

# License Agreement of Tildrakizumab for Psoriasis in Europe

*July 28<sup>th</sup> 2016*

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# Agenda

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Key highlights

Eduardo Sanchiz, Chief Executive Officer

Transaction highlights

Jordi Sabé, Senior Vice President Corporate Development

Tildrakizumab

Thomas Eichholtz , Executive Vice President, Research & Development, CSO

Market opportunity & commercial considerations

Alfonso Ugarte, Executive Vice President, Global Commercial Strategy

Closing remarks

Eduardo Sanchiz, Chief Executive Officer

# Key highlights

*Eduardo Sanchiz*  
CEO

# Strategic framework



# Key highlights

- Bring innovation in Dermatology and leverage key capabilities
- Important moves in BD consistent with our stated strategy
- Partnership with Sun Pharma for Tildrakizumab in Europe
- Balance and combine short-term performance with building for the future
- Almirall increasingly becoming the partner of choice in Dermatology

# Transaction highlights

*Jordi Sabé*

*Senior Vice President, Corporate Development*

# Transaction highlights

- License Agreement with Sun Pharma for the development and commercialization of Tildrakizumab for Psoriasis in Europe
- Almirall will lead regulatory filing, price and reimbursement, sales and marketing activities
- Almirall has a right of first negotiation to extend the license for other indications within Dermatology and Rheumatology
- Almirall will pay Sun Pharma an upfront payment of US\$ 50 million
- Sun Pharma will be eligible to receive developmental, regulatory and sales milestone payments plus royalties

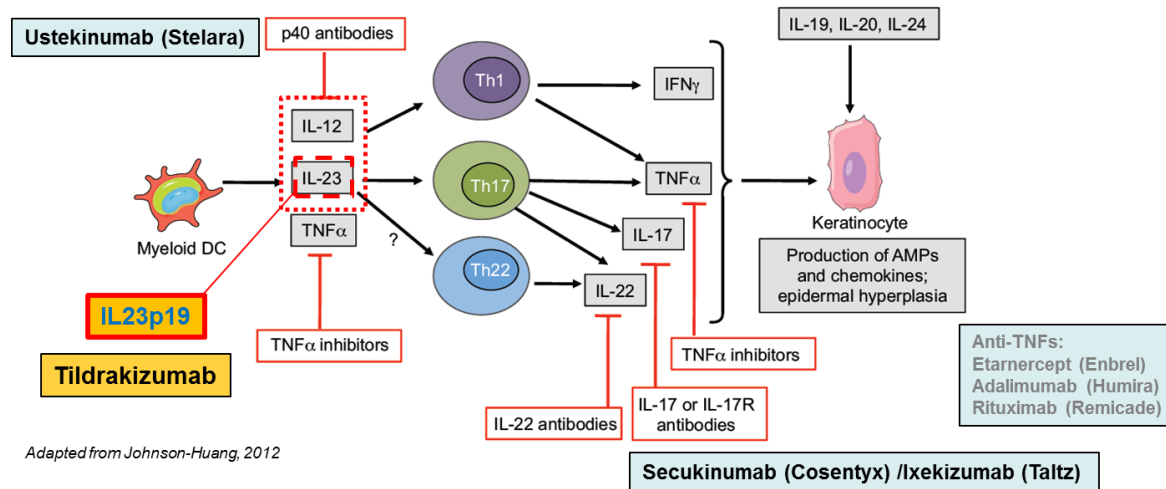


# Tildrakizumab

***Thomas Eichholtz***  
*Executive Vice President, Research &  
Development, CSO*

# Tildrakizumab

- Tildrakizumab is a humanized IgG1 monoclonal antibody (mAb) that selectively targets the IL23 p19 subunit (upstream of IL17) and was developed for the treatment of moderate to severe Psoriasis.
  - ✓ Most advanced anti-IL23 in development: estimated launch in Europe in 2Q18
  - ✓ Competitive product profile: high level efficacy, strong maintenance effect, no rebound following treatment withdrawal
  - ✓ Convenient dosing regimen (0, 4 then every 12 weeks)



