



## Expert evaluation on Phase 3 results for MOB-015

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January 22<sup>nd</sup>, 2020 at 3:00 p.m. CET.

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**Anna Ljung**, CEO

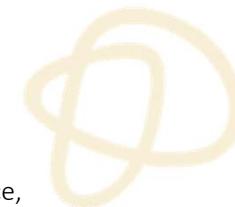
**Peter Wolpert**, Executive Chairman & Founder

**Dr. Amir Tavakkol**, CSO



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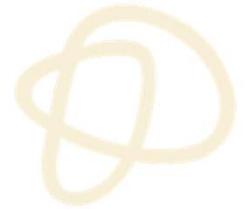
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# Executive Summary

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## Expert evaluation

- The company engaged Key Opinion Leaders to review and analyze the data and photos from the North American Phase 3 study to understand the conflicting data with high mycological cure and low complete cure

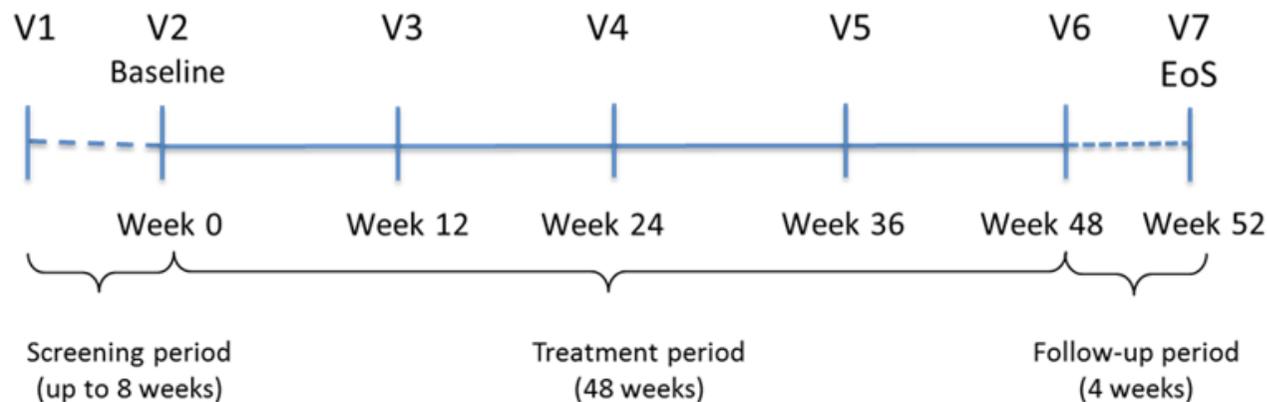
## Key conclusions

- Validity of data confirmed
- MOB-015 delivers a very high mycological cure rate, on par with the gold standard oral terbinafine with the added advantage of an earlier onset of action
- The proprietary vehicle technology increases the hydration and permeability of the nail plate which enable efficient terbinafine delivery but also confounds the assessment of complete cure
- A likely solution to the problem – a shorter dosing regimen with the potential to deliver superior complete cure rates.



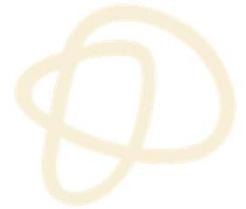
## MOB-015 Phase 3 : Study overview

- North American study with vehicle comparison (N=365)
- EU study with active comparator arm (N=452)
- 48 weeks treatment + 4 weeks follow-up
- The patients had at least one great toenail that was 20–60 percent affected
- Primary endpoint: Complete Cure



## MOB-015 Phase 3 study : Objectives

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- The primary objective of this phase III study is to evaluate the efficacy of topical MOB-015 in patients with mild to moderate DSO
  - Primary endpoint: Patients with complete cure at Week 52, defined as
    - negative fungal culture of dermatophytes,
    - negative direct KOH microscopy and
    - 0% clinical involvement of the target nail } *Mycological cure*
  - Key secondary endpoints :
    - *Mycological cure*
    - *Treatment success* (Mycological cure and less than 10% clinical disease involvement)
- The secondary objective of this phase III study is to evaluate the safety of topical MOB-015 in patients with mild to moderate DSO.

