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Takeda Vaccines Head: Peer Review Process For COVID-19 Vaccines Must Be 'Very Open'

by Anju Ghangurde

The president of Takeda's global vaccines business emphasizes the need to build trust and ensure that pharma is transparent about "what we will and will not know" at the time that COVID-19 vaccines are licensed.

Public confidence and trust in COVID-19 vaccines will be paramount as potential candidates inch towards the market and pharma will need to be upfront on what is established and what is not clearly known at the time of product licensing, a top industry executive asserted at a recent healthcare summit.

Dr Rajeev Venkayya, president of *Takeda Pharmaceutical Company Limited.*'s global vaccine business unit, said that addressing the trust factor will require pharma to be "very transparent" and companies, as they generate data on their vaccine candidates, must "respect" the peer review process. Regulatory agencies too need to be transparent in their decision-making.

"We do need to make data available to external independent experts; the peer review process has to be very open, so people know what very knowledgeable, independent people think about the safety and efficacy of vaccines that are going to be approved," Venkayya said that the virtual edition of the Annual BioPharma and Healthcare Summit of the USAIC (USA-India Chamber of Commerce). (Also see "*Merck CEO Stresses Need For 'Fair Return' On COVID-19 Interventions*" - Scrip, 7 Sep, 2020.)

The executive also underscored the need to be "honest about what we will and will not know at the time the vaccines are licensed." While a lot about the safety and efficacy profile of the products will likely be known since they have gone through large clinical trials, what perhaps won't be known is the durability of protection and all aspects about the long-term safety profile.

"Any risks that we see in long-term safety are likely to be quite small and events quite rare but it will be important to explain that you don't have all the information and you'll be updating the safety assessments on a continuous basis over time," Venkayya stressed at the summit.

The Takeda executive's comments appear all the more relevant against the backdrop of *AstraZeneca PLC*'s decision this week to voluntarily pause all trials of its COVID-19 vaccine candidate AZD-1222 after one patient experienced an "unexplained illness" in the UK part of the Phase III trial. This highlighted that the development of drugs and vaccines is rarely smooth-sailing and safety remains paramount, even amid the urgency to fast-forward things in the pandemic situation. (Also see "*AZ Exercises Caution With COVID Vaccine Safety Pause As Questions Remain Over Vector*" - Scrip, 9 Sep, 2020.) (Also see "*No EUA For COVID-19 Vaccines Prior To Trials Completion, Says India*" - Scrip, 10 Sep, 2020.)

Takeda Participation

While Takeda's current coronavirus-targeted R&D thrust is mainly for the therapeutic use of convalescent plasma and certain repurposed drugs against the viral disease, it is also collaborating with *Novavax, Inc.* for the development, manufacturing and commercialization of the late-stage biotech firm's COVID-19 vaccine candidate NVX-CoV2373 in Japan. (Also see "*Takeda Kicks Off Effort On Globulin, Other COVID-19 Therapies*" - Scrip, 5 Mar, 2020.)

Novavax will license the COVID-19 vaccine technology to the Japanese firm to enable it to manufacture the vaccine antigen and will supply its patented saponin-based adjuvant Matrix-M to Takeda.

In addition, Takeda also plans to distribute *Moderna, Inc.*'s vaccine candidate in Japan. In late August, Moderna confirmed that was in discussions with Japan's Ministry of Health, Labour and Welfare to potentially purchase 40 million or more doses of mRNA-1273, the US firm's vaccine candidate against COVID-19. The arrangement envisages supply of the vaccine by Moderna and distribution in Japan by Takeda beginning in the first half of 2021, assuming the vaccine receives all regulatory clearances.

Coronavirus Update: Japan Makes Moves On Vaccine Manufacturing

By Scrip Team

11 Aug 2020

Takeda has linked up with COVID-19 vaccine frontrunner Novavax, while Daiichi Sankyo has been selected by Japan's Ministry of Health, Labour and Welfare as an official participant under the first round of a national government initiative to build production capacity.

Takeda is also part of the COVID R&D Alliance, a group of over 20 leading biopharmaceutical and life science companies engaged in

speeding up the development of potential therapies, novel antibodies, and antiviral therapies for COVID-19 and its related symptoms. Together with other alliance members *AbbVie Inc.* and *Amgen, Inc.*, the Japanese firm is evaluating the efficacy of cenicriviroc, Otezla (apremilast) and Firazyr (icatibant injection), in severely ill, hospitalized COVID-19 patients who require high-flow oxygen. (Also see "*Coronavirus Update: Lilly Initiates 2,400-Patient Nursing Home Trial*" - Scrip, 4 Aug, 2020.)

