

# AU InforMed

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## Key Inforbits

- New drugs approved by the FDA in 2011
- New FDA-Approved Dosage Forms in 2011
- New Biologicals approved in 2011
- ‘The Last Dose’

## 2011 New FDA Drug Approvals:

Drug	Manufacturer	Mechanism	Indications	Other Information
<b>Arcapta Neohaler</b> (indacaterol)	Novartis	Long-acting $\beta_2$ agonist (LABA)	COPD	Black Box Warning (BBW) for asthma-related deaths, like other LABAs.
<b>Brilinta</b> (ticagrelor)	AstraZeneca	Reversible P2Y <sub>12</sub> antagonist	Secondary prevention of thrombotic events	BBW that maintenance doses of aspirin > 100 mg/day decreases efficacy.
<b>Caprelsa</b> (vandetanib)	AstraZeneca	Multikinase inhibitor	Medullary thyroid cancer	Routine use of antidiarrheal agents is recommended with this agent.
<b>Daliresp</b> (roflumilast)	Forest	PDE-IV inhibitor	COPD	Weight loss within 6 months and diarrhea within 4 weeks are major ADRs.
<b>DaTscan</b> (ioflupane I 123)	GE Healthcare	Binds reversibly to the dopamine transporter	Brain diagnostic imaging	Adjunct in the differential diagnosis of essential tremor from Parkinsonian syndromes.
<b>Dificid</b> (fidaxomicin)	Optimer Pharm.	Bactericidal macrolide antibiotic	<i>C. difficile</i> associated diarrhea	Clinical trials found fidaxomicin non-inferior to vancomycin for <i>C. difficile</i> .
<b>Edarbi</b> (azilsartan)	Takeda	Angiotensin-II Receptor Blocker	Hypertension	BBW against use in pregnancy, same as other ARBs.
<b>Edurant</b> (rilpivirine)	Tibotec	Non-nucleoside Reverse Transcriptase Inhibitor	HIV	Must be taken with a 400-calorie meal for best absorption.
<b>Ferriprox</b> (deferiprone)	ApoPharma	Oral iron chelating agent	Iron overload	BBW for agranulocytosis; monitor absolute neutrophil count.
<b>Firazyr</b> (icatibant)	Shire Human Genetic Therapies	Selective Bradykinin B <sub>2</sub> Receptor Antagonist	Hereditary angioedema	Administered as subcutaneous injection; Decreases efficacy of ACEIs.
<b>Gadavist</b> (gadobutrol)	Bayer	Gadolinium-containing contrast agent	Diagnostic Imaging	BBW for increased risk of nephrogenic systemic fibrosis.
<b>Horizant</b> (gabapentin enacarbil)	GSK	Prodrug of gabapentin	Restless Leg Syndrome	Once daily dosing; recommended with food at 5:00 p.m.
<b>Incivek</b> (telaprevir)	Vertex Pharm.	Serine protease inhibitor	Chronic Hepatitis C	Substrate and strong inhibitor of CYP3A4.
<b>Jakafi</b> (ruxolitinib)	Incyte	Kinase inhibitor	Myelofibrosis	Dose adjustments made based upon degree of thrombocytopenia.

Drug	Manufacturer	Mechanism	Indications	Other Information
<b>Natroba</b> (spinosad)	ParaPRO/Pernix	Pediculocidal and ovicidal	Head lice	Topical shampoo approved for children $\geq 6$ months.
<b>Onfi</b> (clobazam)	Lundbeck	Benzodiazepine	Lennox-Gastaut & Epilepsy (adjunct)	Weight-based dosing for LGS and pediatric epilepsy.
<b>Potiga</b> (ezogabine)	GSK	Neuronal K <sup>+</sup> channel opener	Partial-onset seizures (adjunct)	CNS ADRs of dizziness, somnolence, and fatigue are common.
<b>Tradjenta</b> (linagliptin)	Boehringer Ingelheim	DPP-4 Inhibitor	T2DM	Same MOA as Januvia and Onglyza.
<b>Victrelis</b> (boceprevir)	Merck	Protease Inhibitor	Chronic Hepatitis C	Substrate and strong inhibitor of CYP3A4.
<b>Viibryd</b> (vilazodone)	Trovis	SSRI and 5HT <sub>1A</sub> partial agonist	Depression	Decreased incidence of sexual dysfunction vs. other SSRIs in trials.
<b>Xalkori</b> (crizotinib)	Pfizer	Tyrosine kinase receptor inhibitor	Non-small cell lung cancer	Monitor for hematologic toxicity, LFT elevation $>5X$ ULN, QT prolongation.
<b>Xarelto</b> (rivaroxaban)	Janssen	Factor Xa Inhibitor	Atrial fibrillation & post-op thromboprophylaxis	BBW for increased stroke risk after d/c of therapy and for hematoma occurrence with neuraxial anesthesia.
<b>Zelboraf</b> (vemurafenib)	Genentech	BRAF Kinase Inhibitor	Advanced Melanoma	Used in patients with unresectable or metastatic melanoma with a BRAF <sup>V600E</sup> mutation.
<b>Zytiga</b> (abiraterone)	Centocor Ortho Biotech	Irreversible CYP17 inhibitor	Advanced Prostate Cancer	Adjust dose based upon degree of hepatotoxicity after initiation.

## New Formulations:

- In 2011, several new dosage forms and combination products of previously approved drugs were also introduced. A few highlights from the new preparations list include:

Drug	Dosage Form	Manufacturer	Indication
<b>Abstral</b> (fentanyl)	Sublingual tablet	ProStrakan	Breakthrough pain in opioid-tolerant cancer patients.
<b>AndroGel</b> (testosterone)	1.62% Topical Gel	Abbott	Increased strength, therapy for hypogonadism.
<b>Complera</b> (emtricitabine/rilpivirine/tenofovir)	Tablet	Gilead Sciences	Once daily, three-drug therapy for treatment-naïve HIV infection.
<b>Forfivo XL</b> (bupropion)	450 mg tablet	Intelgenx Corp.	Increased strength, extended-release therapy for depression.
<b>Juvisync</b> (sitagliptin/simvastatin)	Tablet	Merck	Combination tablet for type 2 diabetics with concomitant dyslipidemia.
<b>Oxecta</b> (oxycodone)	Tablet	King Pharmaceuticals	Immediate-release tablet formulated to reduce abuse potential.
<b>Zutripro</b> (hydrocodone/chlorpheniramine/pseudoephedrine)	Suspension	Cypress Pharmaceuticals	Combination antitussive, antihistamine, and decongestant for relief of allergy and cold symptoms.

# New Biologicals:

Name	Manufacturer	Mechanism	Indications	Other Information
<b>Adcetris</b> (brentuximab vedotin)	Seattle Genetics	Antibody drug conjugate directed at CD30	Hodgkin's Lymphoma and systemic anaplastic large cell lymphoma after prior treatment failure	BBW for increased incidence of Progressive multifocal encephalopathy.
<b>Anascorp</b> (centruroides F(ab)2)	Rare Disease Therapeutics	Venom-specific F(ab)2 fragments of IgG that neutralize venom toxins	Antivenom for scorpion stings	Given IV over ten minutes as soon after scorpion sting as possible.
<b>Benlysta</b> (belimumab)	Human Genome Sciences/GSK	B-lymphocyte stimulator-specific inhibitor	Systemic lupus erythematosus	Adjunct to standard SLE therapy in autoantibody-positive SLE.
<b>Corifact</b> (factor XIII)	CSL Behring	Endogenous plasma glycoprotein that is converted to factor XIIIa in the presence of Ca <sup>+2</sup>	Congenital factor XIII deficiency	Dose is adjusted based on factor XIII trough levels which are tested every 4 weeks.
<b>Erwinaze</b> (asparaginase <i>Erwinia chrysanthemi</i> )	EUSA Pharma	Antineoplastic agent that reduces levels of asparagine	Acute Lymphoblastic Leukemia in patients with hypersensitivity to <i>E.coli</i> -derived asparaginase	Hypersensitivity reactions occur in >10% of patients.
<b>Eylea</b> (aflibercept)	Regeneron Pharm.	Vascular endothelial growth factor inhibitor	Neovascular age-related macular degeneration	For intravitreal injection only; associated with endophthalmitis and retinal detachment.
<b>Fluzone Intradermal</b> (influenza vaccine)	Sanofi Pasteur	Induces specific antibody production versus influenza	Active immunity to vaccine-containing strains of influenza virus	Alternative to IM influenza vaccination in 18-64 yo.
<b>Nulojix</b> (belatacept)	BMS	Selective T-Cell Costimulation Blocker	Prophylaxis of organ rejection in kidney transplant recipients	Used concomitantly with basiliximab, mycophenolate, and corticosteroids in Epstein-Barr Virus seropositive patients.
<b>Yervoy</b> (ipilimumab)	BMS	Cytotoxic T-lymphocyte antigen-4 blocking antibody	Unresectable or metastatic melanoma	Can cause severe immune-mediated ADRs including dermatologic, endocrine, GI, hepatic, and ophthalmic toxicities.

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## The last “dose” ...

*“Lost wealth may be replaced by industry, lost knowledge by study, lost health by temperance or medicine; but lost time is gone forever.”*



*-Samuel Smiles, Scottish author and reformer (1812-1904)*



*“Ah, summer, what power you have to make us suffer and like it.”*

*~Russell Baker (American writer, 1925 - )*

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