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Botulinum Neurotoxins: A Comparative Industry Analysis Of Products, Pipelines, Technologies And Stakeholders

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Abstracts

Botulinum Neurotoxins: A comparative industry analysis of products, pipelines, technologies and stakeholders

This business report from July 2014 is based on the identification, description and assessment of all relevant stakeholders in the field of botulinum neurotoxins. The report analyzes the existing product portfolios in regulated and less regulated markets, commercial information, and measures to maintain sales and market shares by upside indications and life cycle management measures. The report addresses the new wave of botulinum neurotoxin product candidates in development, such as biosimilars and biosuperior botulinum neurotoxins.

Special emphasis is put in the report on improvements by pharmaceutical technologies, such as liquid protein formulations and transdermal drug delivery technologies. The significance of recombinant DNA technology is discussed regarding botulinum neurotoxin engineering, modification and manufacturing. Chances and challenges for the stakeholders in the botulinum neurotoxin market are evaluated.

The market for botulinum neurotoxin products has significantly grown over the last years, due to new medical indications developed and due to more cosmetic procedures performed with botulinum neurotoxins in ageing societies in which physical appearance is highly valued. Although the botulinum neurotoxin market commercially is dominated by only one company, existing competitors, new players and technologies are setting the ground for biosuperiors as well as for biosimilars. As biosimilar botulinum toxins will put the price of first generation products under pressure, only innovation can justify higher prices.

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Benefits from the report:

Identify established and emerging players in the field;

Find out which enabling technologies are attractive for the next generation;

Understanding the driving forces for the future of the botulinum neurotoxin market;

Learn the key success factors in marketing new botulinum neurotoxin products;

Recognize the challenges acting on established stakeholders;

Learn which technologies and product candidates are attractive for partnering;

Find out which TCR therapeutic approaches are not yet tapped.

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Contents

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Daewoong Pharmaceutical Co
Eisai
Escape Therapeutics
Galderma
Hugel
Ipsen
Johnson & Johnson (Mentor)
Lanzhou Institute of Biological Producs (LIBP)
Lipella Pharmaceuticals
Malvern Cosmeceutics
Medy-Tox
Merz Pharmaceuticals
OBI Pharma
Revance Therapeutics
Transdermal Corp
US WorldMeds

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Tables

TABLES IN THE REPORT

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COMPANIES MENTIONED IN THE REPORT

Allergan
Alphaeon
Anterios
Bago
Bon-Song
Chong Kun Dang
CROMA Pharma
Daewoong Pharmaceutical Co
Eisai
EpiVax
Escape Therapeutics
Galderma
GlaxoSmithKline
Hugel
Ipsen
Johnson & Johnson
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Medicis
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Oxbridge Pharma
PharmaVital
Revance Therapeutics
Syntaxin
TKJ
Transdermal Corp
University of Tokushima
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About

The comparison of the timelines of approvals and of the approved indications reveals that onabotulinumtoxinA from Allergan was the very first BoNT to be approved, has the most medical indications approved and leads the approvals in esthetic indications. BOTOX is currently approved in approximately 85 countries for 25 different indications. Ipsen's abobotulinumtoxinA (Dysport/Azzalure) has marketing authorizations in more than 75 countries, but it was only in 2009 that it gained approval for cervical dystonia and glabellar lines in the US. In Europe, the esthetic indication glabellar lines was approved for Azzalure in 2010. The approval history of incabotulinumtoxinA (Xeomin) from Merz Pharmaceuticals is rather short and commences on a regional basis in Germany in the year 2005. The market presence in the US only started in 2013.

Xeomin from Merz currently is marketed in 20 countries. The only BoNT-B product on the market in the US, the European Union and in Japan is rimabotulinumtoxinB. Rights for Myobloc are now hold by US WorldMeds and licensed to Eisai for Europe and Japan under the brand name NeuroBloc. Myobloc/Neurobloc is only approved for cervical dystonia.

According to Allergan, BOTOX is one of the world's most widely-researched medicines with approximately 2,300 publications in peer-reviewed scientific and medical journals. Allergan described its cumulative investment in the development of Botox regarding approved indications and those under development to be in the range of US$ 1.6 bln.

Key product features of BoNT products in regulated markets

Each of the four BoNT products approved and marketed in the US and Europe has an individual potency and is not directly interchangeable with any other BoNT product. Botox and Dysport are the oldest BoNT developments and both exist as larger protein complexes including non-toxic proteins. As a foreign protein, BoNT can induce immunogenicity, the formation of neutralizing antibodies leading to therapeutic non-response. Merz claimed its 150 kD BoNT to be less immunogenic than Botox and Dysport as it lacks the non-toxic protein components, but this claim clinically has not been proven. Furthermore, a study analyzing the impact of total cumulative dose of BoNT type A products, injection frequence, a short interval between treatment cycles and a long duration of treatment on immunogenicity did not confirm an association between these variables and BoNT-A antibody formation (Bakheit, 2012).

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Biosuperior, Next Generation BoNTs

The development of new BoNT products at present is focused on three approaches:

Liquid, injectable formulations;

Transdermal, topical formulations;

Recombinant, engineered molecules.

In addition, the development of new BoNT products includes incoporation of state-of-the-art manufacturing processes utilizing animal-source free culture media and avoiding use of human-derived materials (e.g. purified human serum albumin).

Ready-to-use injectable BoNT in liquid formulation

Although there exists already one BoNT product on the market available as liquid formulation, it does not have much commercial success. Myobloc/NeuroBloc from US WorldMeds and marketing partner Eisai (for Europe and Japan) is a type B botulinum neurotoxin approved for cervival dystonia only. The major advantage of a liquid formulation is the time saving of the dissolution step required for lyophilisate and improved safety by avoiding exposure to cannulas.

However, the BoNT-B drug product is formulated at an acidic pH which can cause pain during and after injection.

Next after US WorldMeds is Ipsen with the development of a liquid, ready-to-use BoNT-A product development. Ipsen recently completed a worldwide (EU and US) phase III study of „Dysport Next Generation“ (DNG) in cervical dystonia and also completed a phase II study in glabellar lines. The principal investigator of the study said that this „phase III study was the very first international Phase III trial to show that a liquid toxin A is safe and efficacious. Although the statistical non-inferiority criterion between DNG and Dysport was not formally met in the Double Blind Phase of the trial, this is unlikely to reflect clinical meaningful differences between the two formulations. In addition, the Open Label Long Term data show sustained and robust efficacy of DNG with a good

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safety profile.“ Ipsen plans to file DNG in Europe and the rest of the world, i.e. Latin America, Middle East and Asia (ex Japan and China).

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