



16.–17. Januar 2009 · Köln

**1. Deutscher Kongress
für patientenorientierte Arzneimittelinformation**



Informationsquellen für Spezialfragen: Arzneimittel in Entwicklung

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Pharmazie, Master of Public Health

16.–17. Januar 2009 · Köln

**1. Deutscher Kongress
für patientenorientierte
Arzneimittelinformation**



Inhalt / Ziele

▪ Informationsquellen für Arzneimittel in der Entwicklung

- in frühen Entwicklungsphasen
- in klinischen Studien an Patienten
- für neu zugelassene AM, Post-Marketing-Surveillance

▪ Bewertung der Informationsquellen für die Klinik

- Spezialfragen aus der Klinik
- Exemplarische Antworten
- Checkliste: Kriterien für Bewertung von Informationsquellen

▪ Tipps für regelmäßige Informationsbeschaffung über neue AM und AM in Entwicklung



Informationsquellen für AM in Entwicklung

Prälinik	Phase I	Phase II	Phase III	Zulassung	Post-Marketing
Tierstudien	ca.10-50 Gesunde	ca.100-500 monomorb. Pat.	500 – X*1000 multimorbide Pat.		große Patientengruppe
F&E, Grundlagenforschg	offene		RCT	Pivotalstudie	RCT, Anw.beobachtung
	Wirkung, Nebenwirkung Dosisfindung		Wirksamkeit, Sicherheit Unbedenklichkeit		Nebenwirkungen, Langzeitwirksamkeit

R&D Datenbanken: Fakten-DB (z.B. ADIS R&D Insight),
Literatur-DB (Derwent Drug File, Current Contents–Clinical Medicines/SciSearch)

Pharm. / Biotech Unternehmen

PubMed, Embase, Cochrane Library, Biosis Previews

Clinical Trials Portale

Journals, AM-Info-Portale im Internet

EMA / FDA ...

**AM-Datenbanken: ABDA,
Drugdex, AHFS ...**

Patientenindividuelle Spezialfragen

Spezialfragen zu neuen AM und AM in der Entwicklung

- Stand der Entwicklung: Klinische Phase? Indikation? Studienzentren?
- Wirkstoff / Substanzklasse: neu, innovativ, me-too, biological
- Wirkungsmechanismus
- Nebenwirkung
- Interaktionen
- Verfügbarkeit von neuen AM o. Darreichungsformen in Dtl. / Ausland
- „Compassionate use“-Programm
- Marktchancen, geplante Markteinführung in Deutschland
- Kostenübernahme durch Krankenkasse



Ausgewählte Spezialfragen aus der Klinik

1. Bitte um Info zu neuem RSV-Impfstoff Motavizumab in der Entwicklung:

- Stand der Entwicklung?
- wann verfügbar in Deutschland?
- Neueste Studienergebnisse?
- Größe der Studienpopulation?
- Vergleichsstudien zu Synagis® (Palivizumab)?
- Applikationsart i.m. oder i.v.?
- Anwendung zur Prophylaxe oder auch Therapie von RSV-Infektionen?

Arzneimittel vor Zulassung – Motavizumab

AM-Info-Portale im Internet: Beispiel Pharmatrix.Info

Arzneimittel	
Wirkstoff	Motavizumab
Synonym	MEDI-524
Hauptgruppe	Impfstoffe
ATC	J06BB
Indikation	Prävention der durch das Respiratory-Syncytial-Virus (RSV) hervorgerufenen schweren Erkrankungen der unteren Atemwege, die Krankenhausaufenthalte erforderlich machen, bei Kindern mit hohem Risiko für RSV-Erkrankungen:RSV-Infektionen bei
Wirkweise	Motavizumab ist ein humanisierter monoklonaler IgG1κ-Antikörper, der das A-Epitop des Fusionsproteins des Respiratory Syncytial Virus (RSV) bindet. Im Vergleich zu Palivizumab (SYNAGIS), wirkt Motavizumab potenter.
pharm. Unternehmer	AstraZeneca/Medimmune
Stadium	Phase III
Erstelldatum	08.10.2007
Weitere Infos	Zulassung verzögert sich durch Forderung weiterer Daten zu Motavizumab, 28.11.2008 Studien zu Motavizumab Wu H et al. Immunoprophylaxis of RSV infection: advancing from RSV-IGIV to palivizumab and motavizumab. Curr Top Microbiol Immunol 2008;317:103-23.