Read the full article here

The study is a collaboration between members of the COVID R&D Alliance, Quantum Leap, and the US Food and Drug Administration.

Political Influence On Regulatory Decisions

Meanwhile, Takeda's Venkayya also noted there is a distinction between the hesitancy seen around COVID-19 vaccines and some of the "historic hesitancy" associated with the other vaccines that have become available over the years.

The group that now has questions is "much larger" than the population that has had concerns about vaccines previously, he said, noting that the key driver of this change is perhaps around the speed at which COVID-19 vaccines are being developed.

"We are going from the standard timeline of 10-15 years down to one to 1.5 years to bring this vaccine to the people that need them. So, many people are understandably saying how's that you reduced the time [to reach people] by 90% to approve these vaccines without compromising somewhere," he said at the USAIC summit.

The other elements that are fueling doubts in people's minds specifically revolve around political influence on decision-making at what "previously have been independent, objective [regulatory] agencies."

There has been much attention to the US emergency use authorizations granted to hydroxychloroquine and more recently on 23 August for convalescent blood plasma. "So in light of recent discussions about a COVID-19 vaccine becoming available by the end of October, just prior to the election, as you can imagine there are questions whether there will be political influences on decision- making," the executive noted.

But big pharma, including the front-runner for a COVID-19 vaccine, *Pfizer Inc.*, has sought to provide assurances it will stick to high scientific standards in developing its vaccine and won't be pressured into filing for any authorization or approval before it is satisfied of safety and effectiveness. (Also see "*Pfizer CEO: Vaccine Could Be Ready In October But Won't Be Hurried By*

Political Pressure" - Scrip, 4 Sep, 2020.)

Interestingly, the role of social media in influencing and driving vaccine hesitancy and conspiracy theories was also highlighted by the Takeda executive. At times, social media has acted like "pouring gasoline or petrol onto a spark," he said.

"These kinds of ideas are not founded at all in science, taking off like wildfire and getting traction in the mainstream of the population in ways we've never seen in the past."

COVID-19 Vaccine Sponsors' Pledge To Wait For Phase III Helps US FDA

By Derrick Gingery

09 Sep 2020
The move reduces the pressure on the companies to rush development, but also relieves burden on the FDA to approve a candidate too soon.

Read the full article here

IQVIA recently calculated that COVID-19 has generated a mind-boggling one billion-plus mentions on social media, with the top five most-discussed drugs being hydroxychloroquine, followed by chloroquine, remdesivir, azithromycin and hydroxychloroquine combination therapy and lopinavir/ritonavir combination treatment. (Also see "*COVID-19 Unveils Social Media Might: Is Pharma Listening Hard Enough?*" - Scrip, 30 Jun, 2020.)

'Existential Threat' To Global Economies

Meanwhile, experts at the USAIC summit also emphasized that while there are no "magic bullets" to end the pandemic, whenever the solution arrives it is going to have to be global one.

Dr Richard Hatchett, CEO, Coalition for Epidemic Preparedness Innovations (CEPI), said that the world cannot end the pandemic in "one country at a time", and that arguments for sharing vaccines globally and treating vaccines as a scarce and critical resource that needs to be distributed in a prioritized way with the goal of ending the pandemic, hold good.

"There's an argument for equity from a humanitarian perspective and also an argument for efficiency and this is a case where the arguments for global distribution, the arguments on basis of equity align very closely with the arguments for efficiency," Hatchett said.

He warned that there is certainly an "existential threat" to global economies if not to global populations, "And if we don't use the tools that we have in a very directed, targeted and focused and prioritized way to end the pandemic, the pandemic will be perpetuated and more people will die and more economic damage will be done."

The executive also referred to the progress made by the Covax Global Vaccine Access Facility, a

mechanism designed to ensure rapid and equitable access to COVID-19 vaccines, once they are licensed and approved, as part of the global Access to COVID-19 Tools (ACT) Accelerator. (Also see "*Coronavirus Notebook: Vaccine Pooling, WHO's Law Lab & The Role Of The Llama*" - Pink Sheet, 22 Jul, 2020.)

COVAX is co-led and coordinated by CEPI, Gavi, the Vaccine Alliance and the World Health Organization (WHO), working in alliance with manufacturers in developed and developing nations. On 24 August, the WHO said that 172 economies were engaged in discussions to potentially participate in COVAX.

80 potentially self-financing nations had submitted non-binding expressions of interest to the facility, joining 92 low- and middle-income economies eligible to be supported by the COVAX Advance Market Commitment, the WHO said at the time.