

Pipeline Report

Fourth Quarter 2011

**FUTURE
SCRIPTS**
A Catalyst Rx Company



The purpose of *The FutureScripts Pipeline Report* is to provide a brief summary of new and generic drugs projected to become available in the near future. This report only includes select drugs that are expected to significantly impact plan sponsors.

Disclaimer: The information contained herein is compiled from various sources and is provided for informational purposes only. Due to factors beyond the control of FutureScripts, information related to prospective drug launch dates is subject to change without notice. Please consult with your account manager to understand more about how these changes can affect your drug trend. This information should not be solely relied upon for decision-making purposes.

GENERICS

Key Generics in the Pipeline, 2012

Brand Drug Name	Generic Drug Name	Brand Manufacturer	Indication/Use	Estimated Launch Date*	Estimated Plan Drug Spend Impact*
Anzemet	dolasetron	Sanofi-Aventis	Antiemetics	Jan. 2012	Low
Avapro	irbesartan	Bristol-Myers Squibb, Sanofi-Aventis	High Blood Pressure	March 2012	Moderate
Avalide	irbesartan/ hydrochlorothiazide	Bristol-Myers Squibb, Sanofi-Aventis	High Blood Pressure	March 2012	Moderate
Gabitril	tiagabine	Cephalon	Anticonvulsant	March 2012	Low
Lexapro	escitalopram	Forest Labs	Antidepressant	March 2012	Moderate
Seroquel	quetiapine	AstraZeneca	Schizophrenia	March 2012	Moderate
Avandamet	rosiglitazone/ metformin	GlaxoSmithKline	Diabetes	April 2012	Moderate
Avandia	rosiglitazone	GlaxoSmithKline	Diabetes	April 2012	Moderate
Avandaryl	rosiglitazone/ glimeperide	GlaxoSmithKline	Diabetes	April 2012	Moderate
Provigil	modafinil	Cephalon	Attention Deficit Hyperactivity Disorder/ Anti-Narcolepsy/ Anti-Obesity/Anorexiant	April 2012	Moderate
Plavix	clopidogrel	Bristol-Myers Squibb, Sanofi-Aventis	Hematological Agents	May 2012	Moderate
Clarinex	desloratadine	Merck	Allergies	July 2012	Low
Clarinex-D	desloratadine/ pseudoephedrine	Merck	Allergies and Nasal Congestion	July 2012	Low
Lunesta	eszopiclone	Sepracor	Insomnia	July 2012	Moderate
Femcon FE	norethindrone/ ethinyl estradiol	Warner Chilcott	Prevention of Pregnancy	July 2012	Low

*Note – Projected launch dates and estimated drug spend impacts are subject to change based on the results of ongoing clinical trials, FDA approvals, timing of approvals, manufacturer decisions and any possible litigation.

Key Generics in the Pipeline - Continued Next Page

GENERICS

Key Generics in the Pipeline, 2012 (cont.)

Brand Drug Name	Generic Drug Name	Brand Manufacturer	Indication/Use	Estimated Launch Date*	Estimated Plan Drug Spend Impact*
Singulair	montelukast	Merck	Asthma, Allergies	August 2012	High
Actos	pioglitazone	Takeda	Diabetes	August 2012	High
Detrol	tolterodine	Pfizer	Urinary Incontinence	Sept. 2012	Low
Diovan	valsartan	Novartis	Hypertension	Sept. 2012	High
Diovan HCT	valsartan/ hydrochlorothiazide	Novartis	Hypertension	Sept. 2012	High
Geodon	ziprasidone	Pfizer	Schizophrenia	Sept. 2012	Low
Viagra	sildenafil	Pfizer	Erectile Dysfunction	Oct. 2012	Low
Lidoderm	lidocaine	Endo	Dermatologicals	Nov. 2012	Low
Viramune	nevirapine	Boehringer Ingelheim	Antiviral/HIV	Nov. 2012	Low
Atacand	candesartan	AstraZeneca	High Blood Pressure	Dec. 2012	Moderate
Atacand HCT	candesartan/HCTZ	AstraZeneca	High Blood Pressure	Dec. 2012	Moderate
Lescol	fluvastatin	Novartis	High Cholesterol	Dec. 2012	Low
Lescol XL	fluvastatin	Novartis	High Cholesterol	Dec. 2012	Low

*Note – Projected launch dates and estimated drug spend impacts are subject to change based on the results of ongoing clinical trials, FDA approvals, timing of approvals, manufacturer decisions and any possible litigation.

Sources:

- FDA Electronic Orange Book. Available at <http://www.fda.gov/cder/ob/default.htm>. Accessed December 10, 2011.
- Drugs@FDA. Available at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>. Accessed December 10, 2011.

