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New Industry Group Seeking Out Antiviral Candidates For Future Pandemics

by Ian Schofield

An alliance of seven R&D-based pharma firms is putting collaboration and partnerships at the center of the search for new antivirals against emerging pathogens.

A new pharmaceutical industry alliance set up to boost the development of new antivirals for use in future pandemics says it plans to publish an initial list of promising compounds later this year once it has completed a "landscape assessment" and scientific evaluation.

The move will support the "100 Days Mission" that was published by the G7 in 2021 and sets out a plan for making effective treatments, vaccines and diagnostics available within 100 days of a new pandemic being declared, according to the INTREPID Alliance, a collaboration of seven pharma R&D firms: AbbVie, Amgen, Gilead, Johnson & Johnson, Novartis, Roche and Takeda.

In compiling the list of compounds with potential activity against infections with pandemic potential, including coronaviruses and other high-risk respiratory virus families, the alliance said it would monitor and evaluate a wide range of innovative antivirals and projects being researched by academia, government, non-governmental organizations and the private sector.

"The listed compounds will include those that the experts assess to be able to proceed quickly into late-stage clinical development on the onset of a new pandemic."

The landscape assessment is expected to identify some R&D gaps requiring new research projects and collaborations to be set up and funded, INTREPID said, adding

Key Takeaways

- The INTREPID Alliance is looking at a range of innovative antiviral candidates currently under research by academia, the private sector and other bodies.

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that it would "offer advice and consultation to help accelerate the selected antiviral compounds that have the strongest potential to positively alter the course of future pandemics."

- The aim is to bring together industry, governments and other stakeholders to help identify products that could be quickly developed in the event of future pandemics.
- A database of Phase II/III-ready antiviral compounds is being set up under the "100 Days Mission" launched in 2021.
- A number of recommendations have been set out for addressing the "overall pandemic ecosystem," including regulatory collaboration and reliance.

New Forms Of Respiratory Pathogens

According to the alliance, globalization, urban expansion and exploitation of natural habitats "suggest humanity will face new forms of respiratory pathogens that hold the potential to become pandemics."

Orally available small-molecule antiviral drugs for rapid mobilization and distribution are "a critical tool to protect societies from a new viral pandemic," and unlike some vaccines and antibodies, antiviral therapies "might be less prone to the impact of virus genetic evolution, may be effective against a broad range of viruses and can change the course of disease even after infection," it said.

"Moreover, they generally are not subject to the same public distrust that has unfortunately prejudiced some against vaccines."

Most small molecule antivirals can be produced rapidly and cost-effectively at global scale in existing facilities, "but they require years to discover and develop, so research and development work must begin now."

A number of antivirals have been authorized in markets around the world for use in the COVID-19 pandemic: Gilead's Veklury (remdesivir), MSD/Ridgeback Therapeutics' Lagevrio (molnupiravir) and Pfizer's Paxlovid (ritonavir plus nirmatrelvir). However, there is a clear need for more therapeutic products against any future global infectious disease outbreaks.

Collaboration The Key

At the heart of the seven companies' initiative is the need for collaboration and partnerships in finding, developing and producing new medical countermeasures, as evidenced by experience with COVID-19.

"This is exactly what the INTREPID Alliance plans to build on – bringing together the experts

and the platform needed to help ensure we are better prepared for future pandemics," said James Anderson, executive director of global health at the International Federation of Pharmaceutical Industries and Associations, who chairs the alliance.

Carl Dieffenbach of the US National Institute of Allergy and Infectious Diseases said an integrated plan for pandemic preparedness would address "key research gaps in top viral families" and accelerate the development of vaccines, therapeutics and diagnostics for prototype and priority pathogens. "It is critical that there is close coordination between governments, key global stakeholders, and industry to put in place the best possible preparation for any future pandemic."

The Biotechnology Innovation Organization, representing US biotech firms, noted that "vaccines alone may not be sufficient for the next pandemic," and "we will need new treatments to reduce the number of deaths and speed our recovery." The INTREPID Alliance would allow "early cross-sector collaboration and data sharing to further antiviral research," it added.

"While Congress works on legislation aimed at supporting initiatives to counter pandemics and health emergencies, members of the pharmaceutical industry are taking it upon themselves to press on with preparation," BIO declared. This is a reference to legislation currently going through the US Congress on a pathogen preparedness program requested by the Food and Drug Administration. (Also see "*US FDA Gets Wanted Pathogen Program, Manufacturers Get Longer BARDA Contracts In Competing Pandemic Prep Bills*" - Pink Sheet, 20 Jul, 2023.)

100 Days Mission

The work of the alliance is in line with the 100 Days Mission's call for the establishment of a database of Phase II/III-ready antiviral compounds with strong potential for efficacy against viral pandemic pathogens that can be deployed into efficacy clinical trials immediately following the declaration of a new pandemic.

The compounds will already have been successfully moved through preclinical and early-stage development and be ready to move to late-stage clinical trials to test their efficacy against the relevant pandemic pathogens, it noted.

INTREPID says it plans to classify antiviral candidates into three groups:

- Clinical agents with approval for clinical trials.
- Preclinical agents.
- Exploratory agents that are in earlier stages of optimization and profiling.

Entry to each of the three groups would be gained by meeting "strict pre-determined entry criteria or target product profiles that would be developed by the INTREPID Alliance in collaboration with multiple external expert groups."

Recommendations

The alliance's work was presented at a one-day Antiviral Summit in March, where a number of recommendations on how to address the "overall pandemic ecosystem" were made by thought leaders and stakeholders from government agencies, industry and multilateral organizations.

A report on the recommendations was published on 20 July, although the alliance stressed that they did not necessarily represent its views or a consensus.

The recommendations include:

- Aim for global alignment across regulatory agencies on protocols, clinical trial design and criteria for authorizing medicines in emergency situations, with streamlining and harmonization of regulatory processes as far as possible.

- Promote regulatory reliance to speed approvals and deliver authorized antiviral medicines to populations faster.

- Create a centralized system of promising investigational candidates and encouraging investment in them, ensuring that gaps are addressed and innovations from small companies are included.

- Collaborate on producing target product profiles to guide research into new antivirals that reflect the needs of patients in low-resource countries.

- Provide government incentives for the discovery, development and manufacturing of antivirals with limited commercial interest.

- Build a network of antiviral trial sites and flexible platforms for rapid response, such as those developed for vaccines by the Coalition for Epidemic Preparedness Innovations (CEPI).