R&D Trends: Insulin Antidiabetics - The Future is Analogs

Description: The insulin antidiabetic pipeline can be split between small manufacturers, often targeting reformulations of existing insulin, and major manufacturers pursuing novel insulin analogs. Pipeline products will need to show improvements in the clinical safety/side-effect profile of insulins, as change in delivery method alone will not be enough to gain market share.

Features and benefits

- Comprehensive analysis of the current insulin antidiabetic pipeline including both reformulations of marketed insulins and novel analog products.
- Establish the minimum acceptable and target product profiles necessary for success in the insulins market.
- Assess future directions in insulin therapies in diabetes.
- Provide insight into clinical trial design and trends in insulin antidiabetics.

Highlights

- The insulin pipeline consists of 26 clinical trial candidates, of which 20 are in Phase I or Phase II development. Small manufacturers are developing reformulations of human insulin to improve delivery or pharmacological profile, while major insulin players are focusing entirely on analog insulins and combinations.
- Comparator insulins Lantus, NovoRapid, and Novomix are well accepted in the market, but pipeline products can target unmet needs associated with clinical safety and side effects, particularly by reducing hypoglycemia and reducing weight gain.
- A key future trend in insulin use is the growing utilization of technology: sophisticated pen injectors are replacing traditional vial and syringe delivery, and the use of insulin pumps to deliver a calibrated dose regime is growing.

Your key questions answered

- Datamonitor's updated, comprehensive overview of the diabetes pipeline.
- Assess the remaining market opportunities and barriers to uptake for novel insulin therapies and formulations.
- Identify clinical trial requirements and trends in insulin antidiabetics.

Contents:

Executive Summary
  - Strategic scoping and focus
  - Datamonitor key findings
  - Diabetes reports in the seven major markets
  - Growth markets diabetes reports

OVERVIEW
  - Catalyst
  - Summary

CLINICAL PIPELINE OVERVIEW
  - Insulin antidiabetics
    - Prandial insulins comprise more than half the pipeline
    - Key companies in insulins market: Novo Nordisk continues to build insulin analog franchise
    - Small manufacturers focus on reformulations of human insulin
    - Traditional injectable delivery is favored by developers
    - Development compounds recently discontinued
      - Linjeta (VIAject insulin; Biodel)

TARGET PRODUCT PROFILE
  - Comparator insulin therapies
    - Basal insulin comparator: Lantus (insulin glargine; Sanofi-Aventis)
    - Fast-acting insulin comparator: NovoRapid (insulin aspart; Novo Nordisk)
    - Premixed insulin comparator: Novomix (insulin aspart+insulin aspart protamine; Novo Nordisk)
Target product profile versus current level of attainment
Side effects of insulin treatment
Insulin delivery and dosing

CLINICAL TRIAL DESIGN IN INSULIN ANTIDIABETICS
Clinical endpoint: efficacy
Safety and side effects in insulin clinical trials
Hypoglycemia
Weight gain
Insulin and cancer
Cardiovascular safety
Comparators and combinations in clinical trials
Future trends in clinical trial design
Devices and formulations increasingly form part of trial programs

INNOVATIVE EARLY-STAGE APPROACHES
Injected fast-acting insulin
rHuPH20 insulin (Halozyme Therapeutics)
Buccal fast-acting insulin
Oral-lyn (buccal insulin; Generex)
Oral fast-acting insulins
IN-105 (Biocon)
ORMD-0801 (Oramed Pharmaceuticals)

THE FUTURE OF INSULIN DIABETES TREATMENT
Increased dominance of analog insulins
Insulin delivery
Continued growth of pen injectors instead of syringes
Pumps will find a place in the diabetes patient population
Technological progress: continuous glucose monitoring and closed loop systems

BIBLIOGRAPHY
Journal papers
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APPENDIX
Report methodology

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