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In a bid to rid the world of infectious diseases, pharmaceutical companies are continuously striving to align their financial considerations – specifically, maximizing their return on R&D investment (ROI) – with corporate social responsibility. Drug and vaccine developers can reach this compromise by partnering with public authorities and other entities in order to mitigate upfront R&D risk, while at the same time positioning products for use in low income settings where they are often needed most, according to GlobalData, a leading data and analytics company.

Since January 2012, malaria and 17 other tropical diseases have been listed by the World Health Organization (WHO) as meeting their recommended requirements for control and eradication. In 1980, smallpox, once a debilitating and lethal disease, was officially declared eradicated by the World Health Assembly (WHA), the governing body of the WHO.

Gilbert Saint Jean, <u>Healthcare Analyst at GlobalData</u>, comments: "The success of the smallpox eradication campaign is a template for the multi-sectorial collaboration of government, pharmaceutical, and other private entities that is required for the control and eradication of infectious diseases. Malaria and a suite of other tropical diseases are classified as 'neglected' as companies have traditionally been reluctant to prioritize the development of products to address them. As most of these diseases are prevalent in low-income countries where it is often challenging to achieve sufficient ROI, pharmaceutical companies are working with public authorities to create mechanisms to circumvent this problem."

One such mechanism that is currently being used in the US is the Priority Review Voucher for Neglected Tropical Diseases (PRV-NTD). A PRV-NTD voucher is granted if a pharmaceutical company develops a US-approved drug or vaccine for an indication from an FDA-specified list of tropical diseases, including malaria, and provides the company with the option for a six-month expedited review instead of the standard 10-month period. Orphan Drug Status, which affords a period of market exclusivity, can be simultaneously granted to the drug. Coartem, an artemisinin-based combination therapy (ACT) developed by Novartis for treating malaria, received the first PRV-NTD approval in 2008. Coartem is now a first-line treatment for malaria across Africa and Southeast Asia, where this disease is endemic. The PRV-NTD voucher can also be sold as a commodity. For example, United Therapeutics sold its voucher for \$350M in 2015 to AbbVie.

Saint Jean adds: "Given the moral imperative of disease eradication, we predict that additional, creative public-private investment mechanisms for tropical disease eradication must be created

To help eradicate neglected tropical diseases, pharma must juggle ROI concerns and social responsibility

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and applied to incentivize eradication goals. The funds from selling a PRV-NTD can be reinvested into further pharmaceutical R&D for tropical diseases. This is a form of an investment positive reinforcement cycle that can mitigate R&D costs by increasing the chances that ROI will be achieved."