

Dermatology summit 2020

# Almirall: Doubling Down on Medical Dermatology... Against all odds?

12<sup>th</sup> January 2020



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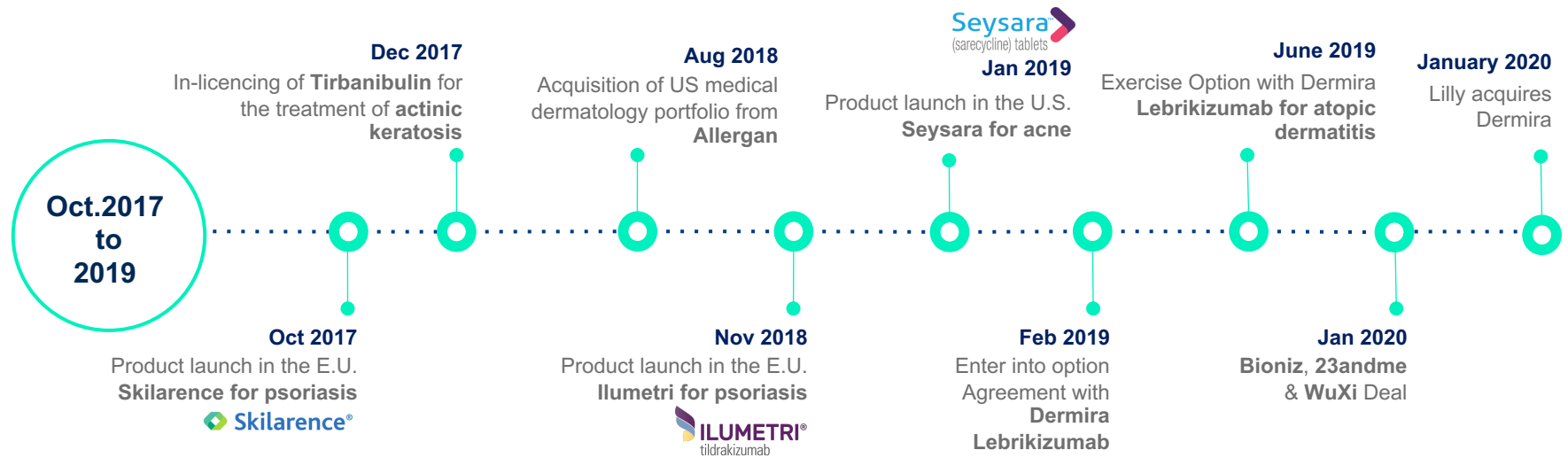
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3. So do the launches get traction?
4. Key takeaways to be successful in Med. Derm.

# 1 Almirall Transformation

# Almirall Transformation

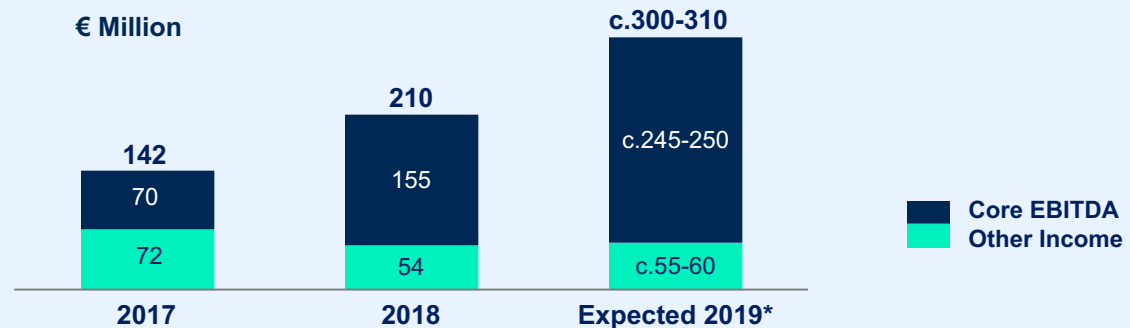
## Building a Medical Dermatology Leader

Creating Long Term Shareholder value through innovation



### Reported EBITDA: Core EBITDA + Other Income

€ Million



\* Upgraded 2019 EBITDA Guidance between €300 – 310 MM at constant exchange rates.

