New Report Demonstrates how R&D Partnerships Serving Neglected Communities have Developed Dozens of Life-Saving Innovations Since 2010

_PDPs reduce investment risks and stretch limited budgets leading to 375 innovations targeting infectious diseases under development_

GENEVA and NEW YORK (28 January 2021)—The public-private initiatives that contributed to COVID-19 vaccine and drug development have showcased a model for accelerating biomedical innovation. This is another powerful example of how public-private partnerships have established themselves as powerhouses for fighting global health threats. According to a new report launched today from a group of 12 product development partnerships (PDPs), over the last decade, such alliances have brought to market 66 new drugs, vaccines, diagnostics and other technologies for a number of diseases—including tuberculosis, malaria, HIV, meningitis and sleeping sickness. These innovations have reached and benefitted more than 2.4 billion people in low-income countries.

“The COVID-19 pandemic has brought the critical nature of medical research and development to the fore, to not only protect life but also our interconnected way of life,” said Dr David Reddy, CEO of MMV. “COVID-19 adds to a growing list of diseases that threatens humanity and undermines progress. The PDP model is a key approach to drive medical innovation to address such challenges, particularly for diseases of poverty, and has demonstrated success time and again. We must ensure sustained funding to deliver on the promise of our pipelines and commitment to improve the lives of people affected by malaria and other diseases of poverty.”

The report notes the stark contrast between the product development for diseases of poverty before and after the ascent of PDPs around the turn of the century. For example, from 1975 to 2000, a mere 16 of some 1400 newly developed medicines targeted diseases that mainly affected least-developed countries. Since their inception, PDPs have marshalled industry, government and philanthropic investments and generated new political capital to pack a once-barren global health R&D pipeline. Currently, the cumulative pipeline of the PDPs behind the report contains more than 375 new innovations, 25 percent of them now in late-stage development. That is three times the size of the 2010 pipeline, which itself was many times larger than it was at the turn of the century.

PDPs build alliances between public, private, academic and philanthropic partners, enabling the sharing of financial risks and coordination of diverse expertise and experience. Further, the report finds that a key factor in the success of the PDPs is that they are developing products that are both affordable and adapted for the populations in need. It also reveals that PDPs are cost effective. For example, DND/i estimated their cost to develop and bring fexinidazole, the first all-oral cure for sleeping sickness, to market at between at US $70 to $225 million, compared to the $1.3 billion estimated by Tufts Center for Study of Drug Development as the average cost for for-profit pharmaceutical developers to develop a novel chemical entity.

The report cautions that in order to continue this impressive track record, the future success of PDPs will require a strong focus on late-stage research and efforts to ensure access to recently launched technologies, given the rapidly maturing pipeline of new products. For example, the report points out that there is a need to ensure funding for research (particularly in the context of emerging drug resistance) manufacturing and distribution as well as training health service providers. The report
concludes that “with more products approaching and reaching the market than ever before, the need to continue to invest in research and access is increasingly critical and urgent.”

Notes for Editors

Examples of innovation delivered by PDPs since 2010 include:

- A drug developed by Medicines for Malaria Venture (MMV) in partnership with GlaxoSmithKline (GSK) called tafenoquine that requires only a single dose to prevent relapse of *P. vivax* malaria. This species of malaria is particularly debilitating since it can lie dormant in the liver and relapse multiple times causing new episodes of disease in the absence of a mosquito bite.

- A new drug from TB Alliance, pretomanid, for highly drug-resistant forms of TB is the first treatment regimen approved for extensively drug-resistant TB—the deadliest form of the disease. Pretomanid is to be used as part of a three-drug, six-month, all-oral regimen.

- A new medication, fexinidazole, from the Drugs for Neglected Diseases initiative (DNDi) that provides the first all-oral cure for sleeping sickness, a disease that is usually fatal without treatment. Before the development of fexinidazole, the only treatment available was complicated to distribute and administer in the poor communities of rural Africa where outbreaks still occur, often prompting the use of a toxic medication that killed one in 20 patients.

- An affordable oral cholera vaccine from the International Vaccine Institute (IVI) to combat a disease that kills 100,000 people every year and sickens 2.5 million.

- The first meningitis vaccine developed specifically for Africa. Known as MenAfriVac, the heat-stable, low-cost vaccine from PATH was introduced in 2010. By 2019, mass immunization of 340 million people had virtually eliminated the deadly disease wherever it was used across Africa’s “meningitis belt.”

- A vaginal ring from the International Partnership for Microbicides (IPM) that delivers a safe, steady dose of the HIV prevention drug, dapivirine, giving women a discreet, long-lasting and effective way to protect themselves from infection.

- Bed nets from the International Vector Control Consortium (IVCC), Interceptor® G2, that can protect against insecticide-resistant mosquitoes that carry malaria, addressing a major threat to one of the most critical tools for fighting the disease.

- A new drug, moxidectin, that could accelerate elimination of onchocerciasis (also known as river blindness). The non-profit biotech PDP Medicines Development for Global Health (MDGH) achieved approval in the U.S. as its sole sponsor.

Meanwhile, the current PDP pipeline includes a number of promising innovations. For example, the International AIDS Vaccine Initiative (IAVI) is developing broadly neutralizing antibodies against HIV that are infusing new promise into the quest for an HIV vaccine. PDPs, including the Tuberculosis Vaccine Initiative (TBVI), have reinvigorated the TB vaccine pipeline, having contributed to the development of 13 of the 20 candidates currently under development, seven of which are in late-stage development. In 2000, there was no TB vaccine in any stage of development.

The European Vaccine Institute (EVI) is supporting the development of a vaccine against a chronic form of leishmaniasis that causes debilitating and disfiguring lesions on the face, limbs and trunk for some 100 million people annually in poor communities across 100 countries. The Foundation for Innovative
New Diagnostics (FIND) and DNDi are part of an effort to develop a self-administered test for hepatitis C.

Tapping PDPs to Fight COVID-19

Meanwhile, the report documents how PDPs have helped build global capacity to conduct cutting-edge medical research, including working with 550 clinical trial sites in some 80 mostly low-income countries. It notes that this global infrastructure has been tapped to speed the development of COVID-19 vaccines and treatments, and that PDPs have contributed in many other ways to fighting the pandemic. For example:

- DNDi and MMV dispatched Pandemic Response Boxes free of charge to researchers in low-income countries, which included 400 compounds active against bacteria, viruses, or fungi, allowing them to be tested for potential use in the COVID-19 response. MMV then launched the COVID Box of 160 compounds with known or predicted activity against SARS-CoV-2.
- IVI has supported the development of COVID-19 vaccines, including work to prepare clinical sites in four African and Asian countries to potentially participate in Phase 3 efficacy trials.
- EVI is also participating in the development of COVID-19 vaccines via its work with the TRANSVAC initiative, which offers free scientific, technical and other services to accelerate the development of urgently needed vaccines for global health.
- IAVI has contributed its considerable expertise in developing broadly neutralizing antibodies against HIV to a collaboration that has identified two monoclonal antibodies with the potential to protect against SARS-CoV2. They will soon advance to clinical trials.
- FIND is co-leading the Diagnostics Pillar of the Access to COVID-19 Tools (ACT) Accelerator, a global collaboration to ensure equitable access to the tests, treatments and vaccines needed to defeat the pandemic.

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