### Brand Products Recently Approved

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Manufacturer</th>
<th>FDA Approval Date</th>
<th>Therapeutic Use</th>
<th>Potential Impact</th>
<th>UM Program Available*</th>
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<td>Namzaric (donepezil/memantine extended-release)</td>
<td>Forest</td>
<td>December 23, 2014</td>
<td>Alzheimer’s disease</td>
<td>Low</td>
<td>QL</td>
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<tr>
<td>Saxenda (liraglutide)</td>
<td>Novo Nordisk</td>
<td>December 23, 2014</td>
<td>Obesity</td>
<td>Low</td>
<td>PA</td>
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<tr>
<td>Savaysa (edoxaban)</td>
<td>Daiichi Sankyo</td>
<td>January 8, 2015</td>
<td>Blood clots</td>
<td>Low</td>
<td>QL</td>
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<td>Glyxambi (empagliflozin/linagliptin)</td>
<td>Boehringer Ingelheim</td>
<td>January 30, 2015</td>
<td>Diabetes</td>
<td>Low</td>
<td>QL</td>
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<td>Toujeo (insulin glargine)</td>
<td>Sanofi</td>
<td>February 25, 2015</td>
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<td>Low</td>
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<td>Corlanor (ivabradine)</td>
<td>Amgen</td>
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<tr>
<td>Viberzi (eluxadoline)</td>
<td>Actavis</td>
<td>May 27, 2015</td>
<td>Irritable bowel syndrome</td>
<td>Low</td>
<td>QL, PA</td>
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</table>

*UM: Utilization Management
QL: Quantity limit designed to encourage appropriate drug use and contain drug cost
PA: Prior authorization designed to ensure appropriate use of potentially expensive, limited use or inappropriately utilized drugs
ST: Step therapy designed to promote use of safe and cost-effective drugs prior to utilizing more costly drug therapy

**Namzaric** (donepezil/memantine extended-release) – Forest

Namzaric was approved by the U.S. Food and Drug Administration (FDA) on December 23, 2014. It is a fixed-dose combination product of existing medications used to treat Alzheimer’s disease: Aricept® (donepezil) and Namenda XR® (memantine extended-release). Namzaric is dosed once daily and the capsule’s contents may be sprinkled on food for easy administration. Namzaric will compete with other treatment options for Alzheimer’s disease, including Razadyne ER® (galantamine extended-release), Aricept (donepezil), Exelon® (rivastigmine) and Namenda (memantine), which are all available as generic agents.

**Saxenda** (liraglutide) – Novo Nordisk

Saxenda is a new formulation of an already existing product, Victoza® (liraglutide). It is a GLP-1 agonist used for the treatment of type 2 diabetes. Although Saxenda and Victoza contain the same active ingredient, dosing is different (3mg and 1.8mg). It is indicated for use in combination with diet and exercise for chronic weight management in obese or overweight adults in the presence of at least one weight-related condition (e.g., diabetes or heart disease). Clinical trials have shown that a larger proportion of non-diabetic patients who were prescribed high-dose liraglutide experienced and maintained at least a 5% decrease in body weight from baseline after 56 weeks. Also, about one-third of patients lost more than 10% of their weight compared to about 10% of those on placebo.
**Savaysa™ (edoxaban) – Daiichi Sankyo**
Edoxaban is an oral direct factor Xa inhibitor similar to Xarelto® (rivaroxaban), Pradaxa® (dabigatran), Eliquis® (apixaban), and warfarin. It is approved for the treatment of blood clots and stroke prevention in patients with atrial fibrillation, an irregular heart rhythm. Compared with warfarin, which is considered the standard of care, the direct factor Xa inhibitors are administered as a fixed dose, do not require continuous monitoring, and do not have dietary interactions. To date, there are no head-to-head clinical trials comparing edoxaban to other factor Xa inhibitors.

