigns that seek to tell stories of real patients in creative ways. The oncology marketing team seeks to listen, hear what patients need, and then push creativity to meet the needs of those living with cancer. (Source: FiercePharma, July 11, 2018)

Eli Lilly and Pfizer shared results from a 16-week phase 3 clinical trial of tanezumab in patients with osteoarthritis pain. Tanezumab met all three co-primary endpoints as measured by three scales related to osteoarthritis. The drug was administered subcutaneously and compared to placebo. Only one percent of participants left the trial due to side effects. (Source: BioSpace, July 18, 2018)

Eli Lilly and Boehringer Ingelheim reported their diabetes drug Tradjenta met its primary endpoint in a cardiovascular outcome trial. The drug demonstrated similar cardiovascular safety compared with placebo. The primary endpoint was measured as time to first occurrence of cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke. (Source: Pharmaceutical Business Review, July 20, 2018)
During its second quarter earnings presentation, Eli Lilly said it will file for an initial public offering for Elanco, its animal health business. Executives believe the move will maximize shareholder value and allow Lilly to focus more on the human pharmaceutical business. (Source: BioSpace, July 24, 2018)

Eli Lilly signed a multi-year agreement which will give it exclusive use of Anima Biotech’s Translation Control Therapeutics platform to discover and develop translation inhibitors for several target proteins. Lilly will pay $30 million upfront plus another $14 million in research funding. Anima will be eligible for more than $1 billion in future milestones as well as single-digit tiered royalties on sales of any products development under the deal. (Source: FirstWord Pharma, July 23, 2018)

Eli Lilly has submitted an application to the Food and Drug Administration for approval to use its nasal glucagon for the treatment of severe hypoglycemia in adults and children. If approved, it would be the first nasal dry powder spray rescue treatment for low blood glucose emergencies. (Source: Healio, July 26, 2018)

**GlaxoSmithKline News**

The Food and Drug Administration expanded the use of GlaxoSmithKline’s Trelegy Ellipta to include long-term, once-daily treatment of airflow obstruction in patients with chronic obstructive pulmonary disease. Removing a boxed warning on the drug was also approved based on recent safety updates for the medication class. (Source: Seeking Alpha, April 24, 2018)

The Food and Drug Administration approved GlaxoSmithKline’s Arnuity Ellipta for maintenance treatment of asthma in patients as young as 5 years old. Previously, the drug was approved for patients 12 years old and older. (Source: Seeking Alpha, May 21, 2018)

GlaxoSmithKline’s shingles vaccine Shingrix posted sales of $150 million in the first quarter, nearly triple the $55 million projection. As a result, Glaxo’s overall vaccine sales increased by 13% to $1.7 billion, though they still remain the smallest unit by revenue. The company forecasts Shingrix sales to reach $600 million for the year. (Source: FiercePharma, April 30, 2018)

The Centers for Disease Control and Prevention reported that during the first four months after the launch of Shingrix, 13 administration errors were reported. As a result, GlaxoSmithKline has upped its provider education efforts with campaigns through the Immunization Action Coalition, the National Foundation for Infectious Disease, and the American College of Physicians. (Source: FiercePharma, June 5, 2018)

Mylan announced the Food and Drug Administration informed them that its generic version of GlaxoSmithKline’s Advair Diskus had “minor deficiencies” and would not be approved at this time. The FDA has also declined to approve a generic version of Advair from Novartis. (Source: BioSpace, June 14, 2018)
GlaxoSmithKline’s two-drug regimen for HIV met the primary end points of two phase 3 trials. The regimen of Glaxo’s Tivicay in combination with either lamivudine or Truvada demonstrated non-inferiority to a three-drug regimen in treating naïve HIV-1 infected adults. (Source: FirstWord Pharma, June 14, 2018)

GlaxoSmithKline launched a new meningitis B awareness campaign which targets students about to enter college and their parents. The ads – appearing in television, print, digital, in-office, and social media – use an animation style designed to grab attention and convey the potential dangers of the virus. Fewer than 10% of all teenagers have received the vaccine for meningitis B according to the CDC and most people don’t realize there are two different types of vaccines. (Source: FiercePharma, June 13, 2018)