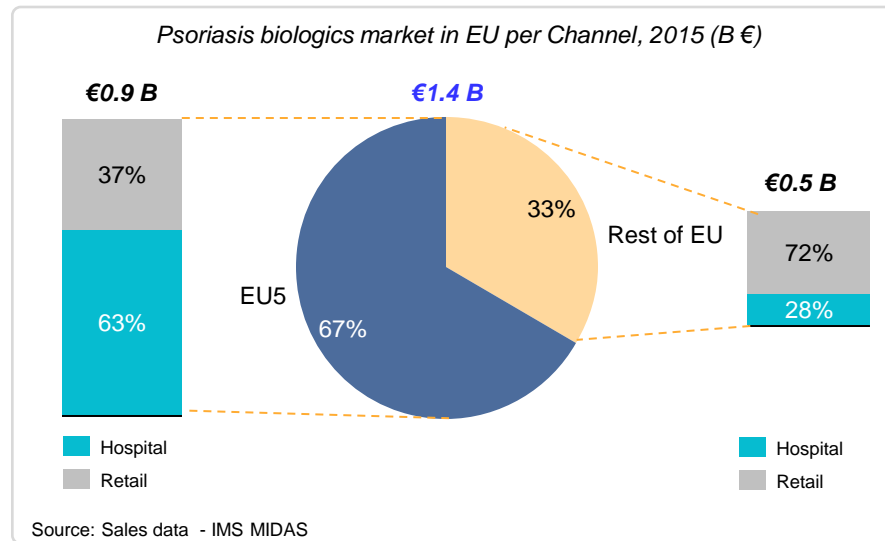
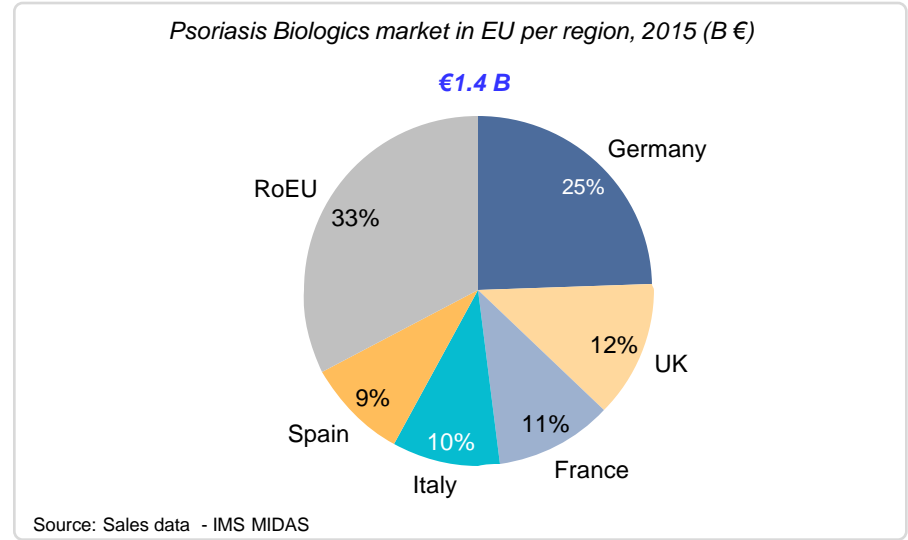
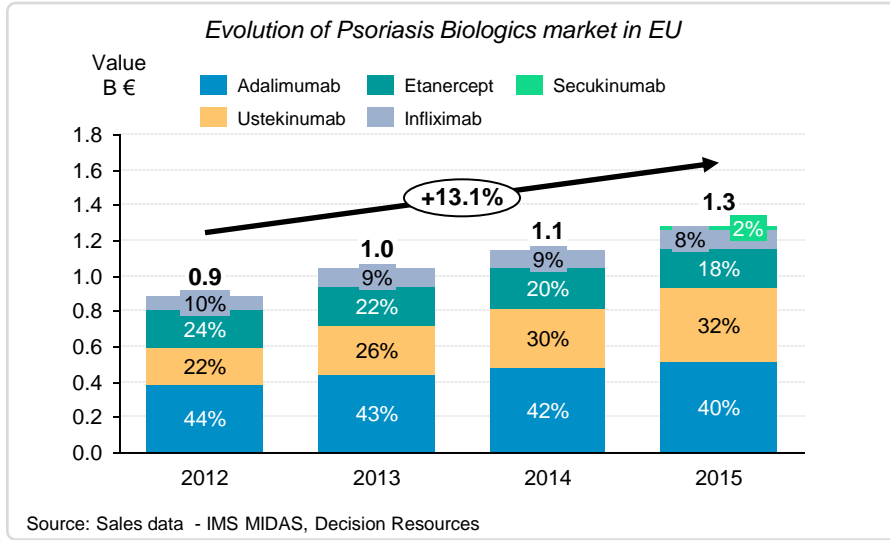
# Tildrakizumab Phase III results

- The two pivotal Phase III clinical trials of Tildrakizumab met their primary endpoints for both evaluated doses (100 & 200mg)
- The co-primary efficacy endpoints were: the proportion of participants with Psoriasis Area Sensitivity Index 75 (PASI-75) response at week 12 compared to placebo and the proportion of participants with a Physician's Global Assessment (PGA) score of clear or minimal with at least a 2 grade reduction from baseline at week 12 compared to placebo
- Secondary endpoints included PASI-90 and -100 scores
- The overall safety profile of Tildrakizumab in both Phase-3 clinical trials was consistent with the safety data observed in previously reported studies
- The second study included an Etanercept comparator arm, with a key positive secondary endpoint comparing Tildrakizumab and Etanercept on PASI-75 and PGA

# Market opportunity: What value will we add?

*Alfonso Ugarte*  
*Executive Vice President, Global Commercial Strategy*

# In EU, Biologics used mainly in severe Psoriasis



# Tildra strongly supported by potential prescribers

Market research exercise carried out jointly with third parties

## 139 dermatologists interviewed



- In practice between 3-35 years
- Personally responsible for the treatment decisions of **adult moderate-severe plaque psoriasis** patients, and responsible for the long-term management of these patients
- Manage a minimum of 30 adult moderate-severe plaque psoriasis patients, with at least 10 severe patients
- Mix of office and hospital setting
- Spend at least 70% of professional time directly caring for patients



