

Stop TB Partnership and Johnson & Johnson, with support from USAID and The Global Fund, Announce Price Reduction for SIRTURO® (bedaquiline) for Treatment of Drug-Resistant Tuberculosis in Low- and Middle-Income Countries

Joint efforts aim to accelerate scale-up of WHO-recommended all-oral treatment regimens – a transition urgently needed to help protect the health of people with drug resistant-tuberculosis who are particularly vulnerable during COVID-19 pandemic

In 2020, the initiative aims to reach at least 125,000 patients and could save National TB Programs in low- and middle-income countries up to USD\$16 million

GENEVA, SWITZERLAND, 6 JULY 2020 – The Stop TB Partnership and Johnson & Johnson – with support from the Global Fund to Fight AIDS, TB and Malaria, and the U.S. Agency for International Development (USAID) – today announced joint efforts to help enable low- and middle-income countries to rapidly scale up use of SIRTURO® (bedaquiline) 100mg tablets in support of new, recently-released World Health Organization (WHO) [treatment guidelines](#).

Effective immediately, Johnson & Johnson will make bedaquiline available to Stop TB Partnership's Global Drug Facility (GDF) at a price of USD\$340 per six-month treatment course for more than 135 eligible countries. To help support and accelerate further scale-up of all-oral treatment regimens, the company will also provide an escalating percentage of free goods when certain volume thresholds are reached on an annual basis: 10% above 55,000, 20% above 125,000 and 30% above 200,000 treatment courses.

With support from the Global Fund and USAID, as well as governments and other partners, the Stop TB Partnership expects to receive confirmed orders for at least 125,000 people with DR-TB in 2020 and will, therefore, receive two treatments for free out of every 10 ordered. This would reduce the effective net price of bedaquiline by 32%, compared to the original USD\$400 price. In the first year alone, this could lead to an estimated savings of up to USD\$16 million for national TB programs – equivalent to the amount needed to treat an additional 30,000 people with short-course DR-TB regimens.

“In a world filled with worrying news, this new agreement is a welcome development and one that will help us move closer to the United Nations High-Level meeting target of treating 1.5 million people with DR-TB by 2022,” said **Dr. Lucica Ditiu, M.D., Executive Director of the Stop TB Partnership**. “Even though these days we fight against the new COVID-19 pandemic, we cannot let this new virus stop our progress against TB, and it's critical that diagnosis and treatment for all forms of TB continue to be prioritized.”

As the leading funder of TB programs in low- and middle-income countries, the Global Fund is working with partners to support countries in reaching the 125,000 MDR-TB treatment target for 2020.

“As the world responds to COVID-19, it is critical that we don't just fight the new pandemic but act decisively to mitigate the knock-on impact on other diseases, protecting lifesaving programs and shoring up overstretched health systems,” said **Peter Sands, Executive Director of the**

Global Fund to Fight AIDS, TB and Malaria. “This new agreement offers an opportunity to save more lives through scaling-up more effective treatment of a difficult-to-treat and deadly disease.”

For its part, USAID, the largest bilateral funder of TB efforts globally, has been a leader in partnering with high-burden TB countries in the successful implementation of their national TB strategies for over 20 years. USAID’s Global Accelerator to End TB is building countries’ commitment and capacity to reach the United Nations High-Level Meeting TB targets by 2022. This significant increase in the availability of bedaquiline will enable USAID to support high-TB burden countries to expand access to and improve the quality of MDR-TB diagnosis, care, and treatment services to save lives.

The new WHO guidance has become even more critical during the COVID-19 pandemic, with [WHO advising](#) TB-affected countries to urgently shift to all-oral treatment to enable home-based care and help protect the safety of people receiving DR-TB treatment. Historically, people with DR-TB had to take lengthy treatment regimens, some of which had suboptimal cure rates and included injectable medicines with significant side effects. In the current crisis, oral treatment regimens eliminate the need for frequent clinic visits to receive injectable medicines, enabling affected people to avoid unnecessary exposure to COVID-19.

