


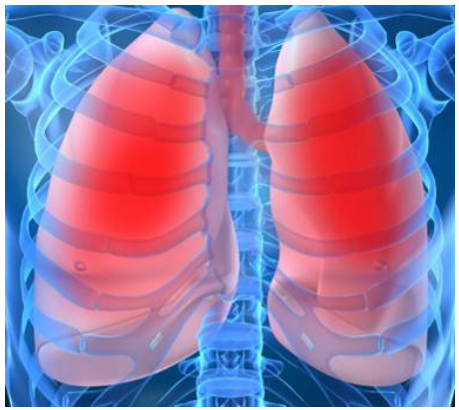

FIGHTBACK

Delamanid for MDR-TB: Current Development Progress and Ongoing Access Plans

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Otsuka

TB innovation for tomorrow.

Background: The Otsuka Philosophy

Different Approach from Other Life Science Companies

- Screening anti-TB compounds for >30 years
- However, “global health” a new area for Otsuka
- Specialize in long-term effective treatments requiring strong safety profile
- Strong commitment to avoid emergence of resistance

Long-term vision: Development of entire disease-management portfolio

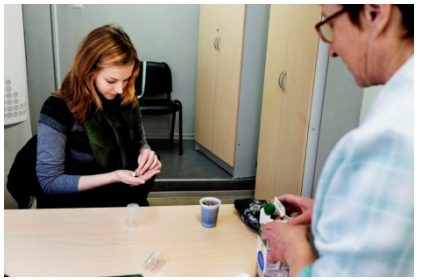
- More than 1 new compound, we have an active R&D portfolio of several products aimed at changing the paradigm of MDR-TB management
  - Only possible by working on issues related to diagnosis, treatment monitoring and treatment regimens

Our Priority: Roll-Out Delamanid *Safely* and *Responsibly*

- Early global health products benefited from wide-scale use prior to introduction in resource-limited settings (e.g. ARVs for HIV)
  - Comfortable post-approval safety database with 10-20x the number of patients in standard phase 2 or phase 3 MDR-TB clinical trial
- Delamanid has received *conditional* approval by stringent regulatory authorities
  - In Japan we are required to track and trace every patient for 10 years
- A risk management plan is implemented for all patients including:
  - Distribution (criteria for patients, physicians, hospitals)
  - Education and training (patients, physicians, hospitals)
  - Data collection (registry)
  - Delamanid drug susceptibility testing
  - Safety reporting (pharmacovigilance)

Update on Development Activities

Phase III Trial



- 511 patients enrolled
  - Randomized 2:1 ratio (DLM:PLC)
  - First use of DLM & moxifloxacin
  - Nested cohort of HIV+ positive patients on ARV treatment
    - ❖ No DDI issues with ARVs or second-line drugs for DLM
- No additional safety concerns to date

Pediatric Development Program

- Delamanid only pediatric formulation of 2nd-line anti-TB drug with ongoing studies and results being published
  - How can we work with the community to stimulate generation of more PK data and encourage pediatric formulations for other 2nd-line drugs?

The Way Forward

- Otsuka believes the way forward for successful introduction of DLM requires:
  - Long-term strategic planning
  - Careful introduction in quality TB management programs
  - Country level support for implementation
  - Prevention of additional drug resistance
  - Strengthened pharmacovigilance systems

- Sometimes perceived as in conflict with pressure to make delamanid available as soon as possible, to as many people as possible, worldwide

- We have heard the urgent needs of TB community and are responding by introducing a comprehensive, multi-stakeholder initiative addressing delamanid access for MDR-TB

“Otsuka’s FighTBack Initiative”

The Goal

“20 by 2020”

By 2020, at least 20% of diagnosed and treated MDR-TB patients should have delamanid as part of their treatment regimen through high-quality programs.

Core Components – 4 Pillars