The Centers for Disease Control and Prevention noted on their website that GlaxoSmithKline has introduced limits on Shingrix orders due to high levels of demand. Delays shipping out the vaccine are also reported. The CDC expects the delays and limits will continue through the end of the year. GSK has decided to postpone its consumer education activities including television advertising until inventory levels are higher. As of May, more than 1.5 million people received the vaccine since its approval in October 2017. (Source: FiercePharma, June 21, 2018)

GlaxoSmithKline sold the rights to an experimental dermatology drug, tapinarof, to Dermavant Sciences. Under the agreement, GSK will receive $198 million upfront and potential milestone payments of up to $132 million. In exchange, Dermavant will hold global rights, excluding China. The drug has been in phase 1 and 2 trials as a treatment for plaque psoriasis and atopic dermatitis and showed positive results in both. (Source: FirstWord Pharma, July 12, 2018)

A Food and Drug Administration advisory committee voted 13-0 in favor of the efficacy of GlaxoSmithKline’s tafenoquine for the radical cure and prevention of relapse of Plasmodium vivax, a common form of malaria. The committee voted in favor of the safety of the therapy 12-1. The one dose treatment was deemed safe for infected patients age 16 and up. (Source: FDAnews Drug Daily Bulletin, July 16, 2018; FierceBiotech, July 16, 2018)

GlaxoSmithKline’s chairman is reportedly discussing with large shareholders the idea of creating a standalone company focused on pharmaceuticals and vaccines. The idea is in response to investor pressure to spin-off the consumer products division. The pharmaceutical division recorded $22.7 billion in sales, more than half of the company’s revenue. Vaccines accounting for 17% of revenue with sales of $6.8 billion. (Source: FirstWord Pharma, July 20, 2018)

ViiV Healthcare presented data from studies showing that after 100 weeks, 89% of patients who had switched from a 3- or 4-drug regimen to Juluca, a 2-drug combination, maintained viral suppression. Of the 513 participants who took the combination of dolutegravir and rilpivirine for 100 weeks, 13 experience snapshot virologic non-response and 6 met the confirmed virologic withdrawal criterion while 34 withdrew due to adverse events. (Source: MD Magazine, July 24, 2018)
GlaxoSmithKline revealed their strategy for research and development going forward. A centerpiece of the strategy is a focus on using genetic data to understand the human body and then develop medicines which target mechanisms of action that have strong genetic validations. GSK has entered a four-year collaboration with 23andMe to use their extensive genetic database to discover novel drug targets. GSK will also use the database to better identify potential recruits for clinical trials. The company reported it currently has 27 immunomodulatory new molecular entities in its clinical pipeline which represent about 60% of the total pipeline. GSK also announced a new restructuring program will deliver $525 million in annual cost savings by 2021 which will be reinvested into R&D. (Source: BioSpace, July 25, 2018; FirstWord Pharma, July 25, 2018)

GlaxoSmithKline announced a Food and Drug Administration advisory panel, by a vote of 16-3, did not support the use of Nucala as an add-on to inhaled corticosteroids for the treatment of exacerbations of chronic obstructive pulmonary disease guided by blood eosinophil counts. The panel urged GSK to further characterize the patient population who would be most likely to benefit from the drug. GSK said it would continue to work with the FDA to address concerns. (Source: FirstWord Pharma, July 25, 2018)

Johnson & Johnson News

Johnson & Johnson sold the U.S. and Canadian rights to Pancreaze, an exocrine pancreatic insufficiency treatment, to Vivus. Vivus paid $135 million for the drug whose 2017 sales have not been disclosed. (Source: Genetic Engineering & Biotechnology News, May 1, 2018)

Johnson & Johnson purchased oncolytic immunotherapy startup BeneVir Biopharm for $140 million upfront and up to $900 million in milestone payments. BeneVir designs viruses which get into cancer cells, replicate, and kill their host but can avoid being consumed by T cells. (Source: FierceBiotech, May 2, 2018)

Johnson & Johnson started a clinical trial program to study Tremfya in Crohn’s disease in an expected 2,000 patients. (Source: FiercePharma, July 11, 2018)

Johnson & Johnson shared trial results of esketamine which showed the drug improved the efficacy of conventional oral antidepressants in patients with treatment-resistant depression. J&J expects to file an application for approval in the second half of the year. If approved, the nasal spray formulation will be the first new approach to treating major depressive disorder in 50 years. (Source: FierceBiotech, May 7, 2018)

The Food and Drug Administration approved Johnson & Johnson’s Darzalex in combination with Takeda’s Velcade and prednisone in first-line multiple myeloma patients who are transplant ineligible. Darzalex is the first monoclonal antibody to gain approval for use in newly diagnosed patients. It is the drug’s fifth approval for myeloma overall. (Source: FiercePharma, May 8, 2018)
A phase 3 trial of Johnson & Johnson’s Erleada found the androgen receptor inhibitor significantly reduced the risk of prostate specific antigen progression in patients with non-metastatic castration-resistant prostate cancer. In combination with androgen deprivation therapy, Erleada decreased the risk of PSA progression by 94% as compared to placebo. Metastasis-free survival was improved by two years. Median time to response was 29 days. (Source: Pharmaceutical Business Review, May 21, 2018)

Johnson & Johnson halted two clinical trials of its experimental Alzheimer’s disease drug atabecestat citing an unfavorable risk-benefit profile. Specifically, the drug caused elevations of liver enzymes. (Source: Genetic Engineering & Biotechnology News, May 18, 2018)

Johnson & Johnson ended two studies which paired Darzalex with PD-1/PD-L1 immuno-oncology therapies after the combinations failed to show a benefit. One study combined Darzalex with Roche’s Tecentriq to treat non-small lung cancer patients after a data monitoring committee noted an increase in mortality-related events. The other was evaluating it with J&J’s own PD-1 candidate in patients with multiple myeloma. (Source: FiercePharma, May 29, 2018)

Kroger and Walgreen filed a lawsuit against Johnson & Johnson claiming the drug maker used exclusionary contracts and bundled discounts to keep insurers from covering biosimilars of its drug Remicade. The plaintiffs contend J&J’s actions prevented the biosimilars from achieving a higher market share and lowering the purchase price of Remicade. (Source: FDAnews Drug Daily Bulletin, June 11, 2018)

The Food and Drug Administration delayed a decision on including cardiovascular benefits information on Johnson & Johnson’s diabetes drug’s label. J&J has applied for an indication that Invokana reduces the risk of major cardiovascular events in patients with type 2 diabetes. The FDA expects to hand down a decision in October. Competitor Jardiance already has the indication on its label. (Source: FiercePharma, July 17, 2018)

A trial of Johnson & Johnson’s diabetes drug Invokana was ended early when the drug achieved its pre-specified endpoints of the study. Invokana was being evaluated as an add-on therapy for patients with chronic kidney disease and type 2 diabetes. The trial considered the effect on time to dialysis or kidney transplantation, levels of serum creatinine, and renal or cardiovascular death when the SGLT2 drug was added to the standard of care. (Source: BioSpace, July 17, 2018)

Johnson & Johnson’s received approval from the Food and Drug Administration for the use of Symtuza in adult HIV patients who are either treatment-naïve or virologically suppressed on a stable antiretroviral regimen. The approval came with a black-box warning for post-treatment acute exacerbation of hepatitis B. Symtuza is the first and only complete darunavir-based single-tablet regimen for the treatment of this patient population. (Source: FiercePharma, July 19, 2018)

Johnson & Johnson reported its “mosaic” HIV vaccine elicited an immune response that lasted one year after vaccination in all participants who received it. Trials are continuing in five African countries. (Source: FiercePharma, July 24, 2018)
Merck News

The Food and Drug Administration awarded priority review status to the combination of Merck’s Keytruda and Eli Lilly’s Alimta plus platinum chemotherapy as a first-line treatment for metastatic non-squamous non-small-cell lung cancer (NSCLC). A final decision will be made by September 23. Keytruda and chemotherapy reduced the risk of death by 51% versus chemotherapy alone according to data Merck submitted with its application. (Source: FirstWord Pharma, April 30, 2018)

Merck expanded its agreement with Moderna to include mRNA-5671, a mRNA KRAS cancer vaccine. The vaccine will be tested in combination with immune-oncology treatments. KRAS mutations occur in 90% of pancreatic cancers, 45% of colon cancers, and 25% of lung cancers. No effective treatments have been developed for these mutations. (Source: FierceBiotech, May 4, 2018)

Merck & Co. submitted an application to the Food and Drug Administration asking for approval to use Keytruda as a first-line treatment for patients with metastatic squamous non-small-cell lung cancer. Subsequently, the drug maker announced a phase 3 study of Keytruda in combination with carboplatin-acklitaxel or Celgen’s Abraxane demonstrated that treatment resulted in significantly longer overall survival and progression-free survival than chemotherapy alone. (Source: FirstWord Pharma, May 3, 2018; FirstWord Pharma, May 23, 2018)

Merck and OncoSec Medical announced a second clinical trial which will combine Merck’s Keytruda and OncoSec’s ImmunoPulse IL-12 to treat patients with locally advanced and inoperable or metastatic triple-negative breast cancer following the failure of systemic chemotherapy or an immunotherapy. OncoSec will sponsor and fund the study and Merck will provide Keytruda. A similar arrangement was made for a phase 2 trial of the combination for the treatment of metastatic melanoma that progressed after an anti-PD-1 therapy. (Source: FierceBiotech, May 8, 2018)

A phase 2 clinical trial of Merck’s Keytruda as a first-line therapy for patients with advanced clear cell renal cell carcinoma showed an overall response rate of 38.2%. In patients who tumors expressed PD-L1, the overall response rate was 50%. In another group with intermediate or poor prognosis risk, the overall response rate was 42%. The lead investigator called the results encouraging for this difficult-to-treat cancer. (Source: Pharmaceutical Business Review, June 4, 2018)

The Food and Drug Administration approved Keytruda for the treatment of recurrent or metastatic cervical cancer in patients whose disease progressed on or after chemotherapy. (Source: Pharmaceutical Business Review, June 13, 2018)
The Food and Drug Administration decided to restrict the use of Keytruda in locally advanced or metastatic urothelial cancer after decreased survival was observed when it was used as a monotherapy as compared to chemotherapy. Keytruda’s new label for this indication will be changed to say it is approved for patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing therapy and whose tumors express PD-L1 or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status. (Source: FDAnews Drug Daily Bulletin, July 6, 2018)

The Food and Drug Administration accepted Merck’s marketing application asking to approve the use of Gardasil 9 for women and men age 27 to 45 for the prevention of certain cancers and diseases caused by the nine human papillomavirus types the vaccine is effective against. Gardasil is currently approved for individuals age 9 to 26. The FDA awarded priority review status and a decision is expected by October 6. (Source: Seeking Alpha, June 13, 2018)

The Food and Drug Administration accepted Merck’s application asking for the approval of Keytruda as a treatment for advanced liver cancer. The application was designated for priority review and its action date is November 9. (Source: Seeking Alpha, July 11, 2018)

Merck reported a phase 3 trial of Keytruda for the first-line treatment of recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) met a primary endpoint of overall survival in patients who tumors expressed PD-L1. An interim analysis found Keytruda as a monotherapy resulted in significantly longer overall survival compared to the current standard of care for HNSCC in a first-line setting. (Source: FirstWord Pharma, July 25, 2018)

Merck announced it would lower prices by 10% or more on certain products. It will not cut the cost of its blockbuster cancer treatment Keytruda or diabetes drug Januvia. The cost of hepatitis C drug Zepatier will be reduced by 60% – a move that doesn’t mean much for a drug whose price after discounts approaches zero. Six other products which will have lower prices are drugs that have lost patent protection and are available from other manufacturers as low-cost generics. Merck also said it would not increase the average net price of its products above the inflation rate for the rest of the year. (Source: The New York Times, July 19, 2018)

For the first time, Keytruda reported higher sales than immuno-oncology rival Opdivo, a Bristol-Myers Squibb drug. In the second quarter of 2018, Keytruda recorded $1.66 billion in sales, an 89% over the same period a year earlier. Opdivo had sales of $1.62 billion in the quarter, a 36% year-over-year increase. Roche’s Tecentriq, another PD-L1 inhibitor, had sales of $321 million for the quarter, a 37% increase. (Source: BioSpace, July 27, 2018)
Pfizer News

▶ The Food and Drug Administration declined to approve Pfizer’s biosimilar of Roche’s Herceptin. The FDA said more technical information was needed and emphasized the data request did not relate to the drug’s safety or efficacy. (Source: FirstWord Pharma, April 23, 2018)

▶ Pfizer’s meningitis B vaccine Trumenba was awarded a breakthrough designation by the Food and Drug Administration for its use in children as young as 1 year. Pfizer’s vaccine is lagging far behind GlaxoSmithKline’s Bexsero in sales and the new approval could give it a lift. Bexsero is also seeking approval for use in children 2 years old and up. (Source: FiercePharma, April 24, 2018)

▶ Pfizer launched a new marketing campaign emphasizing the diversity of its scientists. The newest effort in the “Driven to Discover” series shows actual Pfizer employees of different races, religions, ages, and sexual orientations. The employees take turns saying the words “We come from different places. We look different ways. We live different ways. We love different ways. We worship different ways. But there’s much that we all share. To bring the boldest, brightest thinking to the search for life-saving cures.” The ad then goes on to ask people to join the team. (Source: FiercePharma, April 30, 2018)

▶ Pfizer announced it is ceasing five phase 1 clinical trials for potential cancer drugs including one for a CD19 molecule targeted cytotoxicity CAR-T, one for a chemokine receptor 2 antagonist for pancreatic cancer, and three for a CD137 agonist monoclonal antibody. The company is also stopping development of an acetyl-Coenzyme A carboxylase alpha and beta inhibitor for acne. (Source: FierceBiotech, May 1, 2018)

▶ When asked by analysts what R&D programs Pfizer expects to drive future growth, CEO Ian Reed said he would choose their vaccines, especially the Clostridium difficile vaccine which is undergoing a 16,000-patient phase 3 trial. The market value for a C. difficile vaccine is projected to be $1 billion. (Source: FiercePharma, May 7, 2018)

▶ Pfizer is expanding its partnership with Chinese start-up ZtalPi to include the development of an artificial intelligence-powered platform to model small-molecule drugs. The platform will help predict the pharmaceutical properties of a broad range of molecular compounds to facilitate drug discovery and development. (Source: FierceBiotech, May 9, 2018)

▶ The Food and Drug Administration approved Retacrit, a biosimilar to Amgen’s Epogen and Johnson & Johnson’s Procrit, for the treatment of anemia. Specifically, Retacrit can be used to treat a drop in red blood cells caused by chronic kidney disease, chemotherapy, or the use of zidovudine in HIV patients. Epogen recorded $1.1 billion in sales last year while Procrit posted $972 million. (Source: Reuters, May 15, 2018)
Pfizer began human testing of an early stage vaccine against RSV, a respiratory virus that annually leads to the death of an estimated 120,000 children worldwide. In the U.S., 177,000 older adults are hospitalized for RSV each year. The initial trial will test the vaccine in adults 18 to 49 and 50 to 85 to gather information on safety and tolerability. (Source: FiercePharma, May 23, 2018)

Pfizer agreed to pay $24 million to settle a federal investigation into donations to charities which help Medicare patients pay for prescriptions for specific drugs. The company noted the settlement was not an admission of facts or liability. (Source: The Wall Street Journal, May 24, 2018)

The Food and Drug Administration awarded breakthrough therapy status to Xalkori for the treatment of metastatic non-small cell lung cancer with MET exon 14 alternations with disease progression on or after platinum-based chemotherapy. The same designation was granted for Xalkori for relapsed or refractory systemic anaplastic large cell lymphoma that is anaplastic lymphoma kinase-positive. Xalkori, a tyrosine kinase inhibitor, is the only FDA-approved treatment for ALK-positive and ROS1-positive metastatic NSCLC. (Source: Seeking Alpha, May 29, 2018)

The Food and Drug Administration approved expanding the indication for Pfizer’s Xeljanz to include adults with moderately-to-severely active ulcerative colitis. This is the first approval of an oral therapy for chronic use to treat this condition. (Source: FirstWord Pharma, May 30, 2018)

Pfizer presented phase 3 trial data which demonstrated dacomitinib resulted in better overall survival in patients with non-small cell lung cancer as compared to Iressa. Participants in the dacomitinib arm had a mean overall survival of 34.1 months compared to 26.8 months for those in the Iressa arm. However, dacomitinib, if approved, may struggle to compete with AstraZeneca’s Tagrisso which has a better safety profile and can treat patients with CNS metastases. (Source: FierceBiotech, June 5, 2018)

Pfizer has committed to making $600 million available to its venture capital fund, Pfizer Ventures. It has designated 25% of those funds for investment in startups focused on neuroscience, a field from which the pharmaceutical company has internally retreated. (Source: FierceBiotech, June 6, 2018)

Pfizer announced the Food and Drug Administration granted priority review status to its application for talazoparib as a treatment for patients with metastatic breast cancer with an inherited BRCA mutation. The target action date is in December. (Source: FirstWord Pharma, June 7, 2018)

A documentary film, “This is Living with Cancer,” and its associated campaign received copious praise at Cannes Lions Health though the campaign did not receive an award. The film is about five patients living with cancer and seeks to shed light on the universal truths and experiences that everyone who has cancer faces regardless of type. The campaign also included digital, social, and in-office materials as well as a unique app. (Source: FiercePharma, June 20, 2018)
Pfizer reported Ibrance, in combination with fulvestrant, did not significantly extend overall survival in a phase 3 trial with patients with hormone receptor-positive human epidermal growth factor receptor 2-negative metastatic breast cancer whose disease has progressed after prior endocrine therapy. The study compared Ibrance to placebo. This was a secondary endpoint of the trial which met its primary endpoint of a statistically significant and clinically meaningful improvement in progression-free survival at its interim analysis. *(Source: Pharmaceutical Business Review, June 27, 2018)*

Ray Liotta is the latest “real smoker” featured in an advertisement for Pfizer’s Chantix. Liotta, an actor, is the first celebrity to appear in the long-running testimonial campaign. “Real People, Real Stories” began in 2012 and encompasses 24 different commercials. The campaign also includes digital, social media, and retail advertising. *(Source: FiercePharma, July 6, 2018)*

The Food and Drug Administration admonished Pfizer for a direct-to-consumer video for Estring, a hormonal therapy for postmenopausal women. In the video, the patient says she doesn’t suffer any side effects which the FDA cites as misleading. It also said the video failed to include any risk information associated with the treatment of moderate-to-severe vulvar and vaginal atrophy due to menopause. The drug carries a boxed warning due to several serious, life-threatening risks. *(Source: FiercePharma, July 2, 2018)*

Pfizer raised the prices of 41 products in the U.S. effective July 1 by nearly 10% in total. In response to the move, President Trump tweeted that Pfizer “should be ashamed.” The next day, Pfizer’s CEO said his company would delay the increase to allow the federal government time to work on a healthcare plan. *(Source: The Washington Post, July 10, 2018; BioSpace, July 11, 2018)*

Pfizer announced it plans to reorganize into three business units starting in 2019: Innovative Medicines, Established Medicines, and Consumer Healthcare. The company is currently organized in two units: Innovative Medicines and Essential Health. The consumer health business is included in the Innovative Medicines unit. The restructuring will allow the company to better evaluate its businesses and facilitate selling or spinning off the Established Medicines unit which will include the majority of the company’s products including generic and soon-to-be off-patent brands. Pfizer is still looking for opportunities to sell its lower-margin, non-core consumer healthcare business which includes products such as over-the-counter pain relievers and lip balm. *(Source: Reuters, July 11, 2018)*

The Food and Drug Administration approved Xtandi for the treatment of non-metastatic prostate cancer. The approval will pit the drug from Pfizer and Astellas against Johnson & Johnson’s Erleada. Xtandi had sales of $2.59 billion last year and is projected to have sales of $4.71 billion by 2022. *(Source: FiercePharma, July 16, 2018)*

The Food and Drug Administration approved Pfizer’s fourth biosimilar. Nivestym, a biosimilar to Amgen’s Neupogen, was approved to treat all indications of the reference product which includes decreasing the incidence of infection in patients with non-myeloid malignancies and reducing the time to neutrophil recovery and duration of fever in patients with acute myeloid leukemia. *(Source: BioPharma-Reporter, July 24, 2018)*
Sanofi News

- The Food and Drug Administration accepted Sanofi’s application to expand the use of Fluzone Quadrivale vaccine (0.5 mL dose) in children age 6 months to 35 months. It is currently approved for children age 36 months and up. *(Source: Seeking Alpha, April 25, 2018)*

- Sanofi and Regeneron announced the Food and Drug Administration granted priority review designation to their application for the use of PD-1 antibody cemiplimab to treat patients with metastatic cutaneous squamous cell carcinoma and patients with locally advanced CSCC who are not eligible for surgery. Data supporting the application shows cemiplimab had an overall response rate of 46.3% in this patient population. *(Source: FirstWord Pharma, April 30, 2018)*

- Partners Sanofi and Regeneron agreed to reduce the price of their PCSK9 cholesterol drug Praluent to secure exclusivity on Express Scripts’ national preferred formulary which covers 25 million Americans. Express Scripts will pass the savings to certain patients on commercial insurance plans. PCSK9 drugs such as Praluent have list prices around $14,000 per year. In March, the drug makers announced they would lower Praluent’s annual price to a range of $4,460 to $7,975. *(Source: FiercePharma, May 2, 2018)*

- The Food and Drug Administration accepted Sanofi’s application for Zynquista, a potential treatment for type 1 diabetes. If approved, Zynquista would be used in addition to insulin therapy and would be the first oral antidiabetic drug for type 1 diabetes in combination with insulin. Zynquista is an oral dual inhibitor of SGLT-1 and SGLT-2 proteins. *(Source: Pharmaceutical Business Review, May 23, 2018)*

- Sanofi reported the average price of its drugs fell 8.4% in the U.S. last year after rebates. Sanofi had promised to keep annual list-price increases at or below the federal government’s forecast for annual growth of healthcare spending. It has since modified its pledge to say it will explain any rationale for increases which exceed that rate of growth. Sanofi published a rationale for its 12.5% price increase for Flublok, a drug it acquired through Protein Sciences. The increase was from $40 per dose to $45 per dose and based on research which showed Flublok was 30% more effective than GlaxoSmithKline’s Fluarix Quadrivalent in individuals age 50 and older. Sanofi’s net price decline in 2017 reflected efforts to rebate medications enough so they would appear on lower formulary tiers thereby ensuring patients would have lower co-pays for the drugs. *(Source: The Wall Street Journal, June 1, 2018; FiercePharma, June 6, 2018)*

- Actress Roseanne Barr blamed a racist post to Twitter on Sanofi’s insomnia drug Ambien. The company’s communications team replied with its own tweet which said, among other things, that “racism is not a known side effect of any Sanofi medication.” By the time the tweet was approved and posted, Barr had deleted the Ambien comment and another tweet that mentioned Ambien. But in less than two hours, Sanofi’s tweet received 60,000 likes and 25,000 retweets. The company said it does not plan any other response. *(Source: FiercePharma, May 30, 2018)*
Sanofi agreed to exclusively license Translate Bio’s mRNA technology to develop messenger RNA vaccines. Under the multi-year deal, Sanofi will pay $45 million up front for rights for up to five infectious diseases. An additional $805 million in milestone payments and royalties are possible if Sanofi opts into all the programs and all products go to market. *(Source: Xconomy, June 11, 2018; Pharmaceutical Business Review, June 12, 2018)*

Sanofi agreed to transfer its infectious disease unit including most of its research portfolio and programs to Evotec for $70 million. The deal covers more than 10 infectious disease assets for which Evotec plans to accelerate development as well as 100 of its discovery and development employees. Sanofi retains option rights to development, manufacture, and commercialize any of the anti-infective drugs which result from the licensed assets. *(Source: Genetic Engineering and Biotechnology News, June 18, 2018)*

Sanofi will collaborate with Revolution Medicines to develop SHP2 inhibitors for patients with non-small-lung cancer and other tumor types carrying certain mutations. The companies plan to begin with clinical trials of Revolution Medicines’ RMC-4630 small-molecule drug. Sanofi will pay $50 million up front and has agreed to pay more than $500 million in milestone payments. *(Source: FirstWord Pharma, July 18, 2018)*

Sanofi sold its European generics business, Zentiva, to private equity firm Advent International for $2.2 billion. The deal is expected to close in the fourth quarter. *(Source: FirstWord Pharma, June 28, 2018)*

Sanofi’s venture capital arm led a $17 million funding round for Click Therapeutics, a startup focused on creating an online platform for “prescription digital therapeutics.” Click Therapeutics’ leading product is Clickotine a mobile app designed to help people stop smoking. *(Source: FierceBiotech, July 23, 2018)*
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