# An experienced leadership team capable of driving Long Term Shareholder value



## Mike McClellan

Executive Vice President, Finance, CFO

- 25 years experience in the pharmaceutical industry
- Group CFO, **Teva Pharmaceuticals**, **Sanofi** different roles as CFO: North America, Europe etc.



## Peter Guenter

Chief Executive Officer

- More than 30 years with the Pharmaceutical industry
- Multiple senior positions held at **Sanofi**
- Independent director at Galapagos



## Bhushan Hardas

Executive Vice President Research & Development, CSO

- More than 20 years in the Pharmaceutical industry
- Previously worked as CMO at **Allergan** and CSO at **Merz**



## Amita Kent

Senior Vice President, Legal and Global Data Protection Officer

- c.30 years legal experience in the pharmaceutical industry
- Multiple senior positions held in **Pfizer**, **Merck**, **NovoPharm** etc



Internationally  
Experienced  
Leadership  
Team



## Volker Koscielny

Chief Medical Officer

- c.20 years in the Pharmaceutical industry
- Previously worked at **Celgene**, **GSK** and **Pfizer** etc



## Eloi Crespo Cervera

Vice President, Manufacturing & Technical Services

- c.20 years in the Pharmaceutical industry



## Francesca Domenech Wuttke

Chief Digital Officer

- More than 20 years experience across multiple roles including MD for **Global Health Innovation Fund** (GHI), MSD's venture capital arm and **Novartis** as Global Director and Commercial Strategy



## Alfredo Barón de Juan

Executive Vice President, Global Commercial Operations

- More than 20 years in the Pharmaceutical industry
- Previously worked at **Pfizer**



## Esteve Conesa

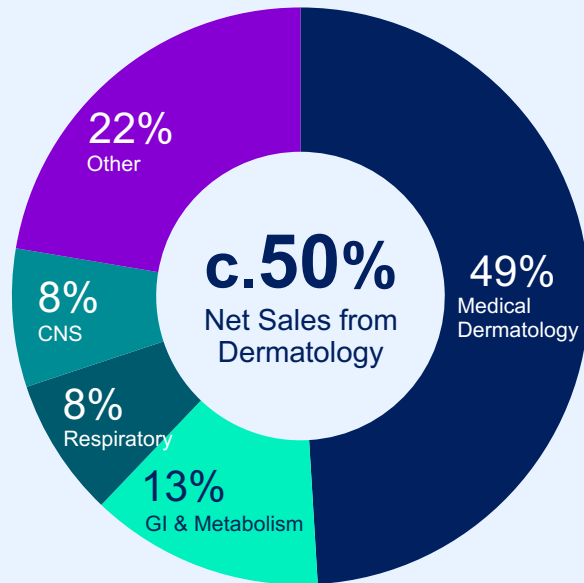
Vice President, Human Resources

- c.20 years in the Pharmaceutical industry
- Previously worked in **Almirall US**

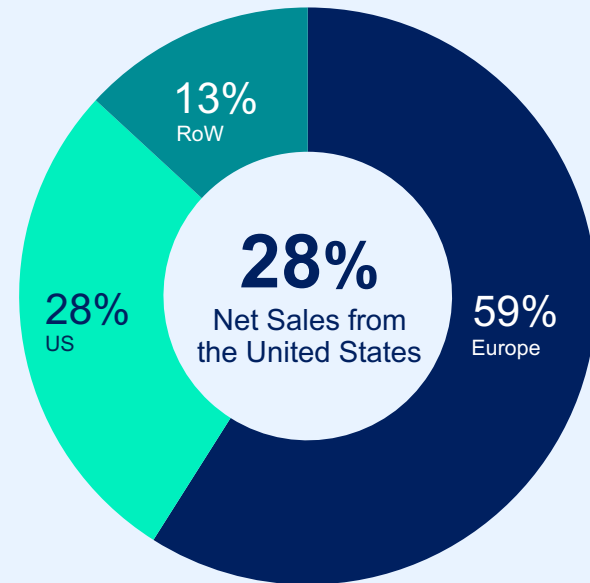
# Almirall Focused speciality care player

