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The Next Wave in Cell and Gene Therapy Still Offers Value to Pharma Companies

(Source: An article by Mandy Jackson for Scrip Citeline)

While some big pharma companies have exited the cell and gene therapy arena, companies such as Novartis, Astellas, AstraZeneca and Gilead's Kite Pharma are eager to pursue opportunities, according to executives at the Alliance for Regenerative Medicine (ARM) Cell and Gene Meeting on the Mesa held on October 7th in Phoenix, Arizona. During a panel session, executives discussed how big pharma can scale up cell and gene therapy for the future and invest in next wave technologies.

Some pharma manufacturers, including Takeda and Pfizer, have ended their cell and gene investments. Takeda announced that it would discontinue all cell therapy research and Pfizer ended its investments in adeno-associated virus (AAV)-based gene therapies last February when it removed the hemophilia B treatment *Beqvez* from the market.

Executives at the ARM meeting noted that their companies are fully committed to cell and gene therapies, with support for the technologies and their next-generation iterations extending up through the CEO level.

"There's a lot of focus, obviously, on the really tough situation facing every CEO of a small independent company right now. How do you make sure you have the [cash] runway?" Astella senior vice president and gene therapy leader Richard Wilson said. He explained further that the big pharma version of that is explaining to leadership why gene therapy is worthy of investment alongside oncology or other programs that have large patient populations and drive current revenue growth.

Additionally, Wilson noted that the gene therapy group at Astellas relies on the unique characteristics of the programs they are working on in severe, life-threatening diseases in which patients have no other treatment options and where gene therapies may have life-changing effects.

Cell and gene therapies have their own specific R&D, manufacturing and commercialization challenges that are unique from those associated with small molecules and monoclonal antibodies, which is why some big pharma companies and their investors have avoided the space. However, the financial resources and massive scale of these big pharma companies, as well as their ability to back partners with unique expertise, may be exactly why larger companies are ideally suited to carry cell and gene therapy into the future.

Novartis, due to its experience commercializing multiple autoimmune disease drugs and its experience with chimeric antigen receptor T-cell (CAR-T) therapies in hematologic oncology, is well positioned to bring forward CAR-T therapies in immunology. The company brought the first CAR-T therapy for hematological malignancies to market in 2017. The CD-19 targeting *Kymriah* was approved in the U.S. for pediatric and adult patients with B-cell precursor acute lymphoblastic leukemia. Novartis is now

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- **Eli Lilly** and computing giant **Nvidia** are teaming up to build a new supercomputer that will be housed in Lilly's facilities and will be entirely run by renewable energy. The supercomputer will be the most powerful owned and operated by a pharma company. Lilly will use the new tool to fuel an "AI factory" (a computing infrastructure that can take in data, train models on experiments performed by Lilly scientists and generate inferences.) Lilly plans to use it for molecule discovery research and to shorten development cycles.
- An unsolicited bid of US$9 billion by **Novo Nordisk** for obesity drug developer **Metsera** was announced just six weeks after the announcement of **Pfizer's** initial bid of US$4.9 billion for Metsera. Novo has offered to pay US$56.50 per share in cash, with an additional US$21.25 per share in cash based on development and regulatory milestones "substantially similar" to those reached in the agreement with Pfizer. Metsera said that per the terms of the existing deal, a four-business day period is now triggered in which Pfizer can re-negotiate its agreement, but that Metsera is allowed to break from the deal if not satisfied. Pfizer has subsequently increased their offer to US$8.1 billion (approximately US$70 per share).
- **Kimberly-Clark** has offered to buy **Johnson & Johnson** consumer health spinoff **Kenvue** for US$48.7 billion. The deal creates a consumer health conglomerate that is expected to

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The Chinese Pharma Sector Moves Toward a Path of Innovation and Growth

(Source: An article by Li Jing for China Daily)

Once driven primarily by generic drug production, China's pharmaceutical industry is witnessing a steady rise in innovative drug development, cross-border partnerships, and record research and development spending, signaling a structural transformation toward high-quality growth, according to experts and industry insiders.

As an example, for the first time, Chinese drug company Jiangsu Hengrui Pharmaceutical Co., Ltd's income from innovative drugs and licensing accounted for more than sixty percent of total revenue. In 2018, most of the company's revenue was generated from generics, while only a small fraction came from innovative products. The shift reflects the fact that innovation and globalization have become the twin engines for China's growth, the company said. "As one of the country's leading R&D-driven pharmaceutical enterprises, we have made continuous innovation our development strategy."

To date Hengrui has secured domestic approvals for 24 Category 1 innovative drugs and four Category 2 drugs. Hengrui's transformation reflects not just the company's evolution, but the transformation of China's broader pharma industry.

Across China, a growing number of once traditional drugmakers such as Jiangsu Hansoh Pharmaceutical Group Co.,

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The Next Wave *(cont'd.)*...

developing CAR-T therapies for autoimmune diseases.

There are challenges to overcome as noted by Christy Siegel, Novartis' senior vice president and U.S. immunology therapeutic head, which includes the capacity for the health care system to administer CAR-T therapies in larger patient populations outside of oncology, in community treatment centers as well as academic centers.

