Developing Long-acting Injectables (LAIs)

KEY OPPORTUNITIES TO DRASTICALLY SHORTEN TREATMENT FOR TB

Developing LAIs for both **latent and active TB** infections

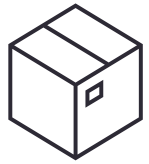
For active TB, treatment could be initiated with **oral lead-in therapy, followed by LAIs**

For latent TB, people could be diagnosed and treated on the **same day** with a single LAI

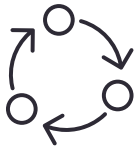
LAI formulations of selective drugs could also have **potential applications** for treating other diseases

LAI development considerations

IMPORTANT CONSIDERATIONS FOR LAI TECHNOLOGY PLATFORM SELECTION

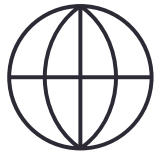


Established technologies in approved commercial products



Simple equipment and an uncomplicated manufacturing process

Established CMC regulatory pathways



Easy to scale up and transfer to global partners/CDMOs

Meets TBA mandate

- AVAILABLE
- AFFORDABLE
- ADOPTABLE

THE GOAL

A universal treatment

KEY OPPORTUNITIES TO SPEED GLOBAL UPTAKE OF NEXT-GENERATION TREATMENTS

ORAL REGIMEN OF

- 3-4 drugs
- Administered for 30 days
- No pre-existing resistance

1 month

SINGLE INJECTION OF

- 2-3 drugs (of the oral regimen)
- Therapeutic PK for 3+ months

DRAFT TARGET PROFILE

TB Regimen LAI for treatment of pulmonary TB

VARIABLE	TARGET
Indication	Regimen with **oral run-in** then LAIs of 2-4 drugs indicated as 1st-line treatment for pulmonary TB (Drugs in LAIs = drugs in oral run-in)
Product	≤4 LAI separate agents with oral run-in, **≤ 3mL** per injection
Duration	One-month oral run-in, then **LAI, effective PK coverage**
Route of administration	**Intramuscular or subcutaneous;** Upper-thigh, arm, abdomen, or gluteal
Formulation Dosage & Administration	Injections **administered by local HCW, no specialized training** Co-packaged components

Status update on LAI development

SORFEQUILINE

A single administration of our long-acting injectable formulation demonstrated sustained systemic exposure for approximately four months in a preclinical model

PRETOMANID

The high-concentration solution formulation demonstrates a promising in vivo release profile, supporting its further development as a long-acting injectable

TBAJ-587

Another diarylquinoline demonstrates a desirable PK profile in animal model

A new frontier in TB therapy is within reach

1

FEASIBILITY CONFIRMED

Long-acting injectables (LAI) formulations are technically feasible for key TB drugs, including:

Bedaquiline, Sorfequiline, TBAJ-587, Pretomanid, Telacebec and Rifabutin

2

CHALLENGES ACCEPTED

While significant hurdles in formulation, stability, and manufacturing remain, these are surmountable with focused effort

3

PROMISE OUTWEIGHS HURDLES

The transformative potential of LAIs to significantly impact and improve treatment adherence, simplify care, and accelerate TB elimination makes this a critical and achievable goal