Source: <http://www.pharmatrix.de>




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Arzneimittel vor Zulassung – Motavizumab

Homepage Fa. AstraZeneca

AstraZeneca 

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- Partnering
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 - ▼ Press releases
 - > 2008
 - > 2007
 - > 2006

Home ▶ Media ▶ Press releases ▶ 2008 ▶

MedImmune Receives FDA Complete Response Letter on Motavizumab

AstraZeneca today announced that MedImmune, its wholly owned biologics business, has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) asking for additional information on motavizumab. The CRL is in connection with the Biologics License Application (BLA) for motavizumab for the prevention of serious respiratory syncytial virus (RSV) disease, which was submitted on 30 January 2008. Motavizumab is an investigational monoclonal antibody (MAb). MedImmune is confident that it can respond to the outstanding questions and, based on the company's current understanding, does not foresee a need to conduct further trials. MedImmune will continue discussions with the FDA reviewers and, subject to this dialogue, currently expects to resubmit in the first half of 2009.

Source: <http://www.astrazeneca.com>

Arzneimittel vor Zulassung – Motavizumab

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

List Results Refine Search Results by Topic Results on Map Search Details

Found 13 studies with search of: **Motavizumab OR MEDI-524**

[Hide studies that are not seeking new volunteers.](#)

- 1 **Completed** [Study of Motavizumab \(MEDI-524\) and Palivizumab in the Same Respiratory Syncytial Virus \(RSV\) Season](#)
Conditions: Respiratory Syncytial Virus Infections; Chronic Lung Disease
Intervention: Drug: MEDI-524
- 2 **Active, not recruiting** [MEDI-524 \(Motavizumab\) for the Prevention of Respiratory Syncytial Virus \(RSV\) Disease Among Native American Indian Infants](#)
Condition: Healthy
Interventions: Biological: MEDI-524; Other: Placebo
- 3 **Completed** [A Study to Evaluate a Single IM Dose of Motavizumab Treatment of Children With RSV \(Respiratory Syncytial Virus\) Illness](#)
Condition: Healthy
Interventions: Biological: MEDI-524; Other: Placebo
- 4 **Recruiting** [A Study to Evaluate a Single Intravenous Dose of Motavizumab for the Treatment of Children Hospitalized With RSV Illness](#)
Condition: Respiratory Syncytial Virus (RSV)
Interventions: Biological: Motavizumab; Other: Biological/Vaccine: Motavizumab; Other: Placebo
- 5 **Completed** [A Study to Evaluate the Safety, Tolerability, and Immunogenicity of MEDI-524 After Dosing for a Second Season in Children](#)
Condition: Healthy
Intervention: Biological: MEDI-524
- 6 **Suspended** [A Phase 3 Trial of the Effect of Motavizumab Prophylaxis on Reduction of Serious Early Childhood Wheezing in Infants](#)
Condition: Wheezing
Interventions: Biological: Motavizumab; Other: Placebo

Source: <http://clinicaltrials.gov>



Arzneimittel vor Zulassung – Motavizumab

R&D Fakten-Datenbanken: ADIS R&D Insight

Motavizumab

DRUG DEVELOPMENT HISTORY

Date	Comment
28 November 2008	MedImmune receives complete response letter from the US FDA for motavizumab in Respiratory syncytial virus infections ³
28 October 2008	Antimicrobial and pharmacodynamics data from Preclinical trials in Respiratory syncytial virus infections presented at the 48th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy and 46th Annual Meeting of the Infectious Diseases Society of America (ICAAC/IDSA-2008) ^{15, 13, 14}
23 September 2008	Sales forecasts reviewed by Lehman Brothers
4 May 2008	Efficacy & adverse events data from a phase III trial in Native American infants for prevention of Respiratory syncytial virus infections released by MedImmune ¹¹
4 February 2008	Preregistration for Respiratory syncytial virus infections in USA (IM)
31 October 2007	Phase-III clinical trials in Respiratory syncytial virus infections in Europe (IM)
31 October 2007	Phase-III clinical trials in Respiratory syncytial virus infections in Israel (IM)
31 October 2007	Phase-III clinical trials in Respiratory syncytial virus infections in Lebanon (IM)
23 August 2007	Results from a phase III clinical trial in Native American infants added to the Viral Infections therapeutic trials section ⁷
19 June 2007	MedImmune has been acquired by AstraZeneca
11 May 2007	Results from a phase III clinical trial in infants at high-risk of RSV infection added to the adverse events section ¹⁰
31 January 2007	Phase-II clinical trials in Respiratory syncytial virus infections in New Zealand (IV)

→ Drug Development Historie von Präklinik (2000) bis post-marketing surveillance

Source: <http://www.adisinsight.com> (kostenpflichtige Datenbank von Wolters Kluwer Health)

Ausgewählte Spezialfragen aus der Klinik

2. Kind mit ADHS, 11 Jahre hat große Probleme mit Schlucken von Kapseln. Gibt es den Wirkstoff Methylphenidat auch als transdermale Darreichungsform?

- Bis zu welchem Alter zugelassen?
- Wirkdauer?
- Kann es auf Kassenrezept verordnet werden?
- Kostenübernahme durch Krankenkasse?



Arzneimittel ohne/vor Zulassung in Deutschland – Methylphenidat transdermal

Zulassungsbehörde FDA – Drugs@FDA

FDA U.S. Food and Drug Administration Department of Health and Human Services
CENTER FOR DRUG EVALUATION AND RESEARCH
Drugs@FDA FDA Approved Drug Products
 Search by Drug Name, Active Ingredient, or Application Number
 Enter at least three characters: [Advanced Search](#)
 Browse by Drug Name
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 Drug Approval Reports by Month
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 CDER Home Page | CDER Site Info | Contact CDER | What's New @ CDER
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 FDA/Center for Drug Evaluation and Research
 Office of Training and Communications
 Division of Information Services
 Update Frequency: Daily

Source: <http://www.fda.gov>

Arzneimittel ohne/vor Zulassung in Deutschland – Methylphenidat transdermal

Zulassungsbehörde FDA – Daytrana (methylphenidate) Transdermal System

Approval History NDA 021514

Note: Not all reviews are available in electronic format from FDA.
Older labels are for historical information only, and should not be used for clinical purposes.
Approval dates can only be verified from 1984 to the present.

Click on a column header to re-sort the table:

Action Date	Supplement Number	Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
04/06/2006	000	Approval	Letter Review	Label is not available on this site.
07/27/2006	001	Labeling Revision	Label	
05/01/2007	005	Labeling Revision	Label	
02/05/2008	003	Labeling Revision	Label	
02/05/2008	006	Labeling Revision	Label	
02/05/2008	007	Labeling Revision	Label	

Source: <http://www.fda.gov>



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Ausgewählte Spezialfragen aus der Klinik

3. Bitte um Info zu neuem Krebsmedikament mit der Bezeichnung ON01910 oder ON01910.Na. Es befindet sich in sehr früher Entwicklung:

- Laufen bereits klinische Studien an Patienten?
- Studienteilnahme möglich?
- Welche Studienzentren gibt es?
- Bei welchen Krebsarten wird es derzeit untersucht?
- Gibt es Daten vom ASCO-Kongress 2008?

Arzneimittel in früher Entwicklung (Phase I): ON01910.Na, Fa. Onconova Therapeutics (USA)

Literatur-Datenbank: Public Medline

NCBI PubMed A service of the U.S. National Library of Medicine and the National Institutes of Health www.pubmed.gov

All Databases PubMed Nucleotide Protein Genome Structure OMIM PMC Journals Books

Search PubMed for ON01910 Go Clear Advanced Search Save Search

Limits Preview/Index History Clipboard Details

Display Summary Show 20 Sort By Send to

All: 5 Review: 1

Items 1 - 5 of 5 One page.

- 1: [Evaluation of the novel mitotic modulator ON 01910.Na in pancreatic cancer and preclinical development of an ex vivo predictive assay.](#)
Jimeno A, Chan A, Cusatis G, Zhang X, Wheelhouse J, Solomon A, Chan F, Zhao M, Cosenza SC, Reddy MR, Rudek MA, Kulesza P, Donehower RC, Reddy EP, Hidalgo M.
Oncogene. 2008 Nov 24. [Epub ahead of print]
PMID: 19029951 [PubMed - as supplied by publisher]
[Related Articles](#)
- 2: [Phase I study of ON 01910.Na, a novel modulator of the Polo-like kinase 1 pathway, in adult patients with solid tumors.](#)
Jimeno A, Li J, Messersmith WA, Laheru D, Rudek MA, Maniar M, Hidalgo M, Baker SD, Donehower RC.
J Clin Oncol. 2008 Dec 1;26(34):5504-10. Epub 2008 Oct 27.
PMID: 18955447 [PubMed - in process]
[Related Articles](#)

Source: <http://www.ncbi.nlm.nih.gov>



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Arzneimittel in früher Entwicklung (Phase I): ON01910.Na, Fa. Onconova Therapeutics (USA)

Clinical Trials Portal der IFPMA: internationale Verband von Pharmaunternehmen und –verbänden



Titel: Safety of ON 01910.Na in Patients With Myelodysplasia

Infobox

Status: **Rekrutierung läuft**

Sponsor: National Heart,...

Orte: United States, Bethesda (Maryland)

[mehr>>](#)

Beschreibung This study will determine the highest dose of the experimental drug ON 01910.Na that can safely be given to patients with the bone marrow disorder myelodysplasia (MDS) and patients with refractory AML with trisomy 8. In this disease, the bone marrow can make some blood cells, but very few of these cells are released into the blood for use in the body. ON 01910.Na is an experimental drug that inhibits a protein called cyclinD1 that is important for keeping MDS cells alive. In laboratory

→ Suche nach laufenden Studien und Studienergebnissen

Source: <http://clinicaltrials.ifpma.org>

Arzneimittel in der Entwicklung - Klinische Studien

Quellen

Das IFPMA Klinische Studien Portal bietet über seine Suchmaschine Links zu Informationen auf Websites Dritter.

Register- und Datenbanksammlungen



ClinicalStudyResults.org
Globale Datenbank aus Studienergebnissen von über **60 Unternehmen**; Gegründet von Pharmaceutical Research and Manufacturers of America (PhRMA).



ClinicalTrials.gov
Register aus weltweit laufenden Studien von über **1200 Unternehmen**, sowie Regierungen und Universitäten; Gegründet von U.S. National Institutes of Health.



[Current Controlled Trials](http://CurrentControlledTrials)
Globales Register laufender Studien von öffentlichen und privaten Organisationen; Gegründet von Science Navigation Group (biomedizinischer Verlagsunternehmen).



[Japan Pharmaceutical Information Center](http://JapanPharmaceuticalInformationCenter)
Japanisches Register laufender Studien von über 50 Unternehmen; Gegründet in Zusammenarbeit mit Japanese Pharmaceutical Manufacturers Association (JPMA).



[Pharmaceutical Industry Clinical Trials database](http://PharmaceuticalIndustryClinicalTrialsDatabase)
Register laufender Studien aus Grossbritannien, die sich in Phase 4 befinden und Phase 3 abgeschlossen haben; Verwaltet durch CMR International und gegründet von Association of the British Pharmaceutical Industry (ABPI).

Source: <http://clinicaltrials.ifpma.org/de/search-trials-ongoing/sources/index.htm>



Ausgewählte Spezialfragen aus der Klinik

4. Neues Medikament gegen Thrombose in der frühen Entwicklung - ALX-0081?

- Gibt es bereits Studien an Patienten?
- Teilnahme möglich?
- Welche Studienzentren gibt es?

Arzneimittel in früher Entwicklung (Phase I): ALX 0018, Fa. Ablynx (Belgien)

R&D Datenbank: ADIS R&D Insight – Auszug aus Monografie

R&D Insight
Database | Home | Search | Searches | What's New | Company Profiles | Alerts | Preferences | Ask The Expert | Help

Revise Search → Back to Results → Document

At A Glance | Organisations | Development | Overview | Properties | Scientific | History | References

ALX 0081

AT A GLANCE

Alternate names	ALX-0081
Originator	Ablynx
Highest development phase	I (Belgium)
Active Development - indications	Thrombosis
Class	Proteins
Mechanism of action	Von Willebrand factor inhibitors

ORGANISATIONS

ORGANISATIONS	ORIGINATOR	Country
	Ablynx	Belgium

* in patients with angina undergoing percutaneous coronary intervention (PCI)

Source: <http://www.adisinsight.com>



Arzneimittel in früher Entwicklung (Phase I): ALX 0018, Fa. Ablynx (Belgien)

R&D Datenbank: ADIS R&D Insight – Auszug aus Monografie

R&D Insight

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At A Glance Organisations Development Overview Properties Scientific History References

ALX 0081

THERAPEUTIC TRIALS Administration of ALX 0081 resulted in anti-thrombotic activity, as evidenced by a biomarker, at doses of ≥ 2mg in a phase I trial in healthy volunteers. **Thromboses** was 12 hours, observed with a 12mg dose ⁵.

DRUG DEVELOPMENT HISTORY

Date	Comment
16 December 2008	Ablynx completes a phase I trial in Thrombosis in Belgium
28 May 2008	Ablynx initiates a phase Ib trial for Thrombosis in Belgium
19 December 2007	Final adverse events and efficacy data from a phase I trial in healthy volunteers released by Ablynx ⁵
5 July 2007	New profile
5 July 2007	Phase-I clinical trials in Thrombosis in Belgium (unspecified route)

- Ablynx is developing an IV formulation of ALX 0081
- Ablynx is also considering development of ALX 0081 for ischaemic stroke.
- Ablynx intends to initiate a phase II trial by the end of 2008.

Source: <http://www.adisinsight.com>

Arzneimittel in früher Entwicklung (Phase I): ON01910.Na, Fa. Onconova Therapeutics (USA)

R&D Datenbank: ADIS R&D Insight

ON 01910

DRUG DEVELOPMENT HISTORY

Date	Comment
29 October 2008	Preclinical trials in Solid tumours in USA (PO)
29 October 2008	Efficacy data from a phase I trial in solid tumours released by Onconova Therapeutics ¹
3 June 2008	Pharmacokinetics and adverse events data from a Phase-I trial in Cancer presented at the 44th Annual Meeting of the American Society of Clinical Oncology (ASCO-2008) ⁷
16 April 2008	Phase-I pharmacokinetics and adverse events data presented at the 99th Annual Meeting of the American Association for Cancer Research ³
31 March 2008	Phase-I clinical trials in Acute myeloid leukaemia in USA (IV)
29 February 2008	Phase-I clinical trials in Solid tumours in USA (IV)
30 September 2007	Phase-I clinical trials in Myelodysplastic syndromes in USA (IV)
7 May 2007	Data presented at the 98th Annual Meeting of the American Association for Cancer Research (AACR-2007) added to the adverse events and pharmacokinetics sections ⁴
19 June 2006	Data presented at the 42nd Annual Meeting of the American Society of Clinical Oncology (ASCO-2006) have been added to the Cancer pharmacodynamics section ⁶

→ Daten von Kongressen werden in der Wirkstoffmonografie regelmäßig nach den Kongressen eingearbeitet

→ in diesem Beispiel: ASCO-2006, AACR-2007, ASCO-2008

Source: <http://www.adisinsight.com>



Arzneimittel in früher Entwicklung (Phase I): ALX 0018, Fa. Ablynx (Belgien)

Homepage Fa. Ablynx



A multiple dose Phase Ib study started in May 2008 in up to 64 patients with stable angina undergoing percutaneous coronary intervention (PCI), in addition to a standard anti-thrombotic regimen.