In addition to cell and gene therapy technology acquisitions, Novartis is looking for partners to aid in commercialization of its complex therapies for novel indications.

Gilead has been expanding from its small molecule HIV and hepatitis C antiviral business base into biologic and cell therapy for several years at the direction of Gilead CEO Dan O'Day, a major proponent of CAR-T technologies. The company recently invested US$350 million to expand its expertise in the area with the acquisition of in vivo CAR-T developer Interius BioTherapeutics.

"From the outside it might look there's an imbalance there in terms of that sort of impact [of antiviral therapies versus CAR-T], but I think there is a real fundamental principle at Gilead around we're in it to cure diseases," Wilson said. "Gilead did that with hepatitis C. We've got the once every six months pre-exposure prophylaxis for HIV and efforts to cure HIV…I think there is a very strong philosophy of innovating and looking at what something is going to deliver."

Chinese Pharma *(cont'd.)*...

Ltd., Simcere Pharmaceutical Group Ltd and CSPC Pharmaceutical Group Ltd. are now achieving similar transitions and reporting rising revenue shares from innovative products as well as report double-digit R&D growth, according to their interim reports.

China's pharmaceutical industry, now the world's second largest, accounts for nearly 30 percent of the global pipeline of innovative drugs in research. Jin Chunlin, director of the Shanghai Institute of Medical Science and Technology Information, said China's pharmaceutical industry is entering a new developmental phase, strengthened by policy reform and accumulated industry expertise. He explained that the generic-drug era was an essential foundation and allowed firms to accumulate funds, master manufacturing techniques and establish a robust drug quality evaluation system. He did note, "Companies cannot remain forever in the comfort zone of generics. Innovation is the only way forward."

The industry's transformation has been propelled by a decade of deep structural reforms. Beginning in 2015 the government overhauled drug review and approval mechanisms, accelerating the path to market for innovative therapies. It was followed in 2018 by a landmark shift with the introduction of the national drug centralized procurement program, designed to pool public hospital demand and negotiate lower prices directly with manufacturers. By reducing inflated generic prices, the reform made funds available for medical insurance coverage and redirected corporate focus toward innovation.

By 2020, a consensus had formed across the industry – the era of high-margin generics was over. This served as the catalyst from imitation to innovation. Complementing these efforts, authorities have rolled out multiple measures to support the high-quality development of innovative drugs, providing full-chain support for R&D, clinical trials, approval, production and commercialization.

In 2025, for the first time, commercial health insurance was formally included in national drug reimbursement negotiation, paving the way for CAR-T cell and gene therapies to enter the domestic payment system.

China's regulatory efficiency for new drugs has also improved dramatically. Over the past decade, the average review cycle for new medicines has been shortened from several years to just months, enabling companies to bring novel therapies to patients faster. The National Medical Products Administration has also implemented a 30-working-day fast track review for key innovative drugs with clear value. Products under the fast-track review include pediatric, oncology, and rare disease treatments, specifically those supported by national R&D programs, or global multicenter trials led or co-led by Chinese principal investigators. More than 200 innovative drugs and 260 medical devices have been approved in the last five years.

In Brief (cont.)

generate annual revenues of US$32 billion, but also could be complicated by Kenvue's top-selling product, *Tylenol* (which has recently been under scrutiny) , as well as Kenvue's talc litigation outside of the U.S. and Canada which remains an legal issue.

- **Aurobindo Pharma** announced the incorporation of a new wholly-owned subsidiary, **Eugia Pharma Chile SpA**, in Chile, marking a strategic move to expand its pharmaceutical business in South America. Eugia Pharma Chile SpA is a wholly-owned subsidiary of **Eugia Pharma B.V.**, which is itself entirely owned by Aurobindo Pharma. According to a stock exchange filing, Aurobindo said this initiative is part of the company's broader strategy to strengthen its presence in international markets, particularly in the pharmaceutical sector.
- **Amazon** announced 14,000 layoffs, the largest number of cuts to Amazon's corporate workforce in the company's history. The cuts will span almost every business unit, according to anonymous source within the company. Amazon plans to eventually lay off as many as 30,000 staffers across its corporate workforce, according to Reuters. Amazon is the U.S.'s second largest private employer with more than 1.54 million staffers globally, as of the end of the second quarter. That figure is primarily made up of warehouse employees. The company points to AI as reshaping how Amazon operates, calling it "the most transformative technology we have seen since the Internet, and it's enabling companies to innovate much faster than ever before (in existing market segments and altogether new ones.) We're convicted that we need to be organized more leanly, with fewer layers and more ownership to move quickly as possible for our customers and business."
- A Japanese health ministry panel has finalized the designation of 762 active pharmaceutical ingredients (APIs) as "supply-ensured medicines," currently known as "stable supply medicines." The list, which was expanded from the initial 759 proposed APIs following a public comment process – will be formally published by the government near the end of November.

(Sources: Drug Store News, Fierce BioTech, FiercePharma, Pharma Japan, and Quartz Daily)