Third Indication: Non Tuberculous Mycobacteria (NTM)

NTM is an FDA disease area of focus with limited options. Patients can die within a few years[1]

How is NTM Caused? [2]

- Acquired by inhalation from the environment
- Water thought to be the main source
- Warmer climates have higher infection rates
- Patient to patient transmission possible

Who is at risk? [2]

- Underlying lung disease and/or genetic predisposition
- Cystic Fibrosis (CF) patients
- COPD (chronic obstructive pulmonary disease)
- Bronchiectasis patients
- Immunosuppressive therapy

NTM Market Dynamics?

AIT is initially targeting NTM *abscessus* (MABSC), the most aggressive and difficult to treat form of NTM. AIT expects to seek approval in NTM MAC (mycobacterium avium complex) following MABSC approval

- There is no competition in MABSC and limited competition in MAC
- Median survival for MAC is 13 years while for non-MAC NTM it is 4.6 years [6]
- 20% - 25% of all NTM cases in a South Korean database are MABSC [5]
- Over 180k NTM cases were estimated for 2014 in the United States[3]
- NTM costs estimated at $1.7b[3] with MABSC costs > 2x MAC costs
- 37% of NTM confirmed Cystic Fibrosis patients in the US are MABSC [4]

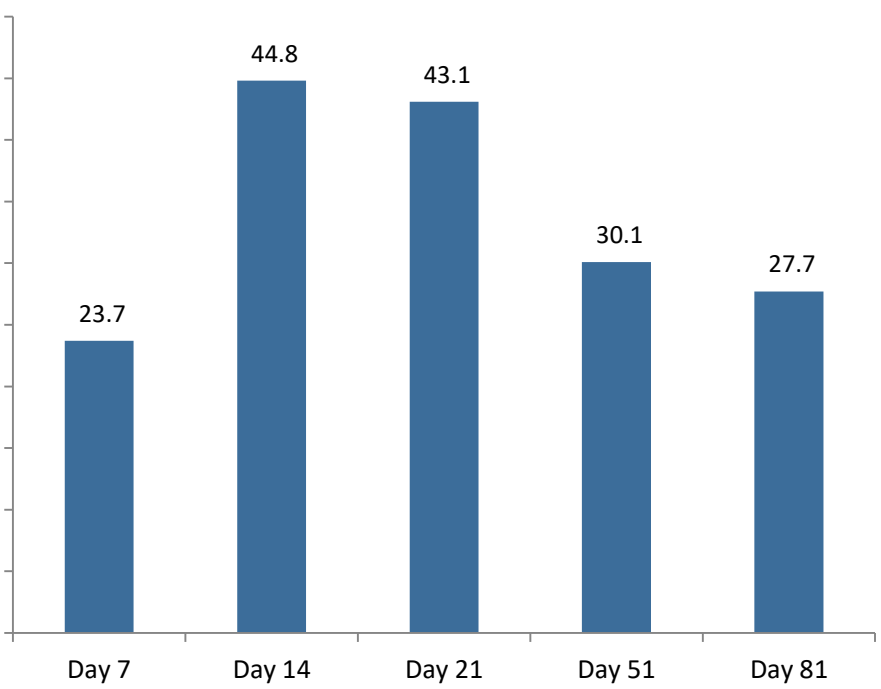
(1) https://www.fda.gov/downloads/Drugs/NewsEvents/UCM471341.pdf
(2) Data: www.ntmfacts.com, FDA
(3) Strolloet al. The Burden of Pulmonary Nontuberculous Mycobacterial. Pub 27-July-2015
(4) Data presented at ATS 2017 (Derek Low et al, Medical University of South Carolina)
(5) Data presented at ATS 2017 (Keun Burn Chung et al, Seoul National University College of Medicine)
(6) Kotilainen, H. et al. "Clinical Findings in Relation to Mortality in Non-Tuberculous Mycobacterial Infections: Patients with Mycobacterium Avium Complex Have Better Survival than Patients with Other Mycobacteria." European Journal of Clinical Microbiology & Infectious Diseases 34.9 (2015)

Pulmonary Infections: eg. Nontuberculous Mycobacteria (NTM)