**Glyxambi® (empagliflozin/linagliptin) – Boehringer Ingelheim**
Glyxambi is a combination product containing Jardiance® (empagliflozin), a sodium-glucose co-transporter 2 (SGLT2) inhibitor and Tradjenta® (linagliptin), a dipeptidyl peptidase-4 (DPP-IV) inhibitor. Empagliflozin inhibits the reabsorption of blood sugar in the kidneys, forcing more sugar to be lost in the urine. Linagliptin increases insulin production and reduces blood sugar production to improve blood sugar levels. Glyxambi is indicated for the treatment of type 2 diabetes in combination with diet and exercise. SGLT2 and DPP-IV inhibitors are considered third-line treatment options and are reserved for patients who are unable to achieve lowered blood sugar levels despite treatment.

**Toujeo® (insulin glargine) – Sanofi**
Toujeo is a new formulation of an existing insulin product, Lantus® (insulin glargine). Toujeo provides a longer duration of action than Lantus – up to 40 hours versus 22 hours. Clinical trials demonstrate that Toujeo is just as effective at lowering blood sugar compared to Lantus, whether added to a meal-time insulin regimen or oral antidiabetic drugs, and results in significantly less nighttime low blood sugar. At this time, it appears that Toujeo is an alternative to Lantus in the treatment of diabetic adults. Its place in therapy will continue to evolve with more real-time experience, guideline placement, and additional drug study data.

**Corlanor® (ivabradine) – Amgen**
Ivabradine is an oral agent that lowers heart rate. Corlanor will treat symptoms of long-term stable angina (pains to the chest, jaw, and back, brought on by physical effort) and congestive heart failure (disease of the heart caused by the obstruction of the blood vessels that supply blood to the heart muscle). Heart failure is a condition affecting 26 million people worldwide and 5.1 million people in the U.S. Corlanor will be used in patients who cannot be treated with beta-blockers or in combination with those patients taking a beta-blocker whose disease is not well controlled, with a heart rate above 60 beats per minute. Results from clinical trials indicated a 25% reduction in the risk of death and hospitalization due to heart failure with those patients on Corlanor.

**Viberzi® (eluxadoline) – Actavis**
Eluxadoline is a first-in-class medication for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). Opioid receptors, which include mu, delta, and kappa, play a key role in the gastrointestinal tract. Eluxadoline works via two opioid receptor types – mu-opioid receptor agonists and delta opioid receptor antagonists. The dual opioid activity is designed to not only treat the symptoms of IBS-D but also to decrease the occurrence of constipation. Eluxadoline will compete with Lotronex® (alosetron), as well as the generically available antispasmodics loperamide, diphenoxylate/atropine, and dicyclomine.
## Brand Products in the Pipeline: 2015

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Manufacturer</th>
<th>Estimated Launch Date</th>
<th>Therapeutic Use</th>
<th>Potential Impact</th>
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<td><strong>Semprana</strong> (dihydroergotamine)</td>
<td>Allergan and MAP</td>
<td>3Q 2015</td>
<td>Migraines</td>
<td>Low</td>
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<td><strong>TBD</strong> (brexpiprazole)</td>
<td>Otsuka</td>
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<td><strong>TBD</strong> (sacubitril/valsartan)</td>
<td>Novartis</td>
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<td><strong>Seebri Breezhaler</strong> (glycopyrronium)</td>
<td>Novartis</td>
<td>4Q 2015</td>
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<td>Low</td>
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<tr>
<td><strong>Tresiba</strong> (insulin degludec)</td>
<td>Novo Nordisk</td>
<td>4Q 2015</td>
<td>Diabetes</td>
<td>Low</td>
</tr>
</tbody>
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*Estimated launch dates are subject to change due to legal proceedings, exclusivity, timing of FDA approvals, additional patents, etc.*