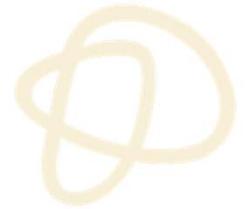
## MOB-015 delivered high mycological cure with an early onset, but lower complete cure than expected



	Current treatments	Mycological cure rate			Complete cure rate
		12W	24W	52W	52W
	MOB-015 (topical Terbinafine)	37%	55%	70%	4.5%
	Ciclopirox (Penlac)			30%	5.5-8.5%
	Efinaconazole (Jublia)			51-53%	15-18%
	Tavaborole (Kerydin)			30-35%	7-9%
	Terbinafine (Lamisil)	15%	40%	70%	38%
	Itraconazole (Sporonox)			54%	14%

Source: U.S. prescribing information for each drug;  
 12W and 24W data for Terbinafine Source: BMJ, volume 318, 17 April 1999

## High levels of Terbinafine (TBF) in nail and nail bed demonstrated in Phase 2



**45  $\mu\text{g/g}$**

TBF IN NAIL BED (MEDIAN)



**40x HIGHER THAN ORAL**

**1610  $\mu\text{g/g}$**

TBF IN NAIL (MEDIAN)



**1000x HIGHER THAN ORAL**

**0.0015  $\mu\text{g/mL}$**

TBF IN PLASMA (MAX)



**1000x LOWER THAN ORAL**

## The vehicle delivers the drug but also confounds the clinical cure assessment

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After analyzing the photos and the data, the company experts and KOLs found that:

- The vehicle enables high delivery of terbinafine through the nail plate,
- The vehicle's hydrating properties also cause transient whitening/discoloration in nails
- The whitening/discoloration makes the assessment of clinical cure challenging and contributed to the low complete cure rate observed.

## Shorter treatment - a solution to the problem

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Based on the expert discussions, and analysis of all available data including the phase 3 data, earlier trials, and literature data, the company experts and KOLs identified a solution:

- A shorter dosing regimen followed by a maintenance period is likely to result in increased complete cure rate, based on:
  - Early onset and high mycological cure demonstrated
  - Very high terbinafine levels in nail/nail bed
  - 3 months treatment with oral terbinafine is effective
  - Reduction of the hydrating effect after the initial treatment phase and thus reducing the impact on the clinical cure assessment at week 52
- The evaluation concluded that a preferred regimen would be once-daily dosing for *not more than three months*, followed by maintenance treatment once weekly until week 48
- Since the primary endpoint was met and provided that the EU study also produces positive results, these studies could form a basis to register the product. The timing to optimize the dosing regimen will depend on the outcome of the EU study.

## Strong support from Key Opinion Leaders

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**Dr Boni Elewski**, Professor and Chair of the Department of Dermatology, University of Alabama.  
*“The high mycological cure rate demonstrated is very impressive and given the rapid onset of the antifungal effect, MOB-015 offers exciting benefits. I will definitely use it for my patients. A higher complete cure rate is likely to be achieved with a shorter treatment period and this would also be much more attractive to patients”*

**Dr Aditya Gupta**, Professor, Department of Medicine, University of Toronto.  
*“I am a strong supporter of this concept. With an optimized dosing regimen this product has great potential and may become the preferred therapeutic option, not only for monotherapy, but also as maintenance therapy to reduce recurrence after oral treatment”*

**Dr Jan Faergemann**, Professor in Dermatology, Sahlgrenska Academy, University of Gothenburg.  
*“Based on decades of experience with terbinafine and the excipients used in MOB-015, I believe a shorter treatment period has the potential to provide higher complete cure rates. Killing the fungus is the driver of also reaching complete cure”*

**Focus on delivering pipeline value**

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**Fully committed to create the next  
market leader in onychomycosis!**





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