Transformed portfolio with Medical Dermatology now **c.50% of Sales**

9M 2019 Net Sales



- Portfolio focused on Medical Dermatology
- Derma launches will further accelerate portfolio transformation



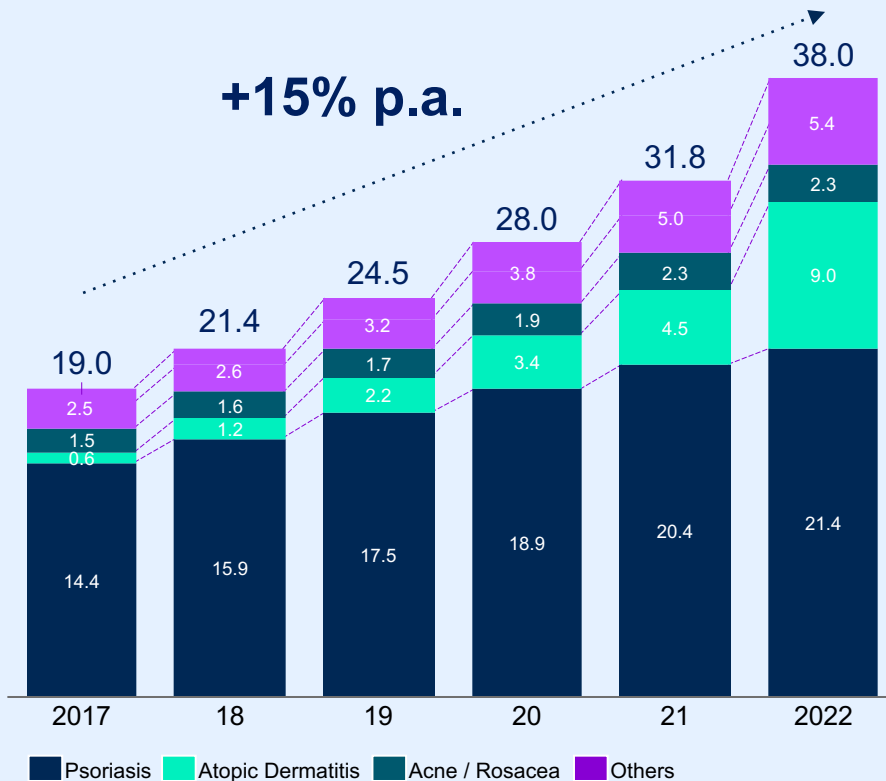
- Focused geographic presence
- US growth from new portfolio and Seysara™ launch
- Expanding psoriasis franchise in Europe (Skilarence® and Ilumetri®)

# 2 Strategy

# Why Focus on Medical Dermatology?


Multiple severe unmet needs, exciting new science, resulting in sustainable high growth...

Worldwide net sales, \$ B\*



## CAGR, % Selected growth drivers


17% Various (onco dermatology, rare diseases...)

Tirbanibulin   
 BNZ01 

9% New products across both Acne & Rosacea

Seysara   
 (sarecycline) tablets

69% Significant increase in biologics development, specially in AD

Lebrikizumab 

8% Launch of innovative biologics Biosimilars adoption

ILUMETRI®   
 tildrakizumab  
 Skilarence® 

\* Net sales are based on Evaluate Pharma's indication-specific sales which are indicative of market expectations and have a degree of uncertainty. Sales are Dermatology-specific (i.e., only products for skin indications)

# Why Focus on Medical Dermatology?

...But do payers still want to pay?



