R&D Trends: Anticoagulants for stroke prevention in atrial fibrillation - Upcoming heavy hitters leave a permanent mark

Description: With Pradaxa (dabigatran) and Xarelto (rivaroxaban) approved for stroke prevention in atrial fibrillation and two other candidates well on their way towards the market, development activity in this arena is at a crossroads. Such is the likely transformation in care represented by these four products that development strategies are already fundamentally changing.

Features and benefits
- Key elements of clinical trial strategy and design for anticoagulant products targeting stroke prevention in atrial fibrillation
- Overview of late stage clinical pipeline, recent discontinuations and the nature of future candidates
- Analysis of target and minimum acceptable product profiles as compared to current standards of care

Highlights
- Anticoagulant pipeline casualties have historically been clinically driven, however, there is evidence that pipeline discontinuations are increasingly being driven by commercial decision making. Developers now face a decision between pursuing costly mega-trial strategies and high risk niche strategies offering few guaranteed returns.
- Very few companies have the resources to fund increasingly complex, expansive trials. Fewer will be inclined to perform these trials as four breakthrough products vie for share. Niche sub-sectors may offer alternative opportunities but may still require assessment against new products for which clear roles are far from established or accepted.
- Datamonitor predicts a hiatus in the aggressive hunt for warfarin alternatives until the current crop are better integrated into clinical practice. This could take years, and is likely to be followed by a wave of me-too products and the systematic fragmentation of the market by competitors seeking to isolate high value patient subgroups.

Your key questions answered
- Understand the factors driving the shape of clinical trial strategies for the current crop of new market entrants
- Predict the likely impact of four breakthrough products on trial strategy and design in stroke prevention
- Identify the prerequisites for the would-be new market entrants of the future

Contents:
Executive Summary
Strategic scoping and focus
Datamonitor key findings
OVERVIEW
Catalyst
Summary
CLINICAL TRIAL DESIGN
Trial strategy
Launch order and risk mitigation
Atrial fibrillation as a showcase indication
One trial or two?
Pivotal trial design
Comparators
Endpoints
Superiority versus non-inferiority
Trial size and duration
Allocation and blinding
Inclusion criteria
Exclusion criteria
Future developments in clinical trial design

CLINICAL PIPELINE OVERVIEW
- Recent late-stage discontinuations

COMPARATOR THERAPIES AND TARGET PRODUCT PROFILES
- Comparator 1: warfarin
- Comparator 2: aspirin
- Target product profile versus current level of attainment

INNOVATIVE EARLY-STAGE APPROACHES
- TB-402: ThromboGenics and BioInvent International
- Infestin-4: CSL

THE FUTURE OF STROKE PREVENTION IN ATRIAL FIBRILLATION
- Cost effectiveness put under the microscope
- Patient and product selection enters new realms of complexity
- Trading convenience for contact while still mitigating risk
- Keeping abreast of broader changes in atrial fibrillation management
- Integrating new approaches into clinical trial design

BIBLIOGRAPHY
- Journal papers
- Websites

APPENDIX
- Report methodology

Ordering:
Order Online - http://www.researchandmarkets.com/reports/2014003/

Order by Fax - using the form below

Order by Post - print the order form below and send to

Research and Markets,
Guinness Centre,
Taylors Lane,
Dublin 8,
Ireland.
Fax Order Form
To place an order via fax simply print this form, fill in the information below and fax the completed form to 646-607-1907 (from USA) or +353-1-481-1716 (from Rest of World). If you have any questions please visit http://www.researchandmarkets.com/contact/

Order Information
Please verify that the product information is correct and select the format(s) you require.

Product Name: R&D Trends: Anticoagulants for stroke prevention in atrial fibrillation - Upcoming heavy hitters leave a permanent mark
Web Address: http://www.researchandmarkets.com/reports/2014003/
Office Code: SCD21WGP

Product Formats
Please select the product formats and quantity you require:

<table>
<thead>
<tr>
<th>Product Format</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic (PDF) -</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single User:</td>
<td></td>
<td>USD 3800</td>
</tr>
<tr>
<td>Enterprisewide:</td>
<td></td>
<td>USD 9500</td>
</tr>
</tbody>
</table>

Contact Information
Please enter all the information below in BLOCK CAPITALS

Title: [ ] Mr [ ] Mrs [ ] Dr [ ] Miss [ ] Ms [ ] Prof
First Name: __________________________ Last Name: __________________________
Email Address: * __________________________
Job Title: __________________________
Organisation: __________________________
Address: __________________________
City: __________________________
Postal / Zip Code: __________________________
Country: __________________________
Phone Number: __________________________
Fax Number: __________________________

* Please refrain from using free email accounts when ordering (e.g. Yahoo, Hotmail, AOL)
Payment Information

Please indicate the payment method you would like to use by selecting the appropriate box.

☐ Pay by credit card: You will receive an email with a link to a secure webpage to enter your credit card details.

☐ Pay by check: Please post the check, accompanied by this form, to:
Research and Markets,
Guinness Center,
Taylors Lane,
Dublin 8,
Ireland.

☐ Pay by wire transfer: Please transfer funds to:
Account number 833 130 83
Sort code 98-53-30
Swift code ULSBIE2D
IBAN number IE78ULSB98533083313083
Bank Address Ulster Bank,
27-35 Main Street,
Blackrock,
Co. Dublin,
Ireland.

If you have a Marketing Code please enter it below:

Marketing Code:

Please note that by ordering from Research and Markets you are agreeing to our Terms and Conditions at http://www.researchandmarkets.com/info/terms.asp