

Phase 2, double-blind, randomized, placebo-controlled, multicenter study to evaluate the efficacy and safety of omadacycline in adults with *Mycobacterium abscessus* complex (MABc) pulmonary disease

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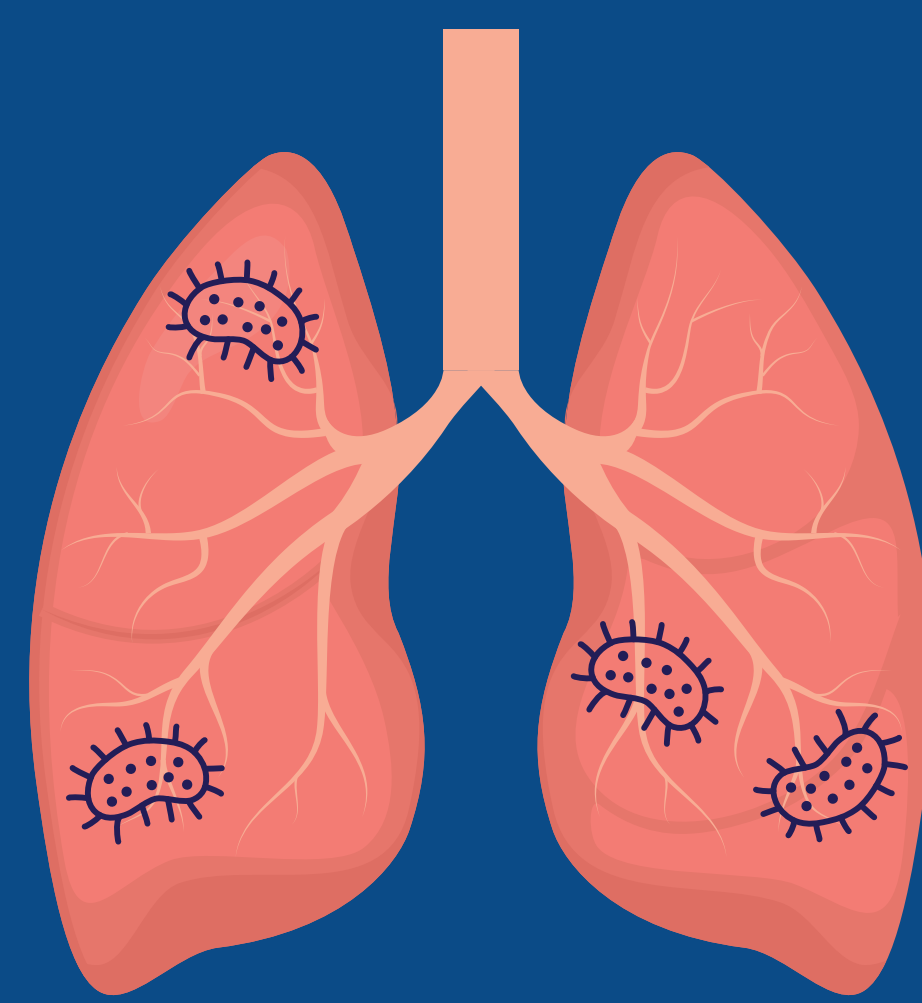
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First prospective human study of omadacycline for MABc pulmonary infections

Objective

Evaluate the efficacy and safety of omadacycline in adults with *Mycobacterium abscessus* complex (MABc) pulmonary disease



Conclusions

This is the first trial to:

- Formally test the impact of omadacycline in the treatment of pulmonary MABc infections
- AND
- Provide insight into the role of omadacycline in the overall care of patients with MABc

Study design and methods

Key eligibility criteria

- Age ≥ 18 years
- Diagnosis of MABc pulmonary disease per guideline criteria
- ≥ 2 NTM infection symptoms at screening and baseline
- ≥ 1 MABc-positive culture ≤ 6 months before screening and again at screening
- CT evidence of MABc within 3 months of screening
- Guideline-directed antibiotic therapy not required within next 3 months



Stratified by prior antibiotics for MABc and randomized 1.5:1

Omadacycline
300 mg PO QD for 84 days

Placebo
PO QD for 84 days

Select assessments: Days 1, 28, 56, 84/EOT

- Adverse events
- Prior/concomitant medications
- Weight and vital signs (VS)
- Chest computerized tomography
- Sputum culture
- Patient-reported outcomes (PRO)
 - Quality of life (QoL – Bronchiectasis)
- Clinician-assessed outcomes



Primary efficacy endpoint

Clinical response at Day 84, including but not limited to improvement from baseline in severity of at least half of the symptoms present at baseline as reported by patients, regardless of whether other symptoms worsened

Safety endpoints

- Tolerability
- Adverse events (AEs) and serious AEs
- Changes in clinical laboratory parameters, ECG, and VS

Secondary endpoints

- PRO
 - QoL – Bronchiectasis
- Microbiological response

Screening
 ≤ 8 weeks

Baseline/
Day 1 visit

Day 14
safety
tele-visit

Day 28 visit

Day 56 visit

Day 84/end
of treatment
(EOT) visit

30 days
after EOT
safety
follow-up call

Please see ClinicalTrials.gov (NCT04922554) for more details, including contact information and study sites

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