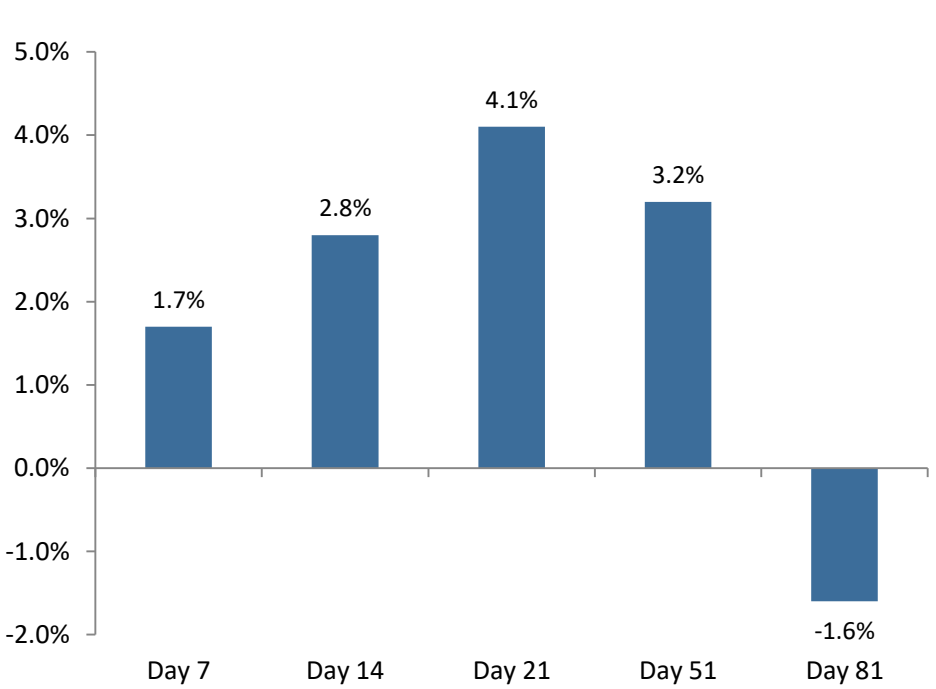
Proprietary NO formulation yielded positive clinical results in humans in its single arm pilot NTM study

- 9 CF patients with refractory MABSC were treated at 3 centers in Israel with NO added to background antibiotic therapy
  - 160 ppm NO was given via mask for 30 min 5x/day for 14 days and 3x/day for 7 days
  - Primary endpoint of safety was met, with no NO-related serious adverse events (SAEs) observed
  - Key secondary endpoints of 6-minute walk (6MW) and FEV1 are shown in the charts below
  - Bacterial load, as measured by qPCR showed a 65% reduction at day 81 versus baseline
    - One patient was culture negative at Day 51 and Day 81
  - Quality-of-Life data showed positive trends on relevant questions (SF-36 used)
  - Tolerability not an issue as no patient requested that any treatment be stopped or not administered

6MW Mean Inc. in Distance (meters) v. Baseline



Mean % change in FEV1 from Baseline



DATA PRESENTED IN AN ORAL SESSION AT AMERICAN THORACIC SOCIETY (ATS) 2018

Source: AIT management

Pulmonary Infections: Nontuberculous Mycobacteria (NTM)

AIT's Goal is to initiate a pivotal trial in United States in 2019

AIT Plans for Approval

- FDA is asking for "evidence of efficacy for a clinically meaningful outcome evaluated in adequate and well controlled trials"
- AIT believes that a placebo controlled trial with a primary endpoint of 6MW, plus relevant secondary endpoints, will be adequate for approval
- Secondary endpoints would include FEV1, bacterial load in sputum, QoL and safety
- Length of therapy would potentially extend beyond 21 days
- The use of our proprietary generator as the source for NO provides the potential flexibility to have patients self-administer at home
- Make our NO therapy available to NTM patients in the US by the end of 2022
- AIT must execute and work closely with FDA to make this happen
- Potentially other severe, chronic and refractory infections can be targeted

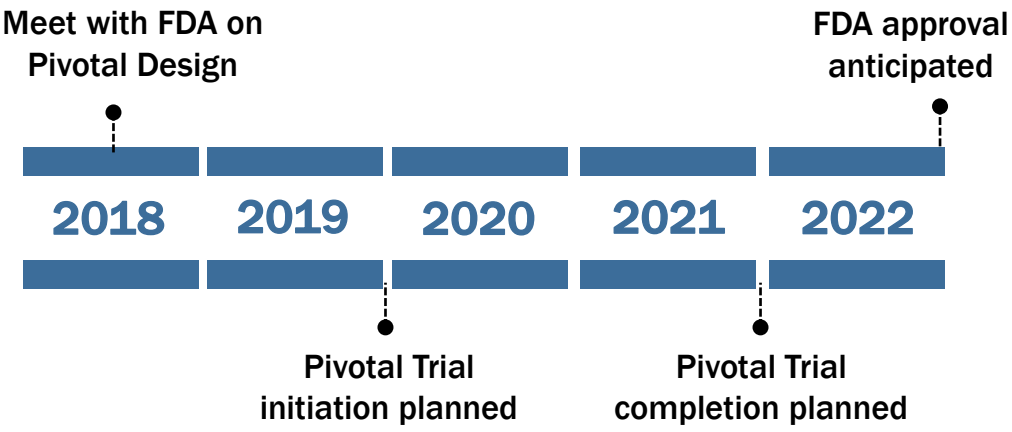
FDA Guidance(1)

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Conclusions

- Drugs need to show evidence of *efficacy for a clinically meaningful outcome* evaluated in *adequate and well controlled trials*
- Surrogate markers can be used for approval if the surrogate has been shown to *predict/correlate with* a meaningful clinical outcome
- PROs, if validated, can be used for approval
- Co-development of a new test drug combination may be possible in certain situations

Timeline & Plan for Registration in the US



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