BRANDS

Key Brand Products in the Pipeline, 2012

Drug	Manufacturer	Indication/Use	Estimated Launch Date*	Estimated Drug Spend Impact*
Brinavess (vernakalant hydrochloride) ¹	Cardiome Pharma, Astellas, Merck	Atrial Fibrillation (AF)	4Q2012	Moderate
Lyxumia (lixisenatide) ²	Sanofi-Aventis, Zealand	Diabetes	4Q2012	Moderate
Tectin (tetrodotoxin) ³	Wex Pharmaceuticals Inc.	Neuropathic & Cancer Pain	4Q2012	Low
Vaginorm (dehydroepiandrosterone) ⁴	Bayer, EndoCeutics	Vaginal Atrophy, Female Sexual Dysfunction	4Q2012	Low

*Note – Projected launch dates and estimated drug spend impacts are subject to change based on the results of ongoing clinical trials, FDA approvals, timing of approvals, manufacturer decisions and any possible litigation.

Comments:

- ¹ Brinavess selectively blocks ion channels in the heart known to be active during episodes of AF. Previously known as MSD and Kynapid.
- ² Lyxumia is a GLP-1 agonist. Previously known as AVE0010.
- ³ Tectin is a selective-sodium channel blocker in studies for neuropathic and cancer pain. Previously known as TTX.
- ⁴ Topical adrenal steroid in studies for vaginal atrophy and female sexual dysfunction. Also known as DHEA.

Sources:

- Drugs.com. New Drug Application Submissions. Available at <http://www.drugs.com/new-drug-applications.htm>. Accessed December 10, 2011.
- Drug Management Forum. Available at <http://www.drugmanagementforum.com/forum/managed-care-drug-coverage/>. Accessed December 10, 2011.
- Drug Pipeline Forecast. Available at <http://www.drugpipelineforecast.com/pipeline/search/>. Accessed December 10, 2011.

BRANDS

Key Brand Product Detail

Brinavess (vernakalant hydrochloride) – Cardiome Pharma, Astellas, Merck

Indication: Atrial Fibrillation (AF)

Route of Administration: Intravenous, Oral

Current Status: The manufacturers received a U.S. Food and Drug Administration (FDA) approved letter on August 11, 2008. An additional confirmatory Phase III trial is in progress.

Description: Brinavess is an investigational drug being evaluated for the acute conversion of AF. The drug selectively blocks ion channels in the heart that are known to be active during episodes of AF.

Comments: In initial Phase III trials, Brinavess was shown to be superior to amiodarone injection, in converting a patients' heart rate from AF to sinus rhythm (SR) within 90 minutes of the start of administration.

Lyxumia (lixisenatide) – Sanofi-Aventis, Zealand

Indication: Type 2 Diabetes

Route of Administration: Subcutaneous

Current Status: The Phase III study achieved its primary endpoint of non-inferiority in HbA1c reduction from baseline, compared with exenatide twice-daily in February 2011. Additionally, the drug improved glycemic control from baseline versus placebo and led to a significant decrease in body weight.

Description: Lyxumia is a GLP-1 agonist and is dosed once daily.

Comments: There are two glucagon-like peptide-1 (GLP-1) receptor agonists currently available: Byetta (exenatide), which is dosed twice daily; and Victoza (liraglutide), which is dosed once daily. Unlike these two products, Lyxumia is being studied in Phase III trials as monotherapy and in combination with basal insulin.

Tectin (tetrodotoxin) – Wex Pharmaceuticals Inc.

Indication(s): Neuropathic & Cancer Pain

Route of Administration: Subcutaneous

Current Status: Interim Phase III clinical trials data were released in September 2010 indicating that the drug is safe, but that the sample size was not large enough to show efficacy. The manufacturer is currently recruiting for additional studies.

Description: Tectin is a selective-sodium channel blocker. Results from animal pharmacology studies found the drug to be more potent than standard analgesic agents such as aspirin, meperidine or morphine.

Comments: The current Phase III study (TEC-006OL) is designed to provide the option for all patients who participated in the TEC-006 study (both Tectin and placebo-treated) to receive or continue to receive Tectin treatment.

Vaginorm (dehydroepiandrosterone) – Bayer, EndoCeutics

Indication(s): Vaginal Atrophy, Female Sexual Dysfunction

Route of Administration: Topical

Current Status: The Phase III trial to demonstrate efficacy in vaginal atrophy began recruiting in October 2010.

Description: Vaginorm is a topical adrenal steroid.

Comments: Oral DHEA agents have been available for years and are classified as dietary supplements.



Key Specialty Products in the Pipeline, 2012

Drug	Manufacturer	Indication/Use	Estimated Launch Date*	Estimated Drug Spend Impact*
Uplyso (taliglucerase alfa) ¹	Protalix, Pfizer	Gaucher's Disease	1Q2012	Moderate
metreleptin ²	Amylin	Diabetes, hypertriglyceridemia in patients with rare forms of lipodystrophy	2Q2012	Low
Revestive (teduglutide) ³	NPS Pharmaceuticals	Small Bowel Sarcoma (SBS), Short-Bowel Syndrome	3Q2012	Low
lomitapide ⁴	Aegerion	Dyslipidemia, Familial Chylomicronemia (FC)	4Q2012	Low

***Note** – Projected launch dates and estimated drug spend impacts are subject to change based on the results of ongoing clinical trials, FDA approvals, timing of approvals, manufacturer decisions and any possible litigation.