## Higher probability / better terms for access

- Orphan diseases CTCL, EB, Alopecia Areata etc.
- Onco – Dermatology AK, BCC, SCC
- Big size markets with high unmet need such as moderate to severe AD, Severe Acne, Vitiligo etc. (Path already established in severe diseases eg Dupi in AD)
- No generic alternatives licensed

# From concept to reality

**Clinical Pipeline evolution:** focus on Innovation and Science

Indication	Commercial name / Molecule code	Phase I	Phase II	Phase III	Under registration	Geography
Actinic keratosis	<b>Tirbanibulin ALM14789</b>					
Atopic dermatitis	<b>Lebrikizumab</b>					
Cutaneous T-cell Lymphoma (CTCL)	<b>BNZ01</b>					
LEGACY PIPELINE						
Androgenic alopecia	<b>Finasteride ALM12845</b>					
Onychomycosis	<b>Terbinafine ALM12834</b>					

**Expected Peak Sales of late stage pipeline & recent launches > €1Bn**

## Potential best-in-disease for atopic dermatitis

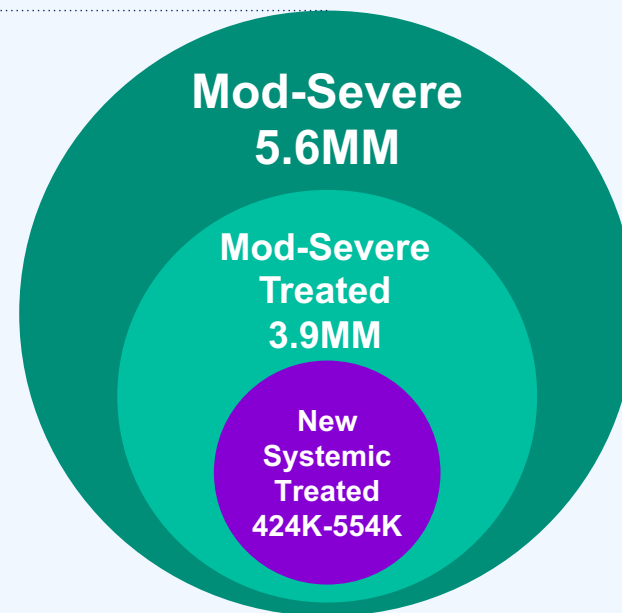
Phase III Program Initiated, fast track in the US

### Atopic Dermatitis Market

- Today only one biologic is registered in EU for treatment of moderate to severe AD
- Strong market access for AD biologic in Europe
- Number of atopic dermatitis patients treated with biologics is expected to be at least comparable with psoriasis by 2026\*
- The launch of lebrikizumab is anticipated early 2023

**18MM atopic dermatitis patients in EU by 2026**

**11-14% of Moderate-Severe patients is expected to be treated with new systemics\***



**c. €450 million Peak Sales expected**

\* Psoriasis – Disease Landscape & Forecast, DRG Nov 2017, Atopic Dermatitis/Atopic Eczema – Disease Landscape & Forecast, DRG Dec 2017

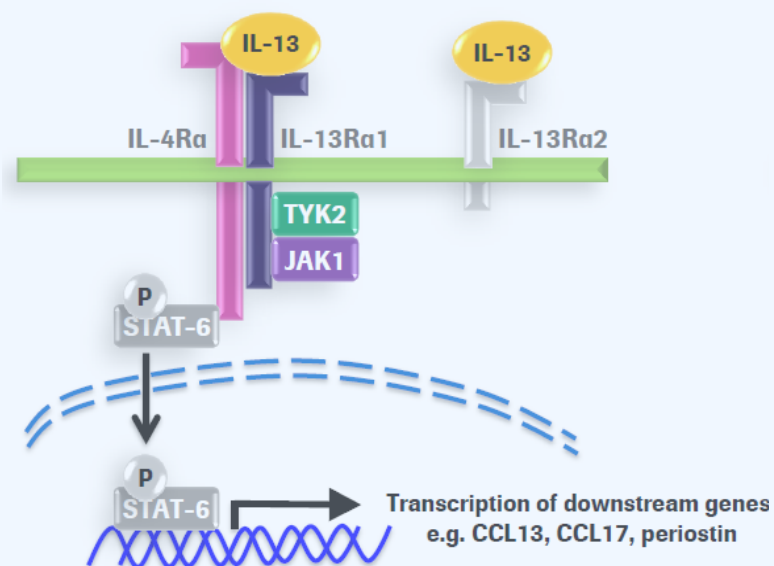
# Lebrikizumab

## Differentiation traits

### Higher affinity and specificity

#### The two receptors of IL-13

- Lebrikizumab has a very high affinity for IL-13
- Atopic Dermatitis is an IL-13 dominant disease
- Lebrikizumab specifically prevents heterodimerization of IL-13Ra1/ IL-4Ra subunits
- Lebrikizumab inhibits type 2 inflammation evoked by IL-13 through this heterodimeric receptor
- Lebrikizumab allows IL-13 to bind to IL-13Ra2 receptor, postulated to have an anti-inflammatory role by neutralizing the excess of IL-13
- Greater specificity enabling better safety profile



