

R&D Trends: Psoriasis - Pipeline outlook following withdrawal of key regulatory filing

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Abstracts

Introduction

Datamonitor identified 128 products in development, with a notable focus on interleukin (IL) targets. 2009 market entrant Stelara, an IL-12/23 inhibitor is fuelling interest in IL therapies. Stelara (ustekinumab) and briakinumab showed benefit over established brand Enbrel (etanercept) in head-to-head trials, augmenting physician view that future trials require more active comparators.

Features and benefits

Enhance understanding of the competitive landscape and potential future market dynamics with an in depth analysis of the psoriasis pipeline

Benchmark novel and existing therapies using the ideal target product profiles identified by Datamonitor and access leading dermatologist opinion

Support R&D decision making by evaluating psoriasis clinical trial designs that have set a precedent, as well as analysis of discontinued projects

Highlights

Interleukins are key targets for late and early-stage programs. If IL selectivity leads to better efficacy and safety, new drugs would gain backing from physicians. However, cardiac risks may be an issue, as shown by briakinumab. In the current risk-adverse

regulatory environment clinical trial designers should consider how to dispel these fears.

The Psoriasis Area and Severity Index (PASI) remains the gold standard tool for efficacy, due to historic use and ease of benchmarking new and existing therapies. Phase III trials like Stelara versus Enbrel lead dermatologists to speculate that regulatory agencies will desire analyses from direct comparator trials in future drug approval.

Drug attrition rates are high in psoriasis, with a mix of commercial and clinical reasons behind this. Established brands and generics seems to deter companies from pursuing some topical agents, while the higher dose of biologics often required to show meaningful efficacy in psoriasis compared to say rheumatoid arthritis creates further challenges.

Your key questions answered

What do key opinion leaders think is the ideal target product profile in psoriasis?

Which innovative therapeutic approaches do leading dermatologists believe are the most promising for small molecules and biologics?

How will biomarkers and comorbidities play a role in the future treatment of psoriasis?

What is the breakdown by delivery methods for candidates being developed for this chronic skin disorder?

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CLINICAL PIPELINE OVERVIEW

The psoriasis pipeline is extensive, but appears to have a high attrition rate
There is an increased focus on targeting interleukins and kinases in the psoriasis pipeline
Topical delivery remains dominant in the psoriasis pipeline, but there is a growing focus on oral drugs
Late-stage development compounds recently discontinued
LEO 80190 (calcipotriol plus hydrocortisone; Leo Pharma)
NYC 0462 (Nycomed)
LY-2525623 (Eli Lilly)
Teplizumab (MGA031; MacroGenics/Eli Lilly)
NN8226 (anti-IL-20; Novo Nordisk)
R348 (Rigel)
TA-5493 (Mitsubishi Tanabe)

TARGET PRODUCT PROFILE

Comparator 1: Enbrel (etanercept; Amgen/Pfizer/Stiefel/Takeda)
Comparator 2: Dovonex (calcipotriol; Leo Pharma/Intendis/Torii/Teikoku Medix)
Comparator 3: Methotrexate
Target product profile versus current level of attainment

CLINICAL TRIAL DESIGN IN PSORIASIS

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Clinical endpoints

Future developments in clinical trial design

Active comparator studies

Measuring treatment efficacy with PASI and PGA will remain over the next five years

Assessing improvements in comorbidities, especially psoriatic arthritis as a secondary outcome measure

INNOVATIVE EARLY-STAGE APPROACHES

Physicians believe interleukin inhibition is the most promising approach for new biologics

Physicians believe Janus kinase inhibition is a promising approach for small molecules

Phosphodiesterase 4 inhibition

Select cluster of differentiation targets are in the pipeline, but physicians remain cautious of this approach

THE FUTURE OF TREATMENT IN PSORIASIS

Selecting treatments based on the presence of comorbidities, especially psoriatic arthritis

Biomarkers to identify clinical subtypes in psoriasis

Dermatologists anticipate a rise in moderate-to-severe patients treated with biologics

BIBLIOGRAPHY

Journal papers

Websites

Datamonitor reports

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The survey questionnaire

APPENDIX B

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