Target	France	Germany	Italy	Spain
Dermatologists	n=27	n=35	n=35	n=42

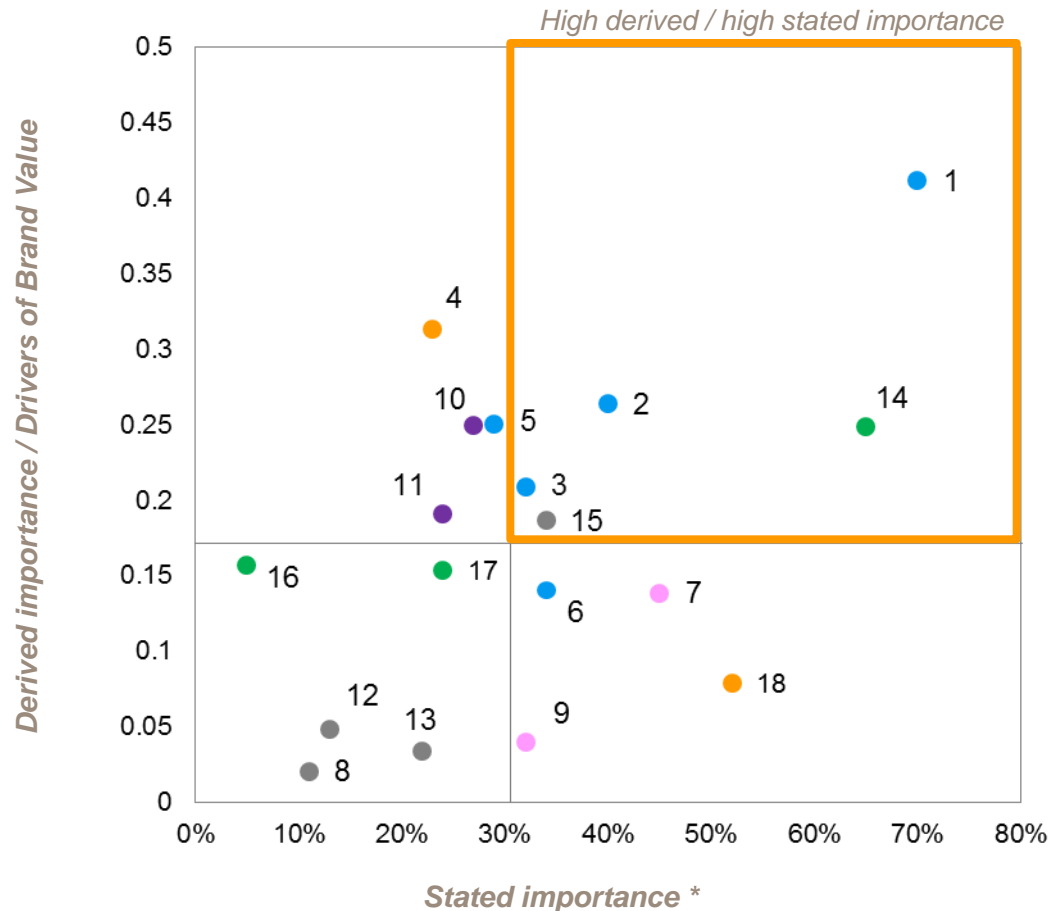
Fieldwork completed between: 21<sup>st</sup> April – 9<sup>th</sup> May 2016

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## Total level stated vs. derived drivers of Brand Value

● Efficacy ● Indication ● Convenience ● Patient benefit ● Safety ● Other



- 1 Achieves high levels of skin clearance (PASI 90)
- 2 Rapid onset of significant effect
- 3 Efficacy continues to improve over time
- 4 Is most suitable as a 1<sup>st</sup> line biologic
- 5 Is efficacious after failure of other biologics
- 6 Efficacy level is maintained after treatment cessation
- 7 Does not increase the risk for serious infections
- 8 No follow up needed after stopping the treatment
- 9 Can be safely stopped and restarted
- 10 Convenient dosing frequency
- 11 Convenient route of administration for both physicians and patients
- 12 Offers dosing flexibility to ensure adequate drug levels in different patient types
- 13 Has good access to reimbursement
- 14 **Significantly improves Patient's Quality of Life**
- 15 I have a good personal experience with the product
- 16 My patients' have a preference / request the product
- 17 Significantly improves patient compliance
- 18 Is also indicated for the treatment of Psoriatic Arthritis (PsA)

