

HORIZON LINES

A Quarterly Review of NDAs

January 1, 2014 to March 31, 2014

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Receiving an approval for a New Drug Application (NDA) is something special for every pharmaceutical company. NDAs can be obtained for new molecules or for existing drug molecules with a new formulation or for a new indication. In this column, we will be summarizing NDAs for a particular quarter. In this particular column, we have put together a review of NDAs receiving approval from January 2014 to March 2014. The accompanied table lists key information on the NDAs approved. FDA awarded 25 NDAs in 1Q14, out of which 9 were for new molecules and 16 were for old molecules (36% new versus 64% old but with new indication or dosage form). Many companies are investing time and energy on large molecules. In this quarter, 20% of large molecules received NDA approval (5 out of 25). Ten drug molecules were granted the Orphan Drug status (40%).

While there has been an increased discussion on combination drug therapy, this quarter saw only 12% of NDAs (3 out of 25) with a combination dosage form granted approval. Most of the dosage forms contained single drug entity (88%). Almost all were prescription drug products (except for Aleve PM). Most of the NDAs approved were for mid- to large-size pharmaceutical companies. Bristol-Myers Squibb purchased Amylin Pharmaceuticals and thus, received 4 NDAs in 1 quarter. Tablets and capsules are still the preferred dosage forms. Nearly one-third of all the approved NDAs were injections. Companies focused on the following main indications: pain, diabetes, cancer, cardiovascular disorders, and infections. The prices for most of the products were obtained from internet research. The pricing structure of pharmaceutical products is complicated and these prices should be considered with caution. Some prices were not available.

Some additional observations of note: For 2 NDAs, 2 companies applied jointly (Eliquis and Nexium). We have to see if this becomes a trend in the future. Six NDAs each were observed in January and February, whereas in March, 13 NDAs were approved. No particular trend was observed in the selection of the trade names and in the first letter in the trade name. The trade names were 5 to 9 letters long.

Approval date (2014)	Trade Name	Drug Name	Dosage Form	Company	Indication	Price
January 8	Farxiga	Dapagliflozin	Tablet	Bristol-Myers Squibb	Type 2 diabetes	~\$12/tablet (5mg)
January 9	Mekenist & tafinlar	Trametinib & dabrafenib	Tablet	GlaxoSmithKline	Melanoma	-
January 16	Aleve PM	Diphenhydramine HCl & naproxen Na	Caplet	Bayer Healthcare	Pain, Insomnia	~\$5/20 tablets
January 29	Copaxone	Glatiramer Acetate	Injection	Teva Pharmaceuticals	Multiple sclerosis	~\$6000/30 syringes
January 31	Hetlioz	Tasimelteon	Capsule	Vanda Pharmaceuticals	Non 24 hr disorder	\$7300/30 capsules (20mg)
January 31	Retin	Tretinoin	Cream, Gel	Valeant Pharmaceuticals	Acne vulgaris	~\$245/45g tube
February 12	Imbruvica	Ibrutinib	Capsule	Janssen Research and Development	Approved use for chronic lymphocytic leukemia	~\$9000/90 capsules (140mg)
February 14	Vimizim	Elosufase alfa	Infusion	Biomarin Pharmaceutical Inc.	Mucopolysaccharidosis Type IVA	~\$1068/vial
February 18	Northera	Droxidopa	Capsules	Lund beck NA Ltd	Neurogenic orthostatic hypotension	~\$500/30 capsules (100mg)
February 24	Myalept	Metreleptin	Injection	Amylin Pharmaceuticals Inc.	Lipodystrophy	-
February 24	Tivorbex	Indomethacin	Capsules	Iroko Pharmaceuticals	Pain-dosage strength 20% lower than current products c	-
February 24	Monovisc	Sodium hyaluronate	Injection	Anika Therapeutics, Inc.	Osteoarthritis	~\$5000/4ml injection
March 3	Bydureon	Exenatide	Injection pen	Amylin Pharmaceuticals and Alkermes plc	Diabetes type 2-once weekly treatment	~\$460
March 5	Aveed	Testosterone undecanoate	Depot injection	Endo pharmaceuticals	Male hypogonadism	~\$900/vial
March 11	Xartemis XR	Acetaminophen and oxycodone hydrochloride	Extended-release tablets	Mallinckrodt	Management of moderate to severe acute pain	~\$300/120 tablets
March 11	Qudexy XR	Topiramate	Extended release capsules	Upsher-Smith Laboratories, Inc.	Tonic-clonic seizures, and Lennox-Gastaut Syndrome	~\$150/30 capsules
March 14	Noxafil	Posaconazole	Delayed release tablet, oral suspension	Schering-Plough Corporation	Fungal infection	~\$285/5 tablets (100mg)
March 14	Hemangeol	Propranolol hydrochloride	Oral solution	Pierre Fabre Dermatologie	Infantile Hemangioma	\$400/120ml
March 18	Eliquis	Apixaban	Tablet	Bristol-Myers Squibb and Pfizer Inc.	To reduce the risk of stroke and systemic embolism	~\$925/180 tablets (5mg)
March 19	Impavido	Miltefosine	Oral capsule	Paladin Labs Inc.	Leishmaniasis	Not yet available at pharmacy stores
March 19	Neuraceq	Florbetaben F18	Injection	Piramal Imaging	Positron Emission Tomography Imaging	-
March 21	Otezla	Apremilast	Tablet, injection	Celgene Corporation	Psoriatic arthritis	~\$2000/60 tablets
March 28	Alprolix	Coagulation Factor IX	Injection	Biogen Idec, Inc.	Hemophilia B	\$2.85/Int.Unit
March 28	Topamax	Topiramate	Tablet, capsule	Janssen Pharmaceuticals Inc.	Migraine headaches in age group 12-17	~\$250/60 tablets
March 31	Nexium	Esomeprazole	Capsule	Pfizer and Astra-Zeneca	Gastroesophageal reflux disease	~\$500/60 capsules