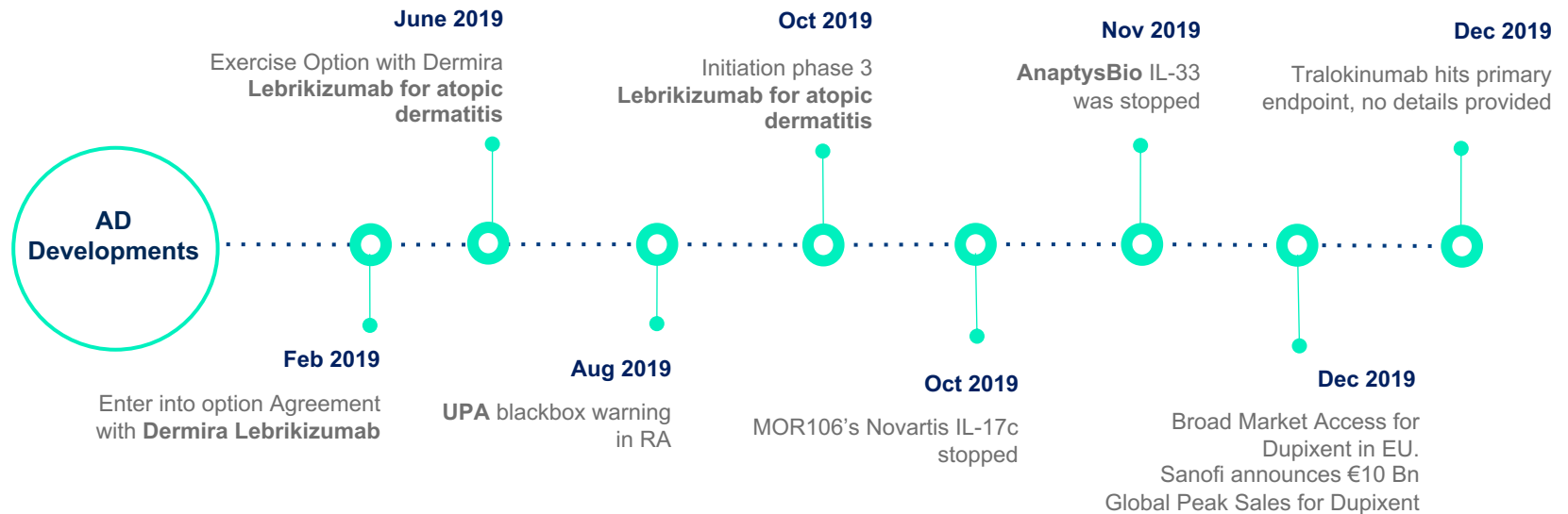
Antibody	Kd	IL-4Ra/IL-13Ra1	IL-13Ra2
Lebrikizumab	<10pM	Inhibition	No effect
Tralokinumab	58pM-165pM	Inhibition	Inhibition

# Lebrikizumab



## Potential best-in-disease for atopic dermatitis

Recent developments in the AD market



# Strategic deal with Bioniz



Global rights on phase 1/2a drug in CTCL, with additional potential in alopecia areata

## First-in-class innovative & unique multiple-cytokine inhibitor technology platform

- **Burden of disease in CTCL:** Overall survival rate (OS) for stage IB 21.5 yrs, IIA is 15.8 yrs, for IIB 4.7 yrs, and IIIB 3.4 yrs\*
- **High unmet need in CTCL** because of risk of disease progression, IB 38% IIA 33%, IIB 58%, and IIIB 73% and relatively long OS timing, high level of switching between systemic therapies due to toxicity profiles and lack of response of today's available treatments.
- **Innovative approach:** one extracellular peptide can block selectively the signalling of three cytokines that share a common receptor
- **BNZ1 blocks IL-2, IL-9 and IL-15** signalling by binding to the yc receptor subunit of the IL-2 cytokine family
- **Orphan drug designation** granted by the FDA .

