### Recent New Drug Application (NDA) Approvals

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosage Form; Strengths</th>
<th>Indication</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oleptro™</td>
<td>Tablet, oral, extended-release; 150 mg and 300 mg</td>
<td>For the treatment of major depressive disorder in adults</td>
<td>February 2, 2010</td>
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<tr>
<td>Labopharm, Inc.</td>
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<tr>
<td>Mirapex® ER™</td>
<td>Tablet, oral, extended-release; 0.375 mg, 0.75 mg, 1.5 mg, 3 mg, and 4.5 mg</td>
<td>For treatment of the signs and symptoms of early Parkinson's disease</td>
<td>February 19, 2010</td>
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<tr>
<td>Boehringer Ingelheim International GmbH</td>
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<tr>
<td>Cayston®</td>
<td>Solution, inhalation; 75 mg</td>
<td>To improve respiratory symptoms in cystic fibrosis patients with <em>Pseudomonas aeruginosa</em></td>
<td>February 22, 2010</td>
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<tr>
<td>Gilead Sciences, Inc.</td>
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### Recent Biologic License Application (BLA) Approvals

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosage Form; Strength</th>
<th>Indication</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xiaflex™ (collagenase clostridium histolyticum)</td>
<td>Injection; 0.9 mg</td>
<td>For the treatment of adult patients with Dupuytren's contracture with a palpable cord</td>
<td>February 2, 2010</td>
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<tr>
<td>Auxilium Pharmaceuticals, Inc.</td>
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<tr>
<td>Menveo® (Meningococcal [Groups A, C, Y, and W-135] Oligosaccharide Diphtheria CRM197 Conjugate Vaccine)</td>
<td>Injection, intramuscular; 0.5 mL dose</td>
<td>For active immunization to prevent invasive meningococcal disease caused by <em>Neisseria meningitidis</em> serogroups A, C, Y, and W-135 in persons 11 to 55 years of age</td>
<td>February 19, 2010</td>
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<tr>
<td>Novartis Vaccines and Diagnostics, Inc.</td>
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<tr>
<td>Prevnar 13™ (Pneumococcal 13-Valent Conjugate Vaccine [Diphtheria CRM197 Protein])</td>
<td>Injection, intramuscular; 0.5 mL single-dose, pre-filled syringe</td>
<td>For the active immunization of children 6 weeks through 5 years of age (prior to the 6th birthday) for the prevention of invasive disease caused by <em>Streptococcus pneumoniae</em> serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F or otitis media caused by <em>Streptococcus pneumoniae</em> serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F</td>
<td>February 24, 2010</td>
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<tr>
<td>Wyeth Pharmaceuticals Inc.</td>
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</tbody>
</table>
### Recent Supplemental New Drug Application (sNDA) Approvals

**Tykerb® (lapatinib)**

- **Dosage Form**: Tablet, oral
- **Indication**: For use in combination with Femara (letrozole) to treat postmenopausal women with hormone receptor-positive metastatic breast cancer that overexpresses the HER2 receptor and for whom hormonal therapy is indicated
- **Approval Date**: January 29, 2010
- **Comments**: This is a new indication for an already approved product. Refer to full Prescribing Information for a complete list of indications.

**Crestor® (rosuvastatin)**

- **Dosage Form**: Tablet, oral
- **Indication**: To reduce the risk of myocardial infarction, stroke, and arterial revascularization procedures in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥ 50 years old in men and ≥ 60 years old in women, hsCRP ≥ 2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease
- **Approval Date**: February 8, 2010
- **Comments**: This is a new indication for an already approved product. Refer to full Prescribing Information for a complete list of indications.

**Lamictal® XR™ (lamotrigine)**

- **Dosage Form**: Tablet, oral, extended-release
- **Indication**: Indicated as adjunctive therapy for primary generalized tonic-clonic seizures and partial onset seizures with or without secondary generalization in patients ≥ 13 years of age
- **Approval Date**: January 29, 2010
- **Comments**: This is a new indication for an already approved product. Refer to full Prescribing Information for a complete list of indications.

**Benicar® (olmesartan medoxomil)**

- **Dosage Form**: Tablet, oral
- **Indication**: For the treatment of hypertension in children and adolescents 6 to 16 years of age
- **Approval Date**: April 1, 2010
- **Comments**: This is a new indication for an already approved product. Refer to full Prescribing Information for a complete list of indications.

**Norvir® (ritonavir)**

- **Dosage Form**: Tablet, oral
- **Indication**: For the treatment of HIV-1 infection in combination with other antiretroviral agents
- **Approval Date**: February 10, 2010
- **Comments**: This is a new indication for an already approved product. Refer to full Prescribing Information for a complete list of indications.

### Recent Supplemental Biologic License Application (sBLA) Approvals

**Rituxan® (rituximab)**

- **Dosage Form**: Infusion, intravenous
- **Indication**: Indicated in combination with fludarabine and cyclophosphamide for treating patients with previously untreated and treated CD20-positive chronic lymphocytic leukemia.
- **Approval Date**: February 18, 2010
- **Comments**: This product will be available through the CVS Caremark Specialty Pharmacy Services Network.

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* Adapted from RxPipeline Services Week In Review. For more information, contact: pipeline@caremark.com
† The Approval Date is established by the FDA but does not necessarily mean a generic product is available as of that date or that such product is available.
‡ A launch date/anticipated launch date may not reflect the actual availability of this medication. Due to circumstances beyond the control of CVS Caremark, information related to prospective medication launch dates is subject to change without notice. This information should not be solely relied upon for decision-making purposes.
New Safety Requirements for Long-Acting Beta-Agonists (LABAs)\textsuperscript{3,4}

On February 18, 2010, the FDA instituted a Risk Evaluation and Mitigation Strategy (REMS) and class-labeling changes for LABAs to facilitate the safe use of these products. Analyses from the Salmeterol Multi-center Asthma Research Trial, the Salmeterol Nationwide Surveillance study, and a meta-analysis conducted by the FDA in 2008 showed LABA use to carry an increased risk of severe exacerbation of asthma symptoms, leading to hospitalization or death in some asthma patients. LABAs are medications that relax muscles in narrowed airways, making it easier for asthma patients to breathe. LABAs do not treat the inflammatory process of asthma, unlike inhaled corticosteroids (ICS), which are the preferred medicines for long-term control of asthma. The FDA will now require LABA product prescribing information to reflect the following:

- Single-ingredient LABAs (Serevent Diskus [salmeterol, GlaxoSmithKline] and Foradil Aerolizer [formoterol, Novartis Pharmaceuticals Corp.]), should be used only in combination with an asthma controller medication; LABAs should not be used alone.

- LABAs should be used long-term only if asthma symptoms cannot be adequately controlled with an asthma controller medication.

- LABAs should be used for the shortest time period required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. Patients should then be maintained on an asthma controller medication.

- Pediatric and adolescent patients who require the addition of a LABA to an ICS should use LABA-ICS combination products (Advair [fluticasone/salmeterol, GlaxoSmithKline] and Symbicort [budesonide/formoterol, AstraZeneca LP]) to ensure compliance.

The agency will require manufacturers of LABAs to conduct further studies to determine if LABA-ICS combination products reduce or eliminate the risk of asthma-related death and hospitalizations.

References: