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How Insurance Executives are Thinking About Novel High-Cost Therapeutics

(Source: An article by Paige Minemyer for FiercePharma)

The pharmaceutical industry is introducing plenty of innovative new therapies to the market. However, companies need to be prepared to field a number of questions from insurers and payers who ultimately hold the purse strings, according to a new survey conducted by KLAS Research (and backed by the Center for Connected Medicine.) The survey polled senior level leaders and executives at eight U.S. health plans, including major national insurers and provider-owned payers. What was discovered was that all were concerned with the rising cost of novel therapies that are coming to market.

Seven of the plans placed this as a "high" concern, and the one remaining insurer considered these costs a "medium" level concern, according to the report. While those concerns extend to payers of all sizes, one executive said the that the smaller plans are likely to feel the impact of these costs the most.

"Novel therapeutics are for orphan or rare diseases, and the complexity in the development of these drugs makes the cost extreme. And by extreme, I am talking over US$100,000 a year in costs," the executive said. "If a small plan has fewer than 50,000 lives, it only takes a couple of members who need novel therapeutics to start impacting the plan's budget significantly."

Another executive noted that the high costs put insurers in a bind, as they aim to strike a balance between managing healthcare spending and ensuring patients can access treatments from which they would benefit. The high cost of new therapeutics may lead to access being restricted largely to the wealthiest patient groups, the executive warned.

"We need to be good stewards of the healthcare dollar. There is a limited amount of money in the system to actually pay for care. We want to be in a position to make care, whether it is therapeutics or procedures, affordable and equitable for all," they said. "We don't want to be in a situation where we are limiting access to care to people who have more money. We don't want to have that disparity in health care."

The 30-minute interviews asked executives what the largest challenges are in managing these expenses. One said that the value of emerging therapies is still hard to pin down, as they're billed as curative, but the incremental effects may be more limited.

Offering novel therapeutics that simply cost more, rather than exceed existing standards of care, is "just wasting resources," the executive said.

The impact on budgets is also obvious but was a key concern for the interviewed executives. Many health plans are towing the line between offering extensive coverage options and turning a profit, according to the survey results detailed in the report.

"For some cases, the cost for one member to receive these therapies might be the same as the cost of insulin for all diabetic members," one executive said. "Some of the costs on the highest

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In Brief...

- **Pfizer** announced a strategic cooperation agreement with Shanghai-based **Sinopharm Group** to expand its market presence in China. The two companies will join to seek approval to market as many as 12 innovative drugs in China through 2025. Sinopharm president, *Liu Yong*, stated that the collaboration aims to speed up the deployment of Pfizer's new treatments to patients. **Merck** also has partnered with Sinopharm to commercialize the oral COVID pill, *molnupiravir* in China, while Pfizer has partnered with **Zhejiang Huahai** to manufacture its oral therapy *Paxlovid* in China.
- **Moderna** has announced that its investigational cancer vaccine, *mRNA-4157/V940*, in combination with *Keytruda* (**Merck's** anti-PD-1 therapy) has been granted Priority Medicines (PRIME) scheme designation by the European Medicines Agency (EMA). It concerns the adjuvant treatment of patients with high-risk stage III/IV melanoma following complete resection. The vaccine *mRNA-4157/V940* stimulates an immune response by generating specific T cell responses based on the unique mutational signature of a patient's tumor. The EMA awarded the PRIME scheme designation following positive data emerging from the phase 2b *KEYNOTE-942/ mRNA-4157-P201* clinical trial. The results from this research will be shared at the **American Association for Cancer Research (AACR)** in mid-April.
- **Walgreens** kicked off sales and in-store donations for the ninth annual *Red Nose Day* campaign to support healthy communities and help end the cycle of child poverty. Now through May 31, customers can visit Walgreens and Duane

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Australian Pharmaceutical Industries Limited Joins IFPW

Australian Pharmaceutical Industries Limited (API) is the newest global wholesale member of IFPW. Located in Melbourne, API is one of Australia's leading pharmaceutical distributors and fastest growing health and beauty retailers. API is the parent company of Priceline Pharmacy, Soul Pattinson Chemist and Pharmacist Advice. API's services include wholesale product delivery, retail services, marketing programs and business advisory services.

API is one of the leading service providers to the pharmacy industry in Australia and today has a relationship with more than 4,000 independent pharmacies. It owns and operates the Priceline retail store brand, a leading health and beauty brand in Australia.

API is also a member of Australia's National Pharmaceutical Services Association. IFPW warmly welcomes API and looks forward to its insights and perspectives, as well as its active participation at IFPW's meetings and events.

Novel Therapeutics (cont.)

end are going to be very complicated."

However, some of these emerging treatments are genuine breakthroughs, and ensuring access is critical, the executive added.

Other common concerns they cited include the high costs to patients as well as the burden on patients in determining eligibility, which could include extensive testing and diagnostics.

All of the surveyed executives said their organizations lean on clinical expertise to make coverage decisions. About two-thirds said their companies use a cross-functional team to advise about coverage, and others said they have a specialty pharma team in place to track these therapies.

What could make the decision easier? More data from the drugmakers, one executive noted.

"There has to be a willingness to collaborate so we can understand how things are going. If a pharmaceutical company is not willing to share information, that could affect my decision to cover the treatment," they said. "I don't have to know everything, but I want to have enough data so that I know whether I should continue to cover novel therapeutics."

South Korea's Push to Become A Biopharma Powerhouse

(Source: An article by Jung Won Shin for Scrip Intelligence)

Korean biopharma companies, along with the government of South Korea, are making collaborative strides in 2023 with the aim of seeking growth the overcome limited resources and capital, further complicated by a difficult investment environment.

With the sharp decrease in out-licensing deals in 2022, particularly those of the large-scale, cross-border variety, collaboration has become the key message in the South Korean biopharma industry. Simultaneously, the government is rushing to unveil measures to support the sector and launch regulatory innovation initiatives.

Meanwhile, Korean bioventures are suffering from funding difficulties amid the generally weak financial and capital markets stemming from global economic uncertainties. According to one venture capital source, VC investment in the Korean bio/medical sector continues to see weakness, totalling just KRW131 billion (US$99.4 million) in the first quarter. A couple of domestic bioventures, including GI innovation, launched initial public offerings in the same period.

Amid this challenging environment, Korean pharmas, led by the Korean Innovative Medicines Consortium (KIMCo), decided for the first time to co-invest in target companies at home and abroad, marking a step forward for domestic firms which up to that point had been making individual moves to find new growth engines and enter global markets.

Such steps have come in line with the government's strategic goal of creating three top 50 global biopharmas in Korea, two global blockbuster drugs developed by in-country firms, and doubling biopharma exports by 2027 through a combination of increased R&D investment, stronger support for exports, fostering expertise, and regulatory innovation and expansion of the supply infrastructure.

After launching a pilot project earlier this year, KIMCo plans to expand into two cycles of investment programs later in 2023. For each selected investment target, it will make joint investments along with a number of Korean pharmas. For the first cycle, investors will mainly be comprised of Korean firms, while some Korean VCs are also expected to participate. The second cycle will include the invitation to global pharma companies to participate, as well as from global VC firms, aside from Korean pharmas and VCs.

The government agency intends to group these firms together to create several development projects, and then set up separate companies to further progress these. The fund plans to inject R&D financing for each project and attract investment from U.S. VC partners, as well as seek partnership with global big pharma companies to progress clinical trials and then share profits if development succeeds.

Meanwhile the Korean government-supported vaccine development funds intend to pursue diverse strategic alliances with both domestic and multinational partners. The funds are led by Yuanta Investment and Mirae Asset Group. They aim to invest the majority of funds in companies conducting clinical trials with new drugs, and focusing on later-stage trials. Collaborations between domestic pharmas and biopharmas and bioventures and out-licensing assets to global big pharma partners is a good business model, according to Yuanta Investment's managing director, Vincent Jeong.

However, there have not been many such successful cases thus far in Korea. This will depend on how pharma companies think and their perspectives on investment. That, coupled with the challenge of convincing big pharma partners that smaller Korean bioventures are credible and worthy partners could prove to be the most significant obstacle.

In Brief (cont.)

Reade locations and show their support by donating in-store via pin-pad or purchasing a Red Nose for $1, with all profits benefiting Red Nose Day. The campaign and its iconic Red Nose return exclusively to Walgreens after a record-breaking fundraising year in 2022 where Walgreens' customers, team members and supplier partners helped raise more than US$38 million for the cause.

- **Merck** will acquire the **Prometheus Bioscience** in an all-cash deal valued at approximately US$10.8 billion. The deal is expected to close in the third quarter of this year and comes amid an uptick of pharma-focused M&A. Earlier in 2023, Pfizer acquired **Seagen** for US$43 billion.
- **UNDBIO**, a South Korean pharmaceutical company focused on diabetic care, will spend US$100 million to build an insulin manufacturing facility in West Virginia. The project is expected to create 200 new jobs in the first three years, according to an April 12 press release issued by Governor Jim Justice's office. UNDBIO, which was founded in 2009, has developed a once-weekly insulin injection system that is not yet approved by the FDA. Under phase one of the company's U.S. project, UNDBIO will work to gain FDA approval for its product.

(Sources: Company press releases, Drug Store News, FiercePharma, PharmaTimes, and Yahoo Finance)