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IQVIA's Global Oncology Trends in 2019 Innovation in Patient Therapies

(Source: A report by Murray Aitken for the IQVIA Institute for Human Data Science)

In recent years, record numbers of new oncology drugs have been approved, bringing new treatment options and guidelines to maximize benefits to patients. However, oncology continues to be the most challenging area for research and development, facing significant risk of failure and long duration. Barriers to adoption of new drugs also remain, delaying patient benefit from treatment advances. As treatment options increase, the impact on spending levels has become a focus across most parts of the world – a trend that is expected to continue.

Fifteen new oncology therapeutics were launched in 2018 for 17 indications. Over half of the new therapies are delivered as an oral formulation, have an orphan indication or include a predictive biomarker on their label. The 57 drugs launched between 2014–2018 have now gained 89 indications across 23 different cancer types. Thirty-one percent of the approved indications over the past five years have been for non-solid cancers – leukemia, lymphoma and multiple myeloma – while lung cancer leads the solid tumors with 12 indications, followed by breast cancer (seven indications) and melanoma (six indications.)

In 2018, several noteworthy successes (and failures) have contributed to breakthroughs in the understanding of disease, including underlying causes, progression and potential opportunities for treatment. Also, recently introduced therapies are being used more broadly across varied tumor populations and in earlier lines of therapy. Immunotherapies were used in over 200,000 patients in 2018 in the United States, more than double the level in the preceding two years. Treatment with novel CDK 4/6 inhibitors for HER-2 negative breast cancer has increased dramatically in both the United States and Europe.

Clinical development activities are underway at more than 700 companies, and are at record high levels. However, despite some improvement in trial productivity and the prospect of further advances over the next five years, development remains high-risk and of long duration. The pipeline of drugs in late-stage development expanded 19% in 2018 alone, and 63% since 2013. Within the pipeline, across all phases of clinical development, the most intense activity is focused on nearly 450 immunotherapies with more than 60 different mechanisms of action. Ninety-eight next-generation biotherapeutics – defined as cell, gene and nucleotide therapies - are also under clinical investigation and leverage 18 different approaches. The combined immunotherapies and next generation biotherapeutics are targeting almost all cancer tumor types with over 80 mechanisms of action.

Of the 711 companies participating in oncology late-stage development, almost 500 are entirely focused on oncology and 463 of these are emerging biopharma. Of the 33 large pharma companies with global pharmaceutical sales over US$5 billion in 2018, 28 have large and active oncology pipelines.

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In Brief...

- HDA President and CEO, *John Gray*, announced he will retire effective May 2, 2020. Mr. Gray, who has led HDA since 2004, is credited with restructuring and streamlining the organization's membership base while strengthening partnerships with stakeholders within and beyond the pharmaceutical supply chain. He also headed the HDA advocacy team to significant federal legislative accomplishments, including the *Drug Supply Chain Security Act* (2013). Mr. Gray has been a friend and strong supporter of IFPW throughout the years, and IFPW wishes him well on his pending retirement.
- The Japanese ethical drug market showed signs of a slowdown in FY2018, dropping 1.8% year-over-year. This is the first decline in two years according to industry analysts at **IQVIA**. In the top 10 products, cancer drug *Avastin* topped the best-selling prescription drug list followed by the hepatitis C drug *Maviret* which also saw a significant increase. Immuno-oncology drug *Opdivo* came in third, up 7.5% year-over-year. Sales of the popular acid-reducer *Nexium* slid, as did the pain treatment *Lyrica*.
- **Sanofi** announced that *Paul Hudson* will replace *Olivier Brandicourt* as CEO. Hudson is currently head of pharma at **Novartis AG** and comes with a wealth of experience in the pharma industry, including head of pharma for AstraZeneca in North America. Brandicourt, who joined Sanofi in 2015, was looking to retire, spurring Sanofi to look for his successor earlier this year. Hudson will be replaced at Novartis by *Marie-France Tschudin*, President of the French nuclear medicine specialist

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Bio Leaders Discuss Balance, the Next Wave of Biosimilars and Patient Engagement

(Source: An article written by Joseph Haas for Scrip)

This year's BIO International Convention, held earlier this month in Philadelphia, PA, offered keen perspectives and insight from some of the industry's most influential leaders, including Ken Frazier (Chairman and CEO of Merck Inc.), Julia Pike (VP of Intellectual Property at Sandoz), and Peter Saltonstall (President of the National Organization for Rare Disorders, aka NORD.)

The "fireside chat" discussion centered on competing concerns faced by the industry when developing and marketing life-saving drug therapies while dealing with the challenge of providing access to those same therapies to those patients who need them.

"We try to do the responsible things around pricing and around marketing, and I hope we do a better job of that going forward," stated Ken Frazier. "I've worked in this industry, including as a lawyer, going back to the 1970s and this industry was referred then as the ethical pharmaceutical industry. It wasn't a joke back then." He was also quick to point out the need for "a framework of shared values in our society" especially when dealing with the

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Oncology Trends (cont.)...

Clinical trial activity remains high-risk with the oncology composite success rate falling to 8.0% in 2018 from 11.7% in 2017. Clinical trial duration remains higher for oncology trials than other disease areas but has generally declined over the past five years. Clinical trial complexity – measured as a combination of endpoints, eligibility criteria, and numbers of subjects, trial sites and countries – has increased sharply for phase I trials over the past five years. The overall productivity of oncology trials – measured as success rates relative to trial effort (complexity and duration) – has improved by 22% since 2010 but remains far lower than trials for other therapy areas.

Progress is being made in accelerating the time it takes for scientific advances to reach cancer patients, but barriers remain in the areas of registration, diagnostics, infrastructure and reimbursement, resulting in a variability in care and delays in patients benefiting from treatment advances. New oncology drugs launched in 2018 took a median of 10.5 years from the time of first patent filing to regulatory approval and launch, down over four years from the 2017 level. After a drug's first global launch, reaching patients in other countries can be a complicated and time-consuming process. In 2018 fewer than half of all new cancer medicines launched in the prior five years are available to patients beyond nine countries. Likewise, many European markets use health technology assessments (HTAs) to inform reimbursement decisions, but the results have been highly variable, and positive decisions are trending downward as a percentage of total decisions which limits access under insurance schemes.

Spending on all medicines used in the treatment of patients with cancer reached nearly US$150 billion in 2018, up 12.9% for the year and marking the fifth consecutive year of double-digit growth. This growth was driven entirely by therapeutic drugs, which grew 15.9%, as supportive care drugs declined 1.5% in 2018. New brands launched in the past two years and protected brand volume contributed nearly all the positive growth in major developed markets, where spending growth exceeded 13% in each market with the exception of Japan.

Japan's adoption of novel therapies is significant but overall spending growth is lower in part due to efforts to drive savings with price cuts – which affect older chemotherapy brands and generics – while newer brands contributed half of positive spending growth.

China led pharmerging markets in spending and growth and grew a remarkable 24% in 2018 to US$9 billion in total spending, even as supportive care treatments in China declined by 10%.

Over the next five years, growth in therapeutics spending of 11–14% is expected on a CAGR basis, bringing the total market to US$200–230 billion. Including supportive care, which is expected to decline by -3 to -6%, overall oncology spending will reach US$220–250 billion, growing 9–12% through 2023.

For more information on IQVIA's Global Oncology Trends for 2019, please visit *https://www.iqvia.com/institute/reports/global-oncology-trends-2019*.

Bio Leaders (cont.)...

cost of medicines. He drew an analogy between biopharma and the fossil fuel industry which is considered a vital resource, but still comes up against opposition from a sector of the population that only sees it as a threat to the environment. Merck looks to strike the right balance by following the science. He pointed out Merck's clinical development of *Keytruda (pembrolizumab)* and how the company used biomarkers to optimize patient selection in its trials.

"I think the analogy with our industry is we have to find ways of getting these life-saving medicines to the patient who need them without destroying the basis upon which we're going to go after tomorrow's medicines," Frazier said. "In other words, defending the duality of capitalism, in that it provides societal advances, but requires the profit motive to drive innovation."

NORD President Peter Saltonstall has been encouraged to see a continued increase in patient involvement regarding the development and approval process for rare disease therapies. A joint effort between NORD and the U.S. Food and Drug Administration (FDA) demonstrated how lacking that input had been previously. But with the passage of the FDA Safety and Innovation Act in 2012, the process has gained momentum and was further propelled forward by the 21st Century Cures Act of 2016.

"I have seen in my estimation a real commitment to get the patients in the center of the conversation." Saltonstall said, "to capture patient data and bring that information back to help industry people like yourselves…have real patient input to be able to better develop drugs."

Sandoz International GmbH executive, Julia Pike, believes that an easing of regulatory expectations for extensive Phase III comparability trials could spur biosimilar sponsors to go after more modest-selling reference biologics.

"I think in the next wave one of the things you're going to see people press on a little bit harder is how to get something approved as a biosimilar without having to engage in large-scale, Phase III clinical trials," she said. She noted that this will change the kind of candidates that biosimilar companies are going to look at developing since there will not be a need to invest US$150 million in order to develop the product. "If you don't have to invest US$150 million in order to develop a product, then you no longer need that to be a US$12-13 billion worldwide blockbuster," she said.

Pike pointed to the increased knowledge and awareness of biosimilars by global health regulators. This familiarity has helped to develop a fairly high degree of sophistication with how to view biosimilars. This sophistication will further refine their guidance of what is required to be considered a biosimilar in the future.

In Brief (cont.)...

company, **Advanced Accelerator Applications SA**.

- U.S. pharmaceutical spending is expected to grow by 2.5% in 2019, topping US$370 billion. Overall healthcare spending is projected to grow by 4% and climb to US$3.6 trillion, according to Fitch Solutions in a report released in May. Estimated pharmaceutical sales will top US$420 billion by 2023, accounting for nearly 1.7% of the national GDP and 9.7% over overall health expenditures.
- Big box retail giant **Walmart** has joined **MediLedger**, a consortium spearheaded by San Francisco-based blockchain company, **Chronicled,** that is building a blockchain for tracking pharmaceuticals. The move represents Walmart's desire to deepen its involvement with blockchain technology. MediLedger uses an enterprise version of the Ethereum blockchain which is built with a modified version of the *Parity* client and a consensus mechanism called *proof of authority*. Other Members of MediLedger include pharmaceutical wholesalers **McKesson**, **AmerisourceBergen** and **Cardinal Health**.

(Sources: CoinDesk, PharmaJapan Press Releases, and Scrip)