



FDA Approval Decisions Report February-April 2007

Overview

For investors in pharmaceutical and biotech companies, rigorous monitoring of drug pipelines is essential. No milestone is more influential than the FDA approval decision date, frequently called the PDUFA date (from Prescription Drug User Fee Act).

This Revere Report features **companies with expected FDA approval decision dates in the next three months**. To provide further insights into **each drug candidate's likelihood of approval and competitive landscape**, the FDA Approval Decisions Report includes **key data based on Revere's patented classification system and proprietary pipeline database** - specifically, whether each drug candidate:

- utilizes a mechanism of action already approved by the FDA in other drugs
- faces two or fewer alternative drugs with the same mechanism of action for the same indication
- would be the first or second FDA approved drug for the company

Contents

- Recent Approval Results/Updates
- Expected PDUFA Dates in the Next Three Months
- Price and Financial Info

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Notes:

1. Some expected PDUFA (Prescription Drug User Fee Act) dates are Revere estimates based on NDA (New Drug Approval) submission dates. Companies are not obligated to disclose NDA submission dates or PDUFA dates, and the FDA may change its approval decision date without prior notice.
2. Drugs developed by private firms or by companies not traded publicly in the U.S. are excluded from this analysis.

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Recent Approval Results/Updates

Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Previous Expected PDUFA Date	Approval results/update
Enzon Pharmaceuticals, Inc. (ENZN) / Cimzia (Certolizumab Pegol)				
	Crohn's Disease	Tumor Necrosis Factor-Alpha Antagonists (TNF-Alpha Antagonists)	01/02/2007	Approvable Letter Received 01/02/2007
Genzyme Corporation (GENZ) / Welchol (Colesevelam Hydrochloride)				
	Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type 2 Diabetes	Bile Acid Binding Agents	01/02/2007	Result Pending
Pfizer Inc. (PFE) / Fesoterodine				
	Overactive Bladder/Urinary Incontinence	Muscarinic Receptor Antagonists	January 2007	Result Pending
Schwarz Pharma, Inc. (SWTZY) / Fesoterodine				
	Overactive Bladder/Urinary Incontinence	Muscarinic Receptor Antagonists	January 2007	Result Pending
Nektar Therapeutics (NKTR) / Cimzia (Certolizumab Pegol)				
	Crohn's Disease	Tumor Necrosis Factor-Alpha Antagonists (TNF-Alpha Antagonists)	01/02/2007	Approvable Letter Received 01/02/2007
Amylin Pharmaceuticals, Inc. (AMLN) / Byetta (Exenatide)				
	Add-On Therapy To Thiazolidinediones (TZDs) In People With Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type 2 Diabetes Who Are Not Achieving Acceptable Blood Sugar Control	Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 Receptor Agonists)	01/02/2007	Approved 12/22/2006
Eli Lilly & Co. (LLY) / Byetta (Exenatide)				
	Add-On Therapy To Thiazolidinediones (TZDs) In People With Type 2 Diabetes Who Are Not Achieving Acceptable Blood Sugar Control	Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 Receptor Agonists)	01/02/2007	Approved 12/22/2006
Abbott Laboratories (ABT) / KOS Pharmaceuticals Niaspan CF (Niacin)				
	Hypercholesterolemia	Free Fatty Acid Inhibitors	01/12/2007	Result Pending
Stiefel Laboratories, Inc. / Connectics Olux E (Clobetasol Propionat)/Formerly Primolux				
	Atopic Dermatitis (Eczema)	Steroidal Anti-Inflammatory Drugs (SAID)	<u>01/17/2007</u>	Approved 01/12/2007
Stiefel Laboratories, Inc. / Connectics Olux E (Clobetasol Propionat)/Formerly Primolux				
	Psoriasis	Steroidal Anti-Inflammatory Drugs (SAID)	<u>01/17/2007</u>	Approved 01/12/2007
Shire plc (ADR) (SHPGY) / Lialda (Mesalamine)				
	Active Mild-To-Moderate Ulcerative Colitis	Cyclooxygenase Inhibitors (COX Inhibitors)/Lipoxygenase Inhibitors	<u>01/19/2007</u>	Approved 01/16/2007
Wyeth (WYE) / Pristiq (Desvenlafaxine Succinate)/Formerly DVS-233				
	Major Depressive Disorder	Selective Norepinephrine Reuptake Inhibitors (SNRI)	<u>01/22/2007</u>	Approvable Letter Received 01/22/2007
Genta Incorporated (GNTA) / Genasense (Oblimersen Sodium)				
	Chronic Lymphocytic Leukemia (CLL) In Combination With Fludarabine and Cyclophosphamide	Antisense Agents	<u>01/29/2007</u>	Non-Approvable Letter Received 12/15/2006
GlaxoSmithKline plc (ADR) (GSK) / Arixtra (Fondaparinux Sodium)				