**Semprana™ (dihydroergotamine) – Allergan and MAP**

Semprana is an orally inhaled formulation of an existing product, dihydroergotamine (D.H.E 45 injection and Migranal® nasal spray), used for the management of migraines. The inhaled formulation is intended to offer a fast onset of action, similar to an intravenous infusion, but without the need for an injection. In a clinical trial, Semprana provided pain relief from migraines within 30 minutes. While not significant, approximately 50 percent more of patients receiving Semprana than those receiving a placebo reported migraine pain relief at 10 minutes as well as for up to 48 hours. Treatment with Semprana was well tolerated, with no serious adverse events reported. Clinical studies directly comparing migraine treatment options are lacking. On June 30, 2014, Allergan announced that they received a third complete response letter from the FDA declining approval of their investigational migraine drug, previously known as Levadex, noting concerns with the manufacturing process. Allergan is addressing the FDA’s manufacturing concerns and anticipates an action date in the third quarter 2015.

**Brand Name to be Determined (brexpiprazole) – Otsuka**

Brexpiprazole is an investigational second-generation antipsychotic agent being studied for the treatment of schizophrenia and as adjunctive treatment for major depressive disorder. It is structurally similar to Abilify® (aripiprazole), a widely used antipsychotic agent, and will compete with other second-generation antipsychotics, such as Risperdal® (risperidone), Zyprexa® (olanzapine), Seroquel® (quetiapine), Invega® (paliperidone), Geodon® (ziprasidone), Saphris® (asenapine), Fanapt® (iloperidone), Latuda® (lurasidone) and Abilify® (aripiprazole). Clinical trials have not been conducted to demonstrate superiority over other available treatment options (listed above), many of which are available generically (e.g., aripiprazole, olanzapine, risperidone, quetiapine, and ziprasidone). If approved, use will likely be limited until more clinical data is obtained that substantiates superiority over existing products.

**Brand Name to be Determined (sacubitril/valsartan) – Novartis**

Sacubitril/valsartan is a fixed-dose combination product for the treatment of those with both heart failure and hypertension. Heart failure affects almost 6 million people in the U.S., with up to 50% dying within five years after diagnosis. Diovan® (valsartan) is currently used for the treatment of hypertension and heart failure. Sacubitril is a novel therapy, neprilysin inhibitor, a blood pressure-lowering agent that works through a different mechanism. A clinical trial, the largest conducted in heart failure, showed sacubitril/valsartan was superior to Vasotec® (enalapril) in preventing heart-related complications. Novartis submitted a new drug application in 2014 and soon after granted a priority review for its use in heart failure. Approval by the FDA is anticipated the third quarter 2015.
Seebri Breezehaler® (glycopyrytonium) – Novartis
Glycopyrytonium is a long-acting muscarinic antagonist (LAMA), being studied as maintenance therapy to relieve symptoms for patients with chronic obstructive pulmonary disease (COPD). COPD is the fourth leading cause of death in the United States. Drug study data demonstrated that patients on glycopyrytonium experienced better lung function, improved shortness of breath and quality of life compared to placebo. These results were similar to Spiriva® (tiotropium) compared to placebo. Clinical studies that directly compare glycopyrytonium with other LAMAs (e.g., Spiriva, Tudorza® [aclidinium]) are not available. New drug application for the treatment of COPD was submitted to the FDA in the fourth quarter 2014.

Tresiba® (insulin degludec) – Novo Nordisk
Insulin degludec is subcutaneous basal insulin with a duration of action up to 40 hours, extending its half-life significantly longer than other currently available long-acting insulin products on the market: Lantus® (insulin glargine) and Levemir® (insulin detemir). The steady blood levels of insulin may result in lower incidences of hypoglycemia (low blood sugar) in both type 1 and type 2 diabetic patients. Insulin degludec, unlike other long-acting insulins, can be mixed with other insulin products. The FDA action date for insulin degludec was originally scheduled for November 2012; however, concerns regarding potential heart-related risks prolonged the FDA’s review. As a result, Novo Nordisk started the DEVOTE trial to address the FDA’s concerns. In April 2015, the FDA accepted interim analysis of the heart outcomes study as the trial will not be completed until 2017/2018.

References: