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BIO 2021 Notebook: Looking Past The Pandemic

Annual Meeting Focuses On Post-COVID R&D, Politics And New Opportunities

by Scrip Team

News and views from day one of the BIO Digital annual meeting include debate about when FDA will go back to the offices, industry's role in pandemic-related policy discussions and how to prepare for the next pandemic.

Cerevel CEO Coles On Post-COVID Opportunities

The COVID-19 pandemic changed the conversation about the biopharma industry from pricing, reimbursement and affordability to "how could we save the world," *Cerevel Therapeutics Holdings, Inc.* CEO Tony Coles said during a 14 June fireside chat on the opening day of the Biotechnology Innovation Organization annual meeting.

Now, with society largely grateful and appreciative of the industry's speedy work and innovation in delivering products for COVID-19, the biopharma industry can't rest on its laurels. "We have to always ask ourselves, 'What is the right thing to do at the intersection of innovation, pricing, affordability and availability?' and continue to challenge ourselves to come up with new solutions," said Coles.

As questions emerge about COVID-19 vaccine pricing and intellectual property transfers to developing nations or areas with high need, the biopharma industry must "be part of the conversation – not just in the halls of science and scientific discourse, but in the halls of politics and political discourse as well," he added.

With the Biden administration pledging 80 million vaccine doses to be shipped outside of the US by the end of June, Coles said industry needs a seat at the table in determining how those doses

will be disseminated. “There’s an important question about whether [vaccine doses] are disseminated first come, first serve or on a greatest need basis, or if [vaccine dissemination] will be part of a broader strategy,” he said. “If [the biopharma industry is] not in the room, we won’t be able to contribute our best thoughts toward that effort.”

China and Russia have ramped up “vaccine diplomacy” in countries across the world, Coles noted, adding that China has for many years invested in infrastructure and provided resources to countries in Africa and Latin America, for example, as part of its diplomatic efforts. Using COVID-19 vaccines as a tool for outreach is not different from what the US has done over the last century, from President Woodrow Wilson’s support of the League of Nations to passage of the Marshall Plan in 1948, said Coles. “China has ripped a page from the US playbook. The real question is how the US will respond.”

Preparing For The Next Pandemic

The COVID-19 pandemic showed how rapidly life sciences could mobilize to address an emerging public health threat, with biopharma, academia and regulators developing diagnostics, treatments and vaccines in less than a year. Now the question is whether the life sciences ecosystem will be ready when the next pandemic rolls around.

A 14 June BIO Digital panel on “COVID-19 Therapeutics: Modality, Efficacy and Implications for Access” discussed steps that the various players can take to ensure preparedness happens even faster in the future.

“What I hear a lot is that, well, now we have RNA vaccines, we know how to make them quickly – the next time there’s a pandemic, we can react in a few months,” *Vir Biotechnology, Inc.* CEO George Scangos said. “But a few months might be too long.”

Vir and GlaxoSmithKline plc gained European Union clearance for a COVID-19 monoclonal antibody, sotrovimab, in May. (Also see "*GSK/Vir’s Covid Antibody Gains EU Clearance, But Demand May Have Peaked*" - Scrip, 21 May, 2021.)

Repurposing became a fast way to find new therapeutics for COVID-19, and Scangos offered three suggestions about how it can be useful for future pandemics: throwing a library of chemicals at a virus to see if something blocks it; applying existing drugs that treat symptoms related to the disease such as lung inflammation; or using high-throughput mass spectrometry or high-throughput genetics to identify cellular pathways and then finding drugs that target those pathways.

“That’s the kind of repurposing that I think is more directed and has a much higher change of leading to something productive,” Scangos said.

Researchers now know what types of viruses are likely to cause future pandemics, such as influenza viruses, coronaviruses and others. As such, Scangos said, it is important to make reagents as well as antibodies and small molecules that have broad activity across those families.

Merck & Co., Inc. president-global pharmaceuticals, commercial analytics and digital marketing Arpa Garay echoed that view, adding that developing broad-spectrum antibiotics and having them available would likewise be important.

"Right now, we're talking about viruses – tomorrow's next national security threat could be a bacteria," she said. "But I do think having that preparedness, having things ready to go before vaccines or other interventions are developed is critically important halt the spread of any potential future threats."

Merck has focused on developing small-molecule drugs for COVID-19, though with mixed fortunes. In April, it said it would discontinue development of MRK-7110 – partnered with *OncoImmune, Inc.* – and focus instead on molnupiravir, under partnership with *Ridgeback Biotherapeutics LP*. (Also see "*Merck's COVID-19 Therapeutic Development Path Gets A Little Harder*" - Scrip, 15 Apr, 2021.)

An Evolution Toward Machine Learning?

Of all the ways that COVID-19 has changed drug discovery and development, one that may be surprising is that it could help to drive interest in the use of artificial intelligence and machine learning by helping to spur interest in biotechnology among young people today.

"I think the kids growing up right now, the folks that are doing their undergrad, their PhDs or postdocs, they're not seeing the [Mark] Zuckerbergs and Evan Spiegels as their heroes, but they're seeing the *Moderna, Inc.* co-founders, the *BioNTech SE* co-founders, the *Recursion Pharmaceuticals, Inc.* co-founders ... as their heroes," Lux Capital partner Zavain Dar said during a BIO panel on transforming drug discovery through machine learning. And not only are biotech CEOs replacing the founders of Facebook and Snapchat as role models, public literacy of drug development has improved. "Everyone now has a vocabulary, has an intimacy, has an intuition for what a randomized controlled trial is," Dar said, "they know the difference between a biologic and a small molecule."

That's building on underlying advances in technology awareness. Within five to 10 years, people going into biotechnology will know the basics of computer science and data science, Dar said, just as biologists and chemists are expected to know the basics of mathematics and statistics.

Another panelist, Reverie Labs CEO Jonah Kallenbach, forecast that in 15-20 years, at least 90% of preclinical candidates across different modalities will include some component of machine learning in their discovery process.

“As the advantages of these types of methods get proven out in more and more different modalities [and] disease areas, we’re going to see a sort of seismic shift from the current way that drug discovery is done, which is focused around high-throughput screening, human intervention et cetera, and it’s going to be much more focused around kind of rational, data-driven design, in many parts enabled by machine learning methods, high-performance computing and awesome datasets.”

Industry Eager For FDA To Get Back To Campus; FDA Isn’t

US Food and Drug Administration leaders are nervous about bringing their staff back to the agency’s White Oak, Md., headquarters and expect more hybrid work and remote interactions long-term. Drug companies on the other hand are eager to meet in person with FDA employees.

“There’s no question that sponsors value the in-person meetings, because it allows you to build a relationship at some level with the people on the other side of the table,” said Richard Pops, chairman and CEO of *Alkermes plc* in a 14 June interview with Center for Drug Evaluation and Research Director Patrizia Cavazzoni and Center for Biologics Evaluation and Research Director Peter Marks at BIO Digital.

Meeting someone in a virtual format is much more difficult and can hinder the complex human interaction that occurs during the pharmaceutical development and approval process, Pops said.

“So you can expect us to continue to be pushing for those types of in-person interactions,” Pops said, adding that industry would be happy to supplement those meetings with more frequent and easily arranged virtual meetings.

Pops remarks echoed those of other industry stakeholders in recent *Pink Sheet* interviews. (Also see "*Pondering The Future Of In-Person Meetings At The US FDA*" - Pink Sheet, 8 Jun, 2021.)

But Cavazzoni and Marks don’t expect most FDA employees to switch back to on-campus work until September at the earliest and anticipate a more flexible hybrid approach to work location in the future.

“I am not so anxious to change the status quo despite the fact that we do see some of the pandemic easing off,” Marks said.

Currently CBER has an even heavier workload than at the beginning of the pandemic as it faces continued emergency use authorizations but also the conversion of EUAs to biologics license applications and a backload of other work, and Marks fears productivity will decrease with an on-campus move.

“There's a lot of concern that if we were to stop working remotely right now, the disruption that

that would cause would actually slow things down," Marks said noting his FDA employees are routinely working ten to 12-hour days. "And many people would say if we have to commute an hour each way that's going to just take away from this. It will also kind of destabilize their routine."

Cavazzoni said CDER is experiencing the same tension, noting that once campus reopens there will be an expectation of back to normal, but CDER will likely still be grappling with a pandemic-size workload.

There are also logistical issues for FDA to hosting these meetings, including enough public conference room space at White Oak.

Still both center directors acknowledged that when sponsors really want face-to-face meetings the agency is likely to oblige and in some cases, FDA may want them too.

"There are some sponsors that really like to come and have in-person conversations and I don't think we will stop that," Marks said.

COVID-19 Vaccines: Look Beyond Neutralizing Antibodies

The scientific community must increase its attention to cellular responses and other potential immune correlates of protection in the efficacy assessment of COVID-19 vaccines against current and future variants, experts said during a BIO Digital panel discussion on the power of vaccines to combat the pandemic.

Hanneke Schuitemaker, global head of viral vaccines discovery and translational medicine at *Janssen Pharmaceutical Cos.*, related the efficacy experience with the company's adenovirus-based vaccine against the B.1.351 variant, now known as the Beta variant, which was first detected in South Africa.

Janssen conducted the 40,000-subject pivotal trial for the vaccine at sites in the US, Latin American and South Africa. Although geographical analyses and genetic sequencing suggested Janssen's vaccine was less effective at preventing moderate-to-severe/critical disease resulting from the Beta variant, efficacy still exceeded 73% in preventing severe/critical disease caused by this variant. (Also see "*J&J's COVID-19 Vaccine May Face Efficacy Comparison Questions At US FDA Panel Review*" - Pink Sheet, 24 Feb, 2021.)

[*Read the complete Pink Sheet story on COVID vaccine endpoints.*]