Company (Symbol) / Drug Candidate			
Acute Coronary Syndrome (ACS)	Thrombin Inhibitors	<u>01/31/2007</u>	Result Pending
Acambis plc (ADR) (ACAMY) / ACAM2000 Smallpox Vaccine			
Smallpox Vaccine	Variola (Smallpox)	<u>02/14/2007</u>	Approvable Letter Received 01/17/2007
MedImmune, Inc. (MEDI) / Cold Adapted Influenza Vaccine-Trivalent (CAIV-T)			
Influenza Vaccine (Flu Vaccine) In Healthy Individuals 5 To 49 Years Of Age	Influenza (Flu)	02/14/2007	Approved 01/08/2007

Expected PDUFA Dates are Revere estimates based on NDA (New Drug Approval) submission dates. Underlined dates indicate that Revere has confirmed directly with the company or indirectly through company filings and press releases.




Expected PDUFA Dates in the Next Three Months

February Drug Candidates

Companies

Merck & Co., Inc. (MRK)
Merck Serono S.A. (ADR) (SRA)
Novartis AG (ADR) (NVS)
Watson Pharmaceuticals, Inc. (WPI)

Sectors

I Biopharmaceuticals
 Digestive System
 Endocrinology/Metabolism
 Neurology

Notes:

1. Some drug candidates are filed jointly by two companies.
2. Companies with multiple drug candidates in the same month are shown in **bold type** with the number of drug candidates in brackets [].

Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 st /2 nd Drug?
Merck & Co., Inc. (MRK) / MK-0517 (Intravenous Aprepitant)						
	Chemotherapy-Induced Nausea And Vomiting (CINV)	Neurokinin-1 (NK-1) Receptor Antagonists	February 2007	Yes	Yes Only Candidate with This PMOA for This Indication	No
Watson Pharmaceuticals, Inc. (WPI) / AndrX Laboratories ACTOplus met XR (Pioglitazone/Metformin Extended Release)						
	Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type 2 Diabetes Who Are Not Controlled Adequately With Metformin Only	Biguanides/Peroxisome Proliferator-Activated Receptor Agonists (PPAR Agonists)	02/05/2007	Yes	Yes Avandamet (Rosiglitazone Maleate/Metformin) / (GSK)	No
Merck Serono S.A. (ADR) (SRA) / Rebif (Recombinant Interferon Beta-1a)						
	New Formulation For The Treatment Of Relapsing-Remitting Multiple Sclerosis (MS)	Interferons	02/05/2007	Yes	Yes AVONEX (Interferon beta-1a) / (BIIB)	No
Novartis AG (ADR) (NVS) / Galvus (Vildagliptin)						
	Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type 2 Diabetes	Dipeptidyl Peptidase (DPP) Inhibitors	02/28/2007	Yes	Yes Januvia (Sitagliptin Phosphate) / (MRK)	No

Expected PDUFA Dates are Revere estimates based on NDA (New Drug Approval) submission dates. Underlined dates indicate that Revere has confirmed directly with the company or indirectly through company filings and press releases. **Two or Fewer Alternatives** -- If Approved, Drug Will Likely Face Two or Fewer Alternatives in Same Drug Class for Same Indication? **1st/2nd Drug** -- 1st or 2nd FDA Approved Drug of the Company?

March Drug Candidates

Companies

Abbott Laboratories (ABT)
 Alexion Pharmaceuticals, Inc. (ALXN)
 AstraZeneca plc (ADR) (AZN)
 Eli Lilly & Co. (LLY)
 GlaxoSmithKline plc (ADR) (GSK)
 Merck & Co., Inc. (MRK)
 Merck Serono S.A. (ADR) (SRA)
 New River Pharmaceuticals, Inc. (NRPH)
 Novartis AG (ADR) (NVS)
 Shire plc (ADR) (SHPGY)

Sectors

- I Biopharmaceuticals
 - Cardiovascular System
 - Digestive System
 - Endocrinology/Metabolism
 - Hematology
 - Neurology
 - Oncology

Notes:

