



First Approval of China mRNA Vaccine May Change China's "COVID Zero" Policy

(Source: An Article by Brian Yang for Scrip Intelligence)

The end of September saw Indonesia's first approval for a China-developed mRNA vaccine. Indonesia's regulatory authorities issued an Emergency Use Authorization for use in people aged 18 and older as primary or a booster injection.

The vaccine, developed by Suzhou-based ABOGEN INC., Walvax Biotechnology Co., Ltd. and China's Academy of Military Medical Science, the vaccine is China's answer to Pfizer/BioNTech *Comirnaty* and Moderna's *SpikeVax*.

To date, China has refused to approve any foreign-developed mRNA vaccines for COVID-19, despite Shanghai Fosun Pharmaceutical (Group) Co., Ltd. licensing for BioNTech's vaccine which started development in 2021.

Walvax said its vaccine showed a protection rate in clinical trials against symptomatic, wild-type SARS-Cov-2 of 85.4% and of 71.7% against the Omicron variant in terms of preventing moderate disease infection. It only requires regular cold chain storage at 2-8°C, rather than the super-cold temperatures needed for overseas mRNA vaccines.

"It's entirely possible that the vaccine works as described in the announcement. But there is a lack of transparency," a former World Health Organization China official told Scrip. "The [efficacy] results are also somewhat lower than what we have seen for the EMA-registered mRNA vaccines," he added.

There are many that believe China has been waiting to approve its own domestic mRNA vaccine before granting a nod to the Fosun/BioNTech product.

Without more effective vaccines such as those based on mRNA platforms, the country will have very few options to open its doors to freer travel after more than two years of effectively sealing off its borders. Its strict "COVID Zero" policies have been an obstacle to its population developing herd immunity through natural infection. That leaves only large-scale immunization campaigns as the only way to protect people.

Notably, China granted a global-first approval to an inhaled COVID-19 vaccine, *Covidecia Air* from CanSino Biologics Inc. for use as a booster. Earlier, CanSino CEO Yu Xuefeng told Scrip that the product targets infections via the nasal mucosa, the first and key immune response against the virus. Despite the approval, rollout has required more time and production of the associated device, and the absorption rate of the inhaled formulation has proven challenging.

The Chinese approval of the inhaled vaccine as a booster signaled a lack of systematic protection, according to Jin Dongyan, a virologist at Hong Kong University. These factors are creating an acute and vital need for an mRNA vaccine in China.

(continued on page 2)

In Brief...

- ◆ **McKesson** has signed an agreement in principle to extend its partnership with **CVS Health** to distribute pharmaceuticals to mail order, specialty pharmacies, retail pharmacies and distribution centers through June of 2027. "We are pleased to continue our long-standing relationship with CVS Health and value the shared commitment of improving health outcomes for all patients," said *Brian Tyler*, McKesson's CEO.

- ◆ **Pfizer** announced the completion of its acquisition of **Biohaven Pharmaceutical Holding Company Ltd.**, the maker of *Nurtec ODT (Rimegepant)*, an innovative migraine therapy approved for both acute treatment and prevention of migraine in adults. This adds Pfizer's portfolio of promising calcitonin gene-related peptide receptor antagonists (CGRP), including *Zavegepant*.

- ◆ **Merck** announced the opening of a secondary packaging facility for vaccines and biologics in Singapore, and broke ground on a plant that will produce inhalers, to be completed by 2026. The fill-finish facility in Singapore now includes a vial-packaging line to produce cancer treatment *Keytruda* and three syringe packaging lines to manufacture another Merck mega blockbuster *Gardasil*. Separately, the company announced that a therapy gained through its US\$11.5 billion acquisition of **Acceleron Pharma** last year met the main goal of a late-stage study in patients with a progressive blood vessel disorder. The drug, *Sotatercept* significantly extended how far patients with pulmonary arterial hypertension could walk in six minutes.

- ◆ **Walgreens** will acquire the remaining 45% stake in **CareCentrix** to extend its focus on primary care, post-acute care, and home care. The deal, valued at US\$392 million (based on the exit multiple agreed to at the time of WBA's initial majority investment announcement) is expected to

(continued on page 2)

Walgreens, CVS and Amazon are Driving More Partnerships and Tech Investment

(Source: An Article by Heather Landi for FiercePharma)

Walgreens, CVS and Amazon are ramping up their focus on in-home medical services and primary care, likely causing major disruptions for more traditional brick-and-mortar providers, according to industry experts.

Major retailers, including Walmart, are extending their reach deeper into the patient care. This has major implications for how and where care is delivered and paid for, and by whom.

Earlier this month, drugstore giant CVS announced it would acquire much sought-after home healthcare company Signify Health for US\$8 billion.

(continued on page 2)

China (cont.)...

The first approval for the Chinese mRNA vaccine also comes just ahead of the major Communist Party National Congress, which will be held in Beijing on October 16th. There is speculation that China may also grant a quick emergency use authorization, if not in October at least ahead of a potential new wave of infections in the winter season.