“Enabling access to affordable, effective all-oral treatments for people with MDR-TB is an urgent and important step towards ending TB,” said **Dr. Tereza Kasaeva, Director of WHO’s Global TB Program**. “WHO welcomes this new agreement and calls all countries and partners to come together and implement ambitious programs to test and treat all people with TB for drug resistance, in line with the new WHO guidelines.”

People affected by TB are among the most vulnerable populations to the COVID-19 pandemic mitigation measures. Lockdowns can result in the interruption or absence of access to treatment, and the pandemic has also brought about new forms of economic hardship, isolation, stigma and discrimination. As such, the COVID-19 pandemic has proven to be a major setback in achieving the [UN TB targets](#), as TB case detection has dramatically fallen, treatment initiation is being delayed, and the risk of treatment interruption and potential increase of people with drug-resistant TB has increased.

“Even as the world wages an unprecedented battle against a new enemy – COVID-19 – we must continue to protect vulnerable people around the world who are suffering from other health challenges, such as DR-TB,” said **Dr. Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer of Johnson & Johnson**. “As we strive for people with TB to be safely treated at home where possible, during this challenging time of a global lockdown and social distancing, our joint efforts will help enable countries to transition to simpler, all-oral regimens and achieve that goal as quickly as possible.”

A recent [modeling study](#) released by the Stop TB Partnership in collaboration with the Imperial College, Avenir Health, and Johns Hopkins University shows a range of adverse impacts on TB diagnosis, treatment and mortality rates due to the national lockdowns and gradual restoration measures required to contain the COVID-19 pandemic. The study reported the potential for an additional 6.3 million TB cases between 2020 and 2025, and an additional 1.4 million TB deaths in this same period.

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Notes to editors

About TB

TB is a forgotten respiratory disease that still kills 1.5 million people each year, more than any other infectious disease. It is a bacterial, airborne disease with the [WHO reporting](#) cases in all countries worldwide in 2018. Incidence and deaths due to TB have been declining steadily over the last several years as a result of intensified activities by high-burden countries to find people with TB early and provide appropriate treatment.

About Drug-Resistant TB

Growing resistance to the most commonly used drugs is compounding this public health challenge. In 2018, there were nearly 500,000 new cases of DR-TB and, today, DR-TB is the leading contributor to deaths from antimicrobial resistance (AMR). Of those 500,000 new cases, 78% had multidrug-resistant TB (MDR-TB)—a form of TB that does not respond to at least isoniazid and rifampicin, the two most powerful anti-TB drugs.

Improvements in diagnosis and treatment rates are needed to help control the DR-TB epidemic. In 2018, only one-third of people with DR-TB were diagnosed, meaning that approximately 300,000 people with the disease were not even aware they are infected, posing a significant threat to human health and global health security.

About Bedaquiline Access Efforts to Date

When bedaquiline received its initial accelerated approval by the U.S. Food & Drug Administration in 2012 to treat MDR-TB as part of combination therapy, it was the first targeted TB medicine with a novel mechanism of action in more than 40 years. It is one of only three new TB medicines to be introduced in half a century. Bedaquiline has formal regulatory approval in 64 countries, and access pathways have been identified for all UN Member States.

To date, Johnson & Johnson has provided more than 210,000 courses of bedaquiline to people in need in 141 countries, including the 30 countries with the highest burdens of DR-TB globally. From 2015-2019, the company provided 105,000 courses free of charge through a four-year donation program with USAID and JSC Pharmstandard.

GDF served as the procurement partner for the donation program, ultimately supporting 83 countries to access free products. GDF utilized its Strategic Rotating Stockpile to minimize supplier transaction costs and expedite delivery to countries. GDF provided technical assistance on quantification and supply planning, and support for new regimen introduction following changes in WHO DR-TB Treatment Guidelines, and conducted rapid assessments in more than 80 countries, triangulating data on inventory, enrollment, and existing orders to ensure equitable allocation of the donation across all eligible countries.

- For ordering information – please see [GDF Catalog](#)
- For information on the FDA approval of bedaquiline, please see the [FDA website](#)
- For WHO DR-TB Treatment Guidelines, please see the [WHO website](#)

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About the Stop TB Partnership

The Stop TB Partnership is a unique United Nations hosted entity based in Geneva, Switzerland, committed to revolutionizing the tuberculosis (TB) space to end the disease by 2030. The organization aligns more than 2,000 partners worldwide to promote cross-sectoral collaboration. The Stop TB Partnership's various teams and initiatives take bold and smart risks to identify, fund and support innovative approaches, ideas, and solutions to ensure the TB community has a voice at the highest political levels and that all TB affected people have access to affordable, quality, and people-centered care. Learn more at www.stoptb.org, and follow us at [@StopTB](https://twitter.com/StopTB).

About the Global Drug Facility

[GDF](#) is the world's largest procurer of TB medicines and diagnostics. Since its creation in 2001, GDF has facilitated access to TB medicines and diagnostics in more than 140 countries, making quality-assured treatments available to over 32 million people with TB. In 2019 alone, GDF delivered nearly USD\$ 264 million worth of TB medicines and diagnostics to 116 countries. GDF has led the introduction of advanced diagnostics and supplies, all-oral regimens for DR-TB as recently recommended by WHO, child-friendly medicines for drug-sensitive TB and shorter regimens for multidrug-resistant TB. Since 2012, GDF has secured price reductions of over 50 percent for most second-line TB medicines, primarily by reducing risk to suppliers and minimizing their transaction costs. Between Jan 2019 – Mar 2020, GDF saved National TB Programs approximately USD\$53 million: USD\$33 million in medicine price reductions from competitive tenders; USD\$15.3 million by readjusting inaccurate quantification/order numbers; and, USD\$4.2 million by allowing flexibility to cancel and postpone previously paid orders

Over the last decade, GDF's efforts have spurred a more than five-fold increase in the number of companies producing TB products—from just five in 2007 to 28 in 2019, and an 11-fold rise of quality-assured products from eight in 2007 to 89 in 2019. GDF's approach to bundle procurement with technical assistance on quantification and supply planning allows GDF to monitor for risks of future stockouts via national early warning systems and take necessary action to avoid stockouts.

About Johnson & Johnson

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based healthcare company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity.

Johnson & Johnson has been a committed partner in the fight against TB for more than two decades. Building on this commitment, in September 2018, Johnson & Johnson [announced a comprehensive 10-year initiative](#) in support of the United Nations Sustainable Development Goal target of ending the TB pandemic by 2030. The initiative aims to improve the global detection of undiagnosed TB cases, broaden access to bedaquiline for MDR-TB, and accelerate research & development (R&D) to discover next-generation TB treatments. Additionally, in October 2019, Johnson & Johnson [committed to invest USD\\$500 million over the next four years](#) to help end the TB and HIV epidemics.

Learn more at www.jnj.com/tb, and follow us at [@jnjglobalhealth](https://twitter.com/jnjglobalhealth).

About USAID

USAID is the world's premier international development agency and a catalytic actor driving development results. USAID's work advances U.S. national security and economic prosperity, demonstrates American generosity, and promotes a path to recipient self-reliance and resilience. The purpose of foreign aid should be ending the need for its existence, and we provide development assistance to help partner countries on their own development journey to self-reliance – looking at ways to help lift lives, build communities, and establish self-sufficiency.

About the Global Fund

The Global Fund is a partnership designed to accelerate the end of AIDS, tuberculosis and malaria as epidemics. As an international organization, the Global Fund mobilizes and invests more than USD\$4 billion a year to support programs run by local experts in more than 100 countries. In partnership with governments, civil society, technical agencies, the private sector and people affected by the diseases, we are challenging barriers and embracing innovation.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding SIRTURO® (bedaquiline). The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended 29 December, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.