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Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 st /2 nd Drug?
Merck Serono S.A. (ADR) (SRA) / Serostim (Somatropin)						
	HIV-Associated Adipose Redistribution Syndrome (HARS)/ Lipodystrophy	Growth Hormones	March 2007	Yes	Yes Only Candidate with This PMOA for This Indication	No
New River Pharmaceuticals, Inc. (NRPH) / Vyvance (Lisdexamfetamine Dimesylate)/Formerly NRP104						
	Attention Deficit Hyperactivity Disorder (ADHD) In Pediatric Patients 6-12 Years Of Age	Sympathomimetic Agents	March 2007	Yes	Yes Dexedrine (Dextroamphetamine Sulfate) / (GSK)	Yes
Shire plc (ADR) (SHPGY) / Vyvance (Lisdexamfetamine Dimesylate)/Formerly NRP104						
	Attention Deficit Hyperactivity Disorder (ADHD) In Pediatric Patients 6-12 Years Of Age	Sympathomimetic Agents	March 2007	Yes	Yes Dexedrine (Dextroamphetamine Sulfate) / (GSK)	No
Abbott Laboratories (ABT) / Humira (Adalimumab)						
	Moderate-To-Severe Crohn's Disease	Tumor Necrosis Factor-Alpha Antagonists (TNF-Alpha Antagonists)	<u>03/07/2007</u>	Yes	Yes Cimzia (Certolizumab Pegol) / (ENZN)	No
AstraZeneca plc (ADR) (AZN) / Humira (Adalimumab)						
	Moderate-To-Severe Crohn's Disease	Tumor Necrosis Factor-Alpha Antagonists (TNF-Alpha Antagonists)	<u>03/07/2007</u>	Yes	Yes Cimzia (Certolizumab Pegol) / (ENZN)	No
Eli Lilly & Co. (LLY) / Cymbalta (Duloxetine Hydrochloride)						
	Generalized Anxiety Disorder (GAD)	Serotonin/Norepinephrine Reuptake Inhibitors	03/09/2007	Yes	Yes Only Candidate with This PMOA for This Indication	No
GlaxoSmithKline plc (ADR) (GSK) / Tykerb (Lapatinib Ditosylate)						
	Advanced Or Metastatic HER2 Positive Breast Cancer In Women Who Have Received Prior Therapy	Tyrosine Kinase Inhibitors	03/16/2007	Yes	Yes Only Candidate with This PMOA for This Indication	No
Alexion Pharmaceuticals, Inc. (ALXN) / Soliris (Eculizumab)						
	Paroxysmal Nocturnal Hemoglobinuria (PNH)	Monoclonal Antibodies	03/20/2007	Yes	Yes Only Candidate with This PMOA for This Indication	Yes
Novartis AG (ADR) (NVS) / Tekturna (Aliskiren)/Formerly Rasilez						
	Hypertension	Renin Inhibitors	03/20/2007	No	Yes Only Candidate with This PMOA for This Indication	No
Merck & Co., Inc. (MRK) / JANUMET (Sitagliptin phosphate/Metformin)/Formerly MK-0431A						

Company (Symbol) / Drug Candidate	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 st /2 nd Drug?
Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type 2 Diabetes	Biguanides/Dipeptidyl Peptidase (DPP) Inhibitors	03/31/2007	No	Yes Only Candidate with This PMOA for This Indication	No









Expected PDUFA Dates are Revere estimates based on NDA (New Drug Approval) submission dates. Underlined dates indicate that Revere has confirmed directly with the company or indirectly through company filings and press releases. **Two or Fewer Alternatives** -- If Approved, Drug Will Likely Face Two or Fewer Alternatives in Same Drug Class for Same Indication? **1st/2nd Drug** -- 1st or 2nd FDA Approved Drug of the Company?

April Drug Candidates

Companies

GlaxoSmithKline plc (ADR) (GSK)
 Hana Biosciences, Inc. (HNAB)
 Insite Vision Inc. (ISV)
 Ligand Pharmaceuticals Inc. (LGND)
 Neurochem Inc. (USA) (NRMX)
 Novadel Pharma Inc (NVD)
 Questcor Pharmaceuticals (QSC)
Wyeth (WYE) [3]
 sanofi-aventis (ADR) (SNY)

Sectors

I Biopharmaceuticals
 Allergies
 Digestive System
 Endocrinology/Metabolism
 Immunology
 Infectious Diseases
 Musculoskeletal System
 Neurology
 Oncology
 Weight Management

Notes:

- Some drug candidates are filed jointly by two companies.
- Companies with multiple drug candidates in the same month are shown in **bold type** with the number of drug candidates in brackets [].

Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 st /2 nd Drug?
Wyeth (WYE) / Torisel (Temsirrolimus)						
	Advanced Renal Cell Carcinoma (Kidney Cancer)	Mammalian Target Of Rapamycin (mTOR) Inhibitors	04/06/2007	No	Yes Only Candidate with This PMOA for This Indication	No
Neurochem Inc. (USA) (NRMX) / Kiacta (Eprodinate)/Formerly Fibrillex						
	Amyloid A Amyloidosis (AA Amyloidosis)	Glycosaminoglycan (GAG) Mimetic Agents	<u>04/16/2007</u>	No	Yes Only Candidate with This PMOA for This Indication	Yes
Ligand Pharmaceuticals Inc. (LGND) / Viviant (Bazedoxifene)						
	Prevention Of Postmenopausal Osteoporosis	Selective Estrogen Receptor Modulators (SERM)	04/23/2007	Yes	Yes Only Candidate with This PMOA for This Indication	No
Questcor Pharmaceuticals (QSC) / HP Acthar Gel (Corticotropin)						
	Infantile Spasms (West Syndrome)	Corticotropins	04/23/2007	Yes	Yes Only Candidate with This PMOA for This Indication	No
Wyeth (WYE) / Viviant (Bazedoxifene)						
	Prevention Of Postmenopausal Osteoporosis	Selective Estrogen Receptor Modulators (SERM)	04/23/2007	Yes	No Multiple Drugs	No
sanofi-aventis (ADR) (SNY) / Acomplia (Rimonabant)						
	Treatment Of Obesity	Cannabinoid Receptor Antagonists	<u>04/26/2007</u>	No	Yes Only Candidate with This PMOA for This Indication	No
Wyeth (WYE) / Pristiq (Desvenlafaxine Succinate)/Formerly DVS-233						
	Relief Of Vasomotor Symptoms Associated With Menopause	Selective Norepinephrine Reuptake Inhibitors (SNRI)	04/26/2007	Yes	Yes Only Candidate with This PMOA for This Indication	No
Insite Vision Inc. (ISV) / AzaSite (Azithromycin)						
	Acute Bacterial Conjunctivitis	Macrolides	04/27/2007	Yes	Yes Erythromycin / (BOL)	Yes
GlaxoSmithKline plc (ADR) (GSK) / Allermist (Intranasal Fluticasone Furoate)s						
	Seasonal Allergic Rhinitis, Perennial Allergic Rhinitis	Steroidal Anti-Inflammatory Drugs (SAID)	04/27/2007	Yes	No Multiple Drugs	No
Novadel Pharma Inc (NVD) / Zensana (Ondansetron Oral Spray)						

Company (Symbol) / Drug Candidate	Indications	Primary mode of action (PMOA)	Expected PDUFA Date	Proven PMOA?	Two or Fewer Alternatives?	1 st /2 nd Drug?
	Prevention Of Nausea/Vomiting Associated With Chemotherapy/Radiotherapy, Prevention Of Post Operative Nausea/Vomiting	Serotonin Receptor Antagonists	<u>04/30/2007</u>	Yes	No Multiple Drugs	Yes
Hana Biosciences, Inc. (HNAB) / Zensana (Ondansetron Oral Spray)						
	Prevention Of Nausea/Vomiting Associated With Chemotherapy/Radiotherapy, Prevention Of Post Operative Nausea/Vomiting	Serotonin Receptor Antagonists	<u>04/30/2007</u>	Yes	No Multiple Drugs	Yes

Expected PDUFA Dates are Revere estimates based on NDA (New Drug Approval) submission dates. Underlined dates indicate that Revere has confirmed directly with the company or indirectly through company filings and press releases. **Two or Fewer Alternatives** -- If Approved, Drug Will Likely Face Two or Fewer Alternatives in Same Drug Class for Same Indication? **1st/2nd Drug** -- 1st or 2nd FDA Approved Drug of the Company?

Price and Financial Info

February 2007

Data as of 01/30/2007

Name	Ticker	Last Price	Market Cap.	30d Avg. Volume	Price To Tang. Book Value	Total Debt to Equity %	Cash & Equiv.+ ST Inv.	1 Year Return %	Rel. Perf. vs. ^BPHRM
Merck & Co., Inc.	MRK	44.91	97,499.742	8,683,148	5.55	31.04	9,087.0	30.33%	24.24%
Merck Serono S.A. (ADR)	SRA	21.90	13,400.180	125,074	5.54	27.87	1,759.5	14.30%	8.22%
Novartis AG (ADR)	NVS	57.53	134,476.087	1,821,190	3.27	17.75	7,955.0	5.54%	-0.54%
Watson Pharmaceuticals, Inc.	WPI	27.13	2,779.957	952,352	2.46	26.93	906.8	-18.94%	-25.03%

Definitions: Market Cap. - Market Capitalization, Price To Tang. Book Value - Price to Tangible Book Value, Cash & Equiv.+ ST Inv. - Cash and Equivalents + Short-Term Investments, Rel. Perf. vs. ^BPHRM - Relative Performance vs. Revere Biopharm Index,

March 2007

Data as of 01/30/2007

Name	Ticker	Last Price	Market Cap.	30d Avg. Volume	Price To Tang. Book Value	Total Debt to Equity %	Cash & Equiv.+ ST Inv.	1 Year Return %	Rel. Perf. vs. ^BPHRM
Abbott Laboratories	ABT	53.19	81,639.416	7,619,512	n/a	n/a	n/a	23.87%	17.79%
Alexion Pharmaceuticals, Inc.	ALXN	41.11	1,425.155	519,561	n/a	1,746.41	110.7	40.79%	34.70%
AstraZeneca plc (ADR)	AZN	55.55	85,120.213	1,414,899	8.54	8.19	6,169.0	15.56%	9.48%
Eli Lilly & Co.	LLY	52.73	57,559.486	4,878,228	4.41	37.44	3,618.5	-8.09%	-14.17%
GlaxoSmithKline plc (ADR)	GSK	54.60	156,997.599	1,527,085	15.16	60.09	6,631.6	6.66%	0.58%
Merck & Co., Inc.	MRK	44.91	97,499.742	8,683,148	5.55	31.04	9,087.0	30.33%	24.24%
Merck Serono S.A. (ADR)	SRA	21.90	13,400.180	125,074	5.54	27.87	1,759.5	14.30%	8.22%
New River Pharmaceuticals, Inc.	NRPH	56.63	2,079.382	301,100	n/a	0	162.8	69.45%	63.37%
Novartis AG (ADR)	NVS	57.53	134,476.087	1,821,190	3.27	17.75	7,955.0	5.54%	-0.54%
Shire plc (ADR)	SHPGY	64.36	10,996.318	669,149	12.79	0	955.2	33.89%	27.80%

Definitions: Market Cap. - Market Capitalization, Price To Tang. Book Value - Price to Tangible Book Value, Cash & Equiv.+ ST Inv. - Cash and Equivalents + Short-Term Investments, Rel. Perf. vs. ^BPHRM - Relative Performance vs. Revere Biopharm Index,

April 2007

Data as of 01/30/2007

Name	Ticker	Last Price	Market Cap.	30d Avg. Volume	Price To Tang. Book Value	Total Debt to Equity %	Cash & Equiv.+ ST Inv.	1 Year Return %	Rel. Perf. vs. ^BPHRM
GlaxoSmithKline plc (ADR)	GSK	54.60	156,997.599	1,527,085	15.16	60.09	6,631.6	6.66%	0.58%
Hana Biosciences, Inc.	HNAB	5.32	154.402	207,925	4.20	0	39.9	-14.88%	-20.96%
Insite Vision Inc.	ISV	1.71	158.870	194,570	n/a	0	3.7	7.07%	0.99%
Ligand Pharmaceuticals Inc.	LGND	12.90	1,022.062	971,174	n/a	0	31.9	7.32%	1.24%
Neurochem Inc. (USA)	NRMX	16.74	647.867	730,605	570.95	0	23.5	13.11%	7.02%
Novadel Pharma Inc	NVD	1.66	81.949	243,111	10.19	3	9.2	28.68%	22.60%
Questcor Pharmaceuticals	QSC	1.54	88.143	78,543	10.36	0	9.3	65.59%	59.51%
sanofi-aventis (ADR)	SNY	44.44	120,023.458	1,269,742	n/a	n/a	n/a	-1.59%	-7.68%
Wyeth	WYE	49.36	66,473.062	5,990,800	6.32	62.4	8,166.9	5.18%	-0.91%

Definitions: Market Cap. - Market Capitalization, Price To Tang. Book Value - Price to Tangible Book Value, Cash & Equiv.+ ST Inv. - Cash and Equivalents + Short-Term Investments, Rel. Perf. vs. ^BPHRM - Relative Performance vs. Revere Biopharm Index,