The Indonesian approval may also signal an additional approval for the Fosun mRNA vaccine to ensure supplies are able to meet the large, expected demand.

Rapid regulatory approval would not be new for the Chinese government which approved its domestically developed oral COVID-19 antiviral *azvudine* in record time. The drug gained approval just days after a new drug application was filed, following a domestic authorization for HIV a year ago.

One indicator of future COVID Zero policies is China's rhetoric to minimize the cost of vigilance for flareups. Massive city-side lockdowns such as the lockdown in Shanghai that occurred in April/May should be avoided and COVID-19 should be managed as a regular infectious disease like hepatitis B.

Walgreens (cont.)...

"It's sort of like these companies have been sort of poking around the edges to see what might work and we're finally starting to break through," said Colin Banas, M.D., chief medical officer at DrFirst.

The Signify deal shows that CVS is "putting its muscle" behind its healthcare strategy and broadens its footprint. The move adds in-home care to CVS's vertically integrated system that already included health insurance, drug management, retail and specialty pharmacy, and urgent care, according to Banas.

Signify Health offers analytics and technology to help a network of 10,000 clinicians provide in-home healthcare to 2.5 million patients across the country. CVS will add Signify Health's capabilities and clinician network to its existing portfolio of 40,000 providers, 1,100 MinuteClinic locations, 9,000 retail drug stores and the nation's third-largest health insurer, Aetna. CVS also gains Caravan Health, a company Signify acquired in March of 2022, which enables value-based care through its analytics and practice improvement solutions.

Another example is Walgreens post-acute and home care company CareCentrix, in which Walgreens has a US\$330 million stake investment. Also, Best Buy paid US\$400 million for remote patient monitoring company Current Health as well as Amazon's pursuit to acquire primary care company One Medical for US\$3.9 billion. Walmart is expanding into medical services by opening approximately 20 in-person clinical locations across Georgia, Arkansas, Illinois, and now Florida. These locations are co-located with their supercenter stores.

Banas, a former internal medicine hospitalist and former chief medical information officer for VCU Health System in Richmond, Virginia, has seen the rise of care at home in the past decade and that trend saw a marked acceleration during the COVID-19 pandemic.

"We used to run a housecalls program at Virginia Commonwealth University and it was targeted at the sickest of the sick in an effort to keep them out of the hospital," he said in an

interview. "The ability to go out to meet the patient at home and really spend the time to tailor specific care plans to their needs as well as see the home environment was wildly successful at the time and it allowed us to expand," he noted. "You fast forward now to post-COVID and you're seeing obviously the rise of telehealth."

As the industry shifts to the home as a site of care, legacy patient-provider relationships and business will face disruption. Health systems would be well-advised to consider how they are positioned to deliver care at home as an integrated part of their care models. It also remains to be seen whether CVS, Walgreens and Amazon moving further into medical services will improve patient care. These new home care capabilities coupled with new technology for in-home diagnostics, such as EKGs and blood tests, could be the "game changer" that helps keep patients out of the hospital.

In Brief (cont.)...

close in March of 2023. Separately, Walgreens is opening new robotic fulfillment centers dedicated to packing prescription medications for pharmacy customers. Currently Walgreen's Dallas center, which uses robotics, reportedly fills 35,000 prescriptions for 500 stores every day, reducing pharmacist workload by 25% and producing cost savings of approximately US\$1 billion per year.

- ◆ **Johnson & Johnson** has announced the name for its new spinoff. In a release, the new company, **Kenvue**, embodies "the company's strengths—the geometry of the rectangle representing scientific precision and the rounded edges evoking the warmth of care." While "ken" refers to knowledge in the Scottish language and "vue" refers to sight.

- ◆ Japan's total healthcare spending FY2021 totaled ¥44.2 trillion (US\$311.2 billion) up approximately 4.6% year-over-year, when the number of outpatients slumped amid the COVID-19 pandemic, according to Japan's health minister. The figure was rounded up approximately 1.4% against pre-pandemic period of FY2019 but spending for inpatient care fell below the FY2019 level. The data accounts for approximately 98% of the nation's medical spending

- ◆ A study published by the *British Journal of Clinical Pharmacology* shows a link between drug shortages and medical errors and adverse drug reactions. Medical errors were identified in 11% (51 out of 462) of the cases, mostly occurring at the administration step and involving human factor. Of these cases, life-threatening situations were reported in three of the cases and fatal outcomes were reported in four.

- ◆ **Viartis** is considering a sale of its consumer health products in Europe. The deal is valued at as much as US\$2.9 billion, according to a report by Bloomberg, citing sources familiar with the matter. The drugmaker has hired **Jefferies** to scout for buyers, but no final decision has been made. Viartis recorded US\$96.7 million in proceeds from asset sales in 2021, attributed primarily to a group of U.S. OTC products.

(Sources: Company Press Releases, Drug Store News, FiercePharma, Pharma Japan, PR Newswire, and World Pharma News)