Source: <http://www.ablynx.com>

Ausgewählte Spezialfragen aus der Klinik

5. Neues Arzneimittel Relistor® (Methylnaltrexon)

- Zugelassen bei postoperativem Ileus?
- In welchen Indikationen ist es zugelassen?



Neu zugelassenes Arzneimittel - Relistor®, Fa. Wyeth

EMA – Public assessment report

1	BACKGROUND INFORMATION ON THE PROCEDURE	3
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Source: <http://www.emea.europa.eu>

Ausgewählte Spezialfragen aus der Klinik

6. Neues Arzneimittel Tysabri® (Natalizumab) bei schwerer, schubförmig-remittierender Multipler Sklerose

- Bitte um Info zu aktuellem, schweren Nebenwirkungsfall einer PML (progressive multifokale Leukenzephalopathie verursacht durch JC-Virus) unter Tysabri® - Behandlung in Deutschland.
- Wie lange hat der Patient das Medikament bereits erhalten?



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Neu zugelassenes Arzneimittel - Tysabri®, Fa. Biogen

Homepage Zulassungsbehörde FDA

U.S. Department of Health & Human Services
FDA U.S. Food and Drug Administration
 Protecting and Promoting Your Health

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- Medical Devices
- Biologics, Blood & Vaccines
- Animal & Veterinary
- Cosmetics
- Radiation-Emitting Products
- Combination Products

New Approvals

- New Drug Approvals

Safety

- Index to Drug-Specific Information
- Reporting Product Problems
- Safety Alerts (MedWatch)
- Postmarket Drug Safety Information for Patients/Providers
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Information For:

- Consumers
- Healthcare Professionals

Industry Resources

- Guidances
- Prescription Drug User Fees
- More Industry Resources

A-Z Index

A	B	C	D	E	F	G	H	I
J	K	L	M	N	O	P	Q	R
S	T	U	V	W	X	Y	Z	#

Most Popular

- Influenza Virus Vaccine
- Drugs@FDA
- Qualified Health Claims
- Mammography

[More Information on Drugs](#)

Source: <http://www.fda.gov>

Neu zugelassenes Arzneimittel - Tysabri®, Fa. Biogen

Homepage Zulassungsbehörde FDA

FDA U.S. Food and Drug Administration
 CENTER FOR DRUG EVALUATION AND RESEARCH

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Natalizumab (marketed as Tysabri) Information

FDA ALERT [8/2008]: The FDA has recently received information from the manufacturer about two new cases of progressive multifocal leukoencephalopathy (PML) in patients receiving Tysabri monotherapy for multiple sclerosis in Europe. Both patients had received Tysabri for more than one year. PML, which is usually fatal, is a known risk of Tysabri treatment, but previous cases in patients with multiple sclerosis were seen in combination with other immunomodulatory therapies. About 39,000 patients have received treatment with Tysabri worldwide, with about 12,000 patients having been treated for at least one year. No new cases have been seen in the US, where about 7,500 patients have received the drug for longer than one year and about 3,300 patients have received the drug for at least one and a half years.

In the U.S., Tysabri is available only to patients with relapsing multiple sclerosis (MS) or Crohn's disease (CD) who are enrolled in the risk minimization plan called the TOUCH Prescribing Program. Under the TOUCH Prescribing Program, every Tysabri-treated patient is closely monitored and followed for the occurrence of PML and other serious opportunistic infections.

Source: <http://www.fda.gov>



Neu zugelassenes Arzneimittel - Tysabri®, Fa. Biogen

SEC: „Form 8-K“ - Report nach signifikantem Ereignis (innerh. 4 Werktagen)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **December 15, 2008**

Biogen Idec Inc.
(Exact name of registrant as specified in its charter)

Delaware <small>(State or other jurisdiction of incorporation)</small>	0-19311 <small>(Commission file number)</small>	33-0112644 <small>(IRS Employer Identification No.)</small>
14 Cambridge Center, Cambridge, Massachusetts <small>(Address of principal executive offices)</small>		02142 <small>(Zip Code)</small>

Registrant's telephone number, including area code (617) 679-2000

Source: <http://www.sec.gov/Archives/edgar> (SEC: United States Securities and Exchange Commission)

Neu zugelassenes Arzneimittel - Tysabri®, Fa. Biogen

SEC: „Form 8-K“ - Report nach signifikantem Ereignis

Item 8.01 Other Events.

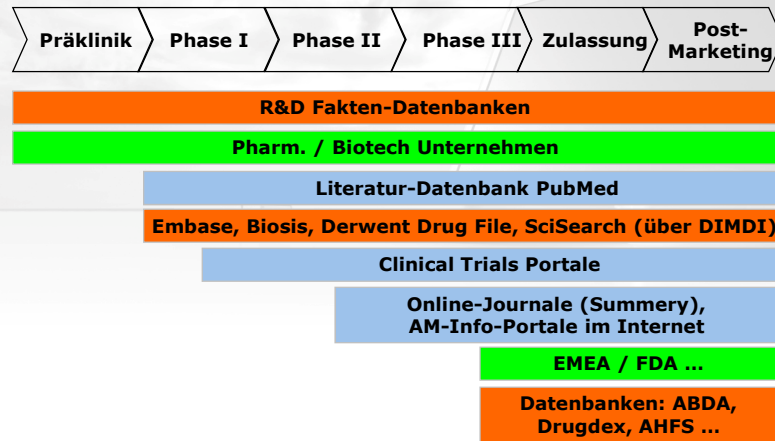
On December 11, 2008, relevant regulatory agencies were notified of a confirmed case of progressive multifocal leukoencephalopathy (PML) in a multiple sclerosis (MS) patient treated with TYSABRI in the commercial setting in the European Union as part of TYGRIS: TYSABRI® Global Observational Program in Safety — ROW. Additional information about this case is set forth below.

- The diagnosis was made based upon the detection of JC Virus (JCV) DNA in the cerebrospinal fluid (CSF) in the setting of clinical signs, symptoms and magnetic resonance imaging (MRI) findings consistent with the diagnosis of PML.
- Background:
 - Patient has a history of MS and prior disease modifying therapies, including beta-interferons,
 - Patient received approximately 26 months of TYSABRI monotherapy,
 - Clinical vigilance led to early identification of signs and symptoms of possible PML and clinical evaluation which included MRI scanning and CSF testing,
 - Patient is under the care of patient's treating physician.

Source: <http://www.sec.gov/Archives/edgar>



Zusammenfassung: Bewertung der Informationsquellen



Legende

Kostenpflichtig:
Umfangreich

Internetzugriff:
Keine Kosten, aktuell

Primärliteratur:
Keine Kosten, aktuell

Kriterien für die Bewertung der Informationsquellen

Checkliste

- **Qualität der Information:** Primär-, Sekundär-, Tertiärliteratur
- **Aktualisierung:** täglich, monatlich, Quartalsweise?
- **Zielgruppe:** Klinik, Forschung, Pharmaindustrie
- **Inhalte / Schwerpunkt:** International o. national?
Neuentwicklungen o. established drugs
- **Umfang:** Hinweis, Kurzinfo, Kurzzusammenfassung von Studien,
Wirkstoffmonografie
- **Kosten?**



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für patientenorientierte Arzneimittelinformation**

Tipps für regelmäßige Informationsbeschaffung über neue AM und AM in Entwicklung

- FDA-MedWatch email updates (Safety alerts)
- PharmaLive Email-Newsticker Studienergebnisse
- NHS / UK Medicines Information News Headlines
- Medscape: Week in Review – MedPulse
- Journal „Drugs of the future“
- Journal „Nature Reviews Drug Discovery“
- Scrip World Pharmaceutical News
- Pharmatrix.Info – Neue Arzneimittel
- Drugs.com™ - New Drug Applications



Vielen Dank für Ihre Aufmerksamkeit!