\* % physicians choosing attribute to be in top 8 most important attributes

# Tildra strongly supported by potential prescribers

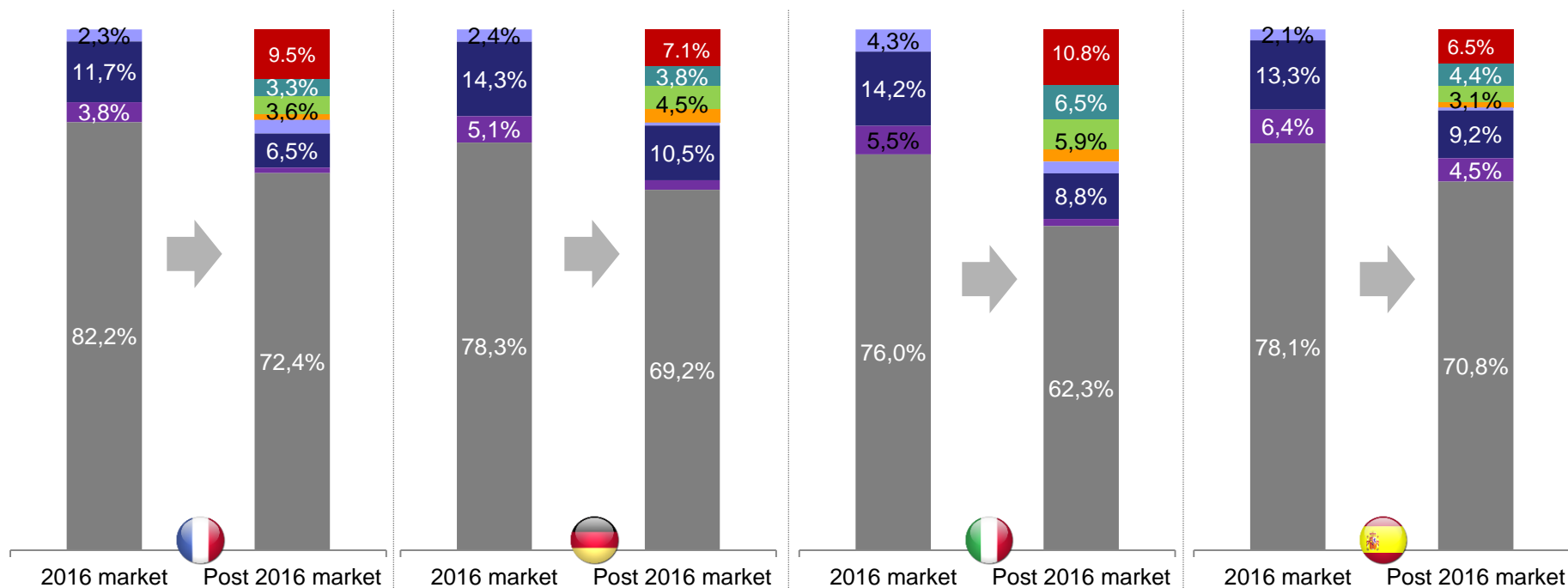
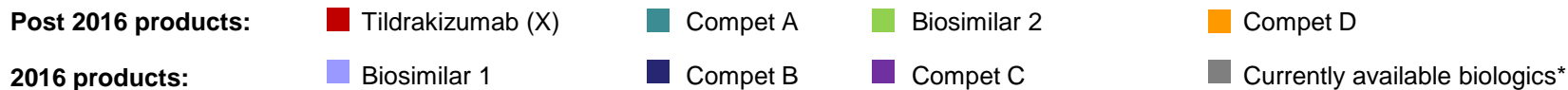
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## Predicted intention to prescribe Tildra & other new entrants

**Shift in intention to Rx once pipeline products are launched...**

(Based on base case Product X profile)

Relative intention % based on patients on biologics only



\*Currently available biologics: Enbrel, Humira, Remicade, Stelara, Cosentyx, Biosimilar (infliximab)

Q33. Of your next 100 adult moderate to severe PsO patients eligible for biologic therapy presenting to you, how many of the following would you prescribe each of the following option listed below if all of these products are approved and available for you to prescribe?

Base: All respondents (n=139)



# Commercial considerations

- Regulatory filing by Q22017
- First launches in major EU markets around mid 2018
- We will leverage & strengthen our existing direct presence in major & other EU markets
  - We have established ongoing relationships with the Dermatology community in EU
  - We expect to introduce LAS41008 in all of these markets prior to the launch of Tildrakizumab
  - We are currently strengthening our ties with the Psoriasis KOLs community in EU & US
- We have already strengthened the Rx Global Marketing and the Medical Affairs Teams in anticipation of the build up of the Psoriasis franchise
  - Global functions already working in tandem with local commercial operations to ensure successful product introductions

# Closing remarks

*Eduardo Sanchiz*

CEO

# Closing remarks

- Strong first half results 2016 on track towards our yearly guidance
- Delivery on our new strategic direction
- Executing, integrating, advancing pipeline, new launches (US) and BD in H1 2016
- Very important short/mid term opportunity with Tildrakizumab
- Continue to develop capabilities and to bring Derma expertise to the organization
- Committed to grow and to advance Almirall's transformation

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