Comments:

- ¹ Plant cell expressed recombinant glucocerebrosidase. Previously known as prGCD.
- ² Metreleptin is an analog of the human hormone, leptin, a neurohormone secreted by fat cells.
- ³ Revestive is a novel, recombinant analog of human glucagon-like peptide 2.
- ⁴ Oral microsomal triglyceride transfer protein (MTP) inhibitor. Previously known as AEGR-733.

Sources:

- Drugs.com. New Drug Application Submissions. Available at <http://www.drugs.com/new-drug-applications.htm>. Accessed December 10, 2011.
- Drug Management Forum. Available at <http://www.drugmanagementforum.com/forum/managed-care-drug-coverage/>. Accessed December 10, 2011.
- Drug Pipeline Forecast. Available at: <http://www.drugpipelineforecast.com>. Accessed December 10, 2011.



SPECIALTY

Key Specialty Product Detail

***Uplyso (taliglucerase alfa)* – Protalix, Pfizer**

Indication: Gaucher's Disease

Route of Administration: Intravenous

Current Status: Treatment protocol was FDA-approved in July 2009 and given a fast-track and orphan designation in September 2009. Standard review with a Prescription Drug User Fee Act (PDUFA) date of February 25, 2011. Data from a switchover trial from Cerezyme to taliglucerase was submitted in November 2010. A complete response letter was received from the FDA in February 2011. Reply submitted to the complete response letter in August 2011. Reply accepted by the FDA with a PDUFA date of February 1, 2012 was assigned in August 2011.

Description: Uplyso is a proprietary plan cell expressed recombinant form of human Glucocerebrosidase (GCD) which is being developed for Gaucher's disease.

Comments: Data from a switchover trial of 26 adults deemed Uplyso to be safe and effective when switched to this from Cerezyme, the current standard for Gaucher's disease.

***metreleptin* – Amylin**

Indication(s): Diabetes, hypertriglyceridemia in patients with rare forms of lipodystrophy

Route of Administration: Subcutaneous

Current Status: Amylin submitted initial sections of a rolling Biologics License Application (BLA) in December 2010 with expected completion in 2011. In April 2011, metreleptin received both orphan drug designation and fast-track designation from the FDA for use in patients with lipodystrophy.

Description: Metreleptin is an analog of the human hormone, leptin. Leptin is a neurohormone secreted by fat cells that play a fundamental role in the regulation of energy homeostasis, fat and glucose metabolism and body weight. Therapy can have significant effects on improving insulin sensitivity, high triglycerides, hyperglycemia and liver fat in patients with lipodystrophy who are not responsive to conventional lipid and glucose-lowering agents.

Comments: If approved, metreleptin will be the first therapy specifically indicated for the treatment of diabetes and high triglycerides in patients with lipodystrophy.

***Revestive (teduglutide)* – NPS Pharmaceuticals**

Indication(s): Small Bowel Sarcoma (SBS), Short-Bowel Syndrome

Route of Administration: Subcutaneous

Current Status: Positive Phase III data reported in June 2009 for SBS. Orphan drug designation granted by the FDA in March 2011. A portion of the New Drug Application (NDA) submitted in August 2011 is expected for approval in the third quarter of 2012.

Description: Revestive (formerly known as GATTEX) is a novel, recombinant analog of human glucagon-like peptide 2, a protein involved in the rehabilitation of the intestinal lining. Studies have shown Revestive was well tolerated and effectively reduced parenteral nutrition and intravenous fluid volume requirements for patients with short bowel syndrome.

Comments: Revestive has received orphan drug status for the treatment of SBS from the FDA and the European Medicines Agency.

***lomitapide* - Aegerion**

Indication(s): Dyslipidemia, Familial Chylomicronemia (FC)

Route of Administration: Oral

Current Status: Pivotal Phase III data showed significant lowering of low-density lipoprotein (LDL) in 2009. Orphan drug designation was granted in March 2011 for the treatment of FC.

Description: Lomitapide is a small molecule microsomal triglyceride transfer protein inhibitor being developed as an oral, once daily treatment for FC. Lomitapide received positive data from a Phase III trial for treatment of FC, a rare genetic type of extremely high cholesterol.

Comments: Expected cost is between \$100,000 to \$300,000/year. Approximately 3,000 Americans have FC and may potentially need to use lomitapide for treatment, with an additional approximate 3,000 in the European nations where it is also up for approval. FC usually kills patients by the age of 30 due to strokes and heart attacks.

