

## **GDF Approach to Access & Recent TB Medicine Price Reductions**

**Brenda Waning, GDF Chief** 

13 October, 2023 TB Situation Room Webinar





# GDF Works End-to-End Approach across Entire Product Lifecyle to Promote Equitable Access to TB Products

Partnership Approach

Goal is to have quality, optimized, affordable products developed and accessible to those who need them as quickly as possible



 $\rightarrow$ 



### Adult Rifapentine/Isoniazid 300/300 (3HP) for TB Prevention

- Lupin and Macleods:
  - **Price:** New price is \$9.99 \$10.96 per treatment course (EXW)
    - 23-30% decrease from previous price of \$14.25
  - Validity: Sep 2023 through end 2024
  - Eligibility: All countries
  - Estimated Savings: \$16.5 million over the 16-month contract period, an amount sufficient to procure an additional 1.7 million 3HP treatment courses
  - Note: Collaboration with USG who committed to \$25million in funding for 3HP procurement

#### • GDF Next steps:

hosted by

**WUN**OPS

- $\odot$  Explore market for additional suppliers
- $\circ$  Prepare for potential demand increase pending ongoing rifapentine research & WHO Guidelines
- $\circ$  Launch a competitive tender mid-2024 with new contract start date of 1 Jan, 2025



### **Delamanid 50mg for DR-TB Treatment in Adults**

• Otsuka:

• **Price:** New price is \$1,190 per treatment course (EXW)

- 30% decrease from previous price of \$1,700 per treatment course
- Validity: Aug 2023 onward (sole supplier)
- Eligibility: 89 low- and middle-income countries
- Estimated Annual Savings: \$3 million

### • Viatris:

 $\circ$  Delamanid in final stages of WHO PQ evaluation for active pharmaceutical ingredient

### • GDF Next steps:

- $\circ$  Launch a competitive tender if/when Viatris receives WHO prequalification approval
- $\circ$  Prepare for potential demand increase pending ongoing delamanid research & WHO guidelines
- Monitor progress on additional suppliers entering market



### **Bedaquiline 100mg for DR-TB Treatment in Adults**

- J&J and Lupin, plus Macleods as auxillary supplier:
  - **Price:** New price is \$130-\$194 per treatment course (EXW)
    - 33-55% decrease from previous price of \$289 per treatment course
  - $\odot$  Price Validity: Sep 2023 through end 2024
  - Eligibility: 134 low- and middle-income countries
  - Estimated Savings to GDF Clients: \$8 million in savings over the 16-month contract period, an amount sufficient to procure more than 51,000 additional bedaquiline treatments
- Other potential generic suppliers:
  - $\circ$  2 other suppliers have submitted applications to WHO Prequalification
- GDF Next steps:
  - Prepare for entry of additional suppliers; Develop strategy for supplier management in a lowvolume market
  - o Launch a competitive tender mid-2024 with new contract start date of 1 Jan, 2025



#### **New GDF Regimen Prices by Medicine\*: BPaLM and BPaL**

hosted by WOPS

->

Regimen	Old Lowest Price	New Lowest Price	
BPaLM	\$585	\$426	26% price decrease BPaLM
Bedaquiline 100mg**	\$289	\$130	
Pretomanid 200mg	\$238	\$238	
Linezolid 600mg	\$31	\$31	
Moxifloxacin 400mg	\$27	\$27	
BPaL	\$558	\$399	29% price decrease BPaL
Bedaquiline 100mg**	\$289	\$130	
Pretomanid 200mg	\$238	\$238	
Linezolid 600mg	\$31	\$31	*GDF prices as of 30-Aug-2023

\*\*BDQ used for 26 weeks (rather than 24 weeks)



### **GDF Services & Resources**

- These 3 medicine price reductions alone are expected to save GDF clients at least \$27 million over the next 15 months
  - Considerable savings considering GDF delivered ~\$71 million worth of DR-TB medicines in 2022
  - Timely development given TB funding constraints
- GDF Technical Assistance

hosted by

**UN**OPS

- Support with procurement and supply planning to phase-in new products/regimens and phase out old products/regimens
- Quantification and early warning systems to prevent stockouts
- $\circ~$  Budget revisions to optimize use of savings
- GDF prices can be found in the GDF Catalog\_and and in GDFs on-line order system
- To order via GDF, visit the STBP website



https://www.stoptb.org/global-drug-facility-gdf/gdf-product-catalog



#### **Proactive, Multi-Stakeholder Interventions via TPMAT to Expedite Access**

Bedaquline 100mg: Process begins with WHO Guidelines



https://www.stoptb.org/global-drug-facility-gdf/market-partner-coordination

hosted by

**WUN**OPS

 $\rightarrow$ 



### **TB Medicines Dashboard**

#### Adult Drug-Resistant TB Medicines Dashboard

This Dashboard has been developed by Stop TB Partnership/Global Drug Facility in collaboration with USAID, the World Health Organization and The Global Fund to fight AIDS, TB & Malaria. Stop TB Partnership/Global Drug Facility licensed the TB Medicines Dashboard under a Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License. Status

Yes No Ineligible for inclusion Removed N/∆ Medicines	WHO Guidelines (DR-TB '20)	WHO Guidelines (DR-TB '22)	EML submitted	EML (2023)	WHO PQ EOI (2021)	WHO PQ Dossier Under Review	WHO PQ listed	Global Fund List of Pharmaceutical Products	Global Fund ERP EOI (July 2023)	Global Fund ERP recommended	GDF Catalog
Bedaquiline 100mg tablet											
							1				
					Submitted to WHO PO: Decision expected seen						
					Submitted to WHO PQ; Decision expected soon						

https://www.stoptb.org/market-partner-coordination/tb-medicines-dashboard





### Thank you

Brenda Waning

Chief, Global Drug Facility

Brendaw@stoptb.org

#### Acknowledgements

- Brian Kaiser for support with presentation
- Entire GDF staff for their relentless efforts and commitment
- GDF's contracted suppliers of these medicines: Lupin, Macleods, Otsuka, Johnson & Johnson
- GDF Donors: USAID and Government of Japan