\* Am J Hematol. 2016 Jan; 91(1): 151–165.

# Strategic deal with Bioniz



Broader Research collaboration: leverage unique platform



## Key features of the collaboration

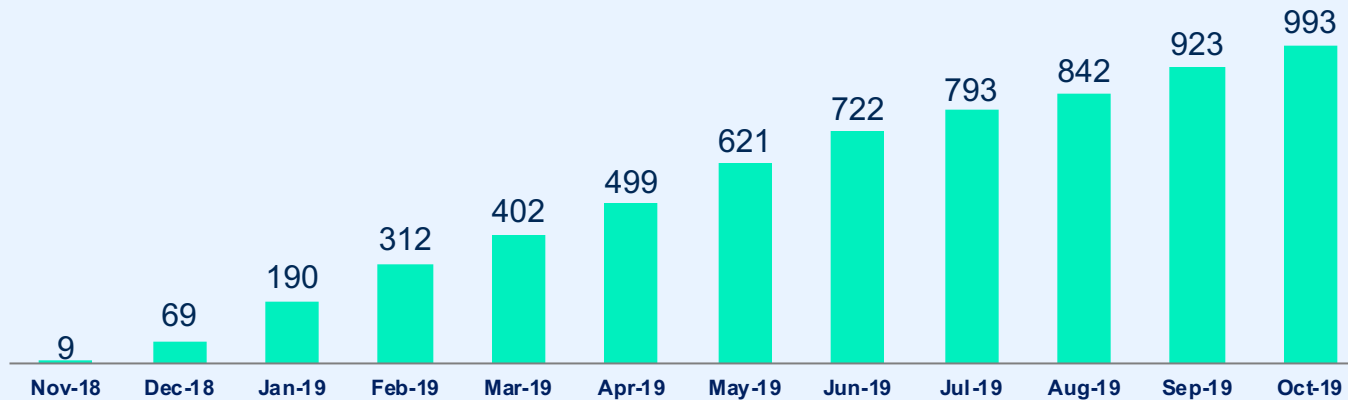
- The parties will work under an agreed Master Research Plan
- Bioniz will deliver three IND approved molecules in Inflammatory and/or other immuno-dermatological indications
- The IND-candidates will be developed using Bioniz multiple-cytokine inhibitory therapeutics
- Ammirall will have the right to acquire the assets after IND approval
- Deal frame:
  - In exchange of the research activities conducted by Bioniz, Ammirall will provide FTE funding and R&D funding
  - If Ammirall opt-in it will acquire the assets (no restrictions) and will compensate Bioniz with certain milestone payments

3

So do the launches  
get traction?

Extensive EU rollout campaign continues as long-term studies confirm excellent efficacy and safety profile

## Ilumetri® Number of patients in Germany since launch\*



### Positive momentum in Europe

- **Recently launched in Austria (July), Switzerland (August), Netherlands (August) and Spain (September)**
- Patient Access Scheme is signed in the UK to offer Ilumetri® as the most cost-effective of the new biologics
- **Rollout continues in the EU with upcoming launches in Italy, Belgium, Czech Republic and France**

### Long-term efficacy and safety profile

- **Two extension studies confirm the long-term efficacy and safety with the longest IL23p19 data published in manuscript**
- Recent study presented at the EADV Madrid shows that up to 4 years of treatment with tildrakizumab 100 mg, PASI and PGA response rates remain high and durable\*\*

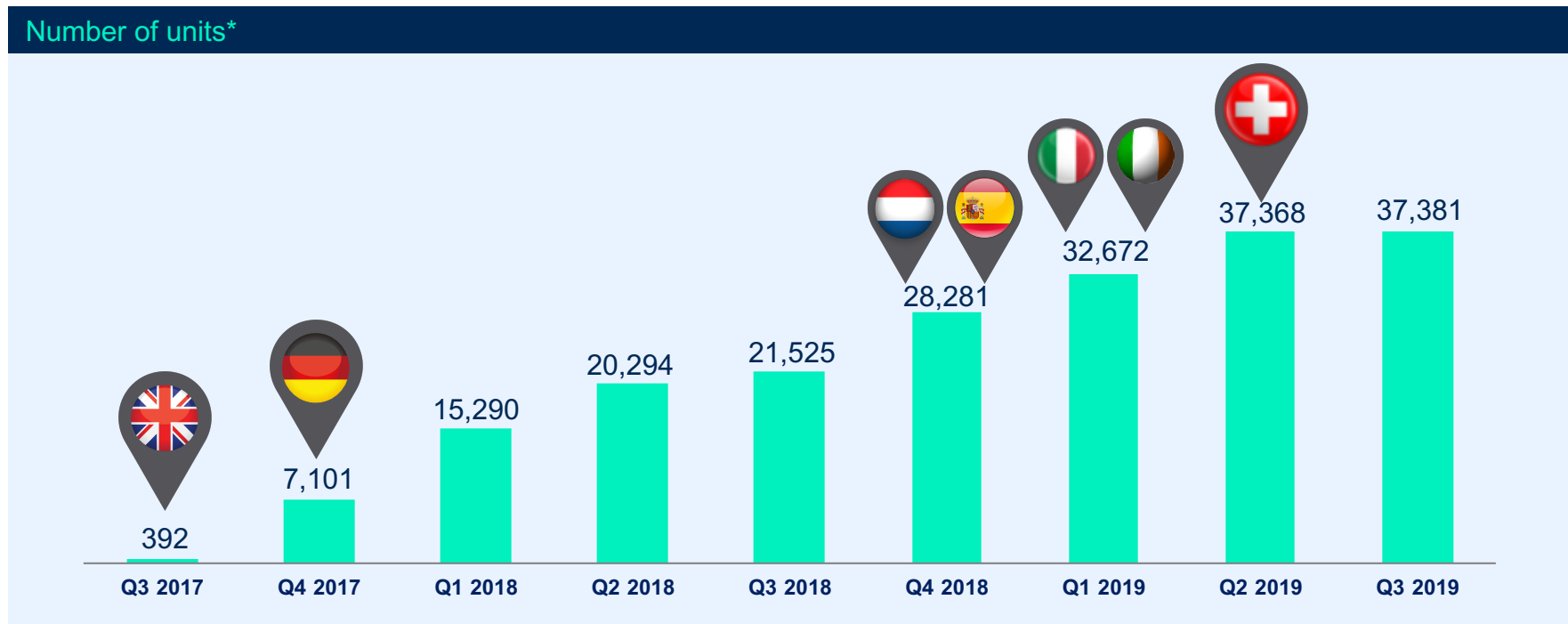
\* Source: IQVIA LRX. New and repeat patients.\*\* Efficacy and Safety of Long-Term Tildrakizumab for Plaque Psoriasis: 4-Year Results from reSURFACE 1. [Abstract]. EADV 2019. Ilumetri biologic for patients with moderate to severe psoriasis



## Market leaders in Fumarates in the key EU markets



Number of units\*



- **Market leader in Fumarates** in Germany and The Netherlands
- **Expected Q3 seasonality impact**
- **Over 80% market share in Germany** of the 30mg initiation pack (new patients)\*\*

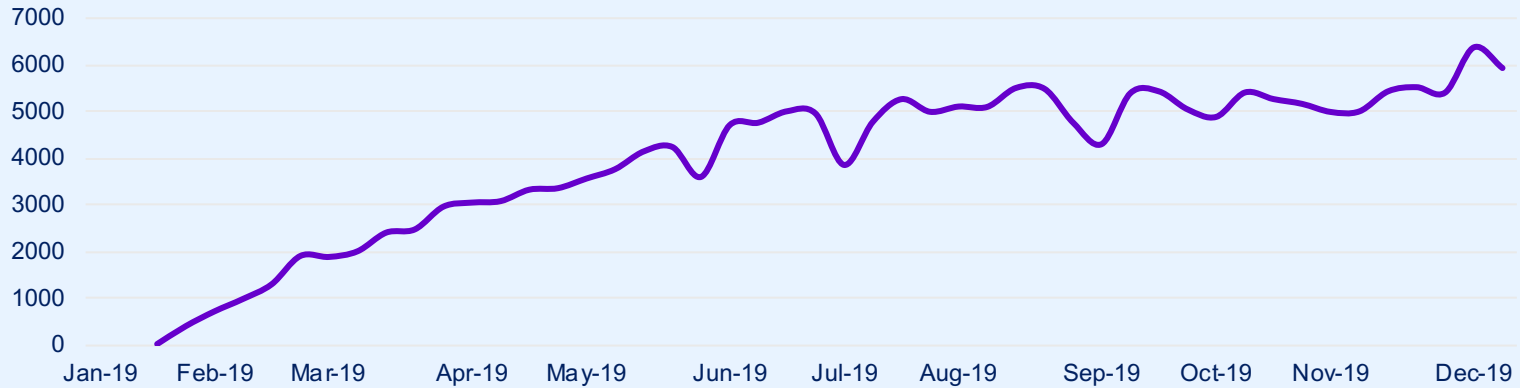
\* Source: IQVIA IMS audited Sales & SAP. \*\* IMS DataView  
Skilarence oral treatment for patients with moderate to severe psoriasis.

# Seysara™

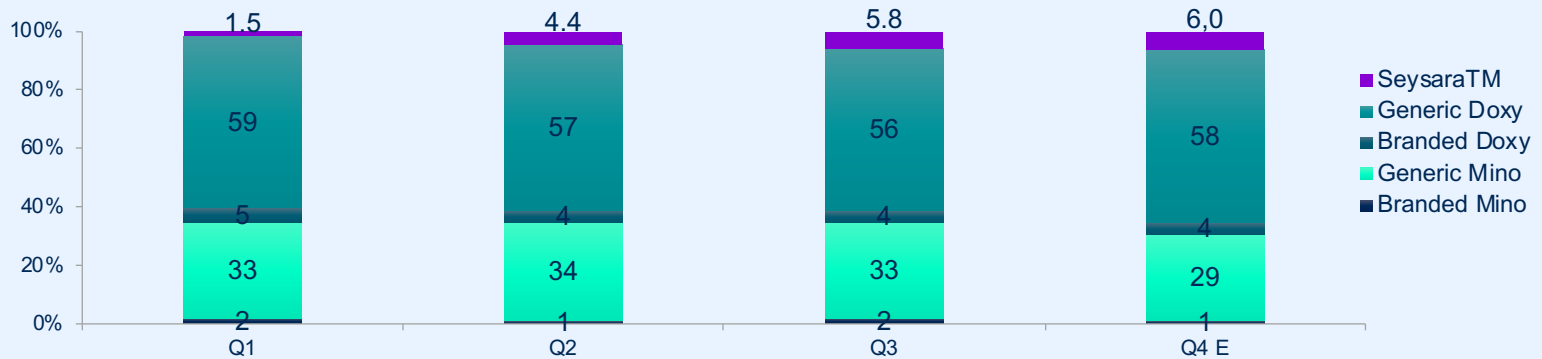
Gaining market share from brands and generics



## Seysara™ TRx volume since launch\*



## Seysara™ TRx Share vs broad market OAB\*\*



\* Source: IQVIA. \*\* Dermatologist TRx. Seysara used to treat moderate to severe acne oral antibiotic. Only two weeks included in December 2019.

# 4

# Key takeaways to be successful in Med. Derm.

# Key takeaways to be successful in Med. Derm.

- 1 Steer away from reformulations, unless significance patient benefit**
- 2 New MOA only relevant if better outcomes**
- 3 Don't compromise on science**
- 4 Engage early on**
- 5 Go for indications / molecules with better POS for "decent" access**
- 6 Focus**



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