December 14, 2015

**Alcensa Approved**

Genotech received U.S. Food and Drug Administration (FDA) accelerated approval for Alecensa® (alectinib) for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib (Xalkori® - Pfizer). The recommended dose of Alecensa is 600mg (four capsules) twice daily with food. Genentech plans on launching Alecensa within two weeks. It will be available through a limited network of specialty pharmacies that includes Accredo. Full prescribing information is available at: [www.alecensa.com](http://www.alecensa.com)

**Chewable Methylphenidate Approved**

Pfizer received U.S. Food and Drug Administration (FDA) approval for QuilliChew ER™ (methylphenidate extended release) tablets CII on Dec. 4, 2015. The chewable, cherry-flavored tablets are indicated to treat attention deficit hyperactivity disorder (ADHD) for children who are at least six years old. The recommended starting dose is 20mg once each morning. Dosing can be increased by up to 10mg per week, but doses above 60mg daily are not recommended. QuilliChew ER will be released in the first quarter of 2016 as 20mg, 30mg and 40mg tablets. The 20mg and 30mg tablets are scored so that they can be split easily to adjust dosing. When switching from another methylphenidate product, however; caregivers are advised against trying to match the strength of the previous medication because QuilliChew ER has a different basic structure and different release properties than other marketed methylphenidates. A boxed warning on QuilliChew ER’s labeling cautions that all central nervous system (CNS) stimulants, including methylphenidate, carry risks for abuse and dependence. Pricing has not yet been released. Full prescribing information is at: [www.QuilliChewER.com](http://www.QuilliChewER.com)

**Vistogard Approved for Fluorouracil Toxicity**

Wellstat Therapeutics’ Vistogard® (uridine triacetate) has been approved to treat adults and children who receive an overdose of the cancer treatment fluorouracil, or its prodrug capecitabine. It has also been approved to treat patients who develop certain severe or life-threatening toxicities within four days of receiving these cancer treatments. Vistogard should not be used for treating non-emergency adverse reactions associated with fluorouracil or capecitabine as it may lessen the efficacy of these drugs. Wellstat Therapeutics is planning to make Vistogard available on the U.S. market as soon as possible. Prescribing information will be available on the company’s website at: [www.wellstattherapeutics.com](http://www.wellstattherapeutics.com)
**Otiprio Approved**

FDA approved Otonomy’s Otiprio™ (ciprofloxacin otic suspension, 6%), a physician-administered single-dose treatment for patients with bilateral otitis media (ear infections) with effusions undergoing tympanostomy tube, or ear tube, placement. The recommended dose is a single 0.1mL (6mg) intratympanic (middle ear) administration into each affected ear, following suctioning of the middle ear effusion. Otiprio is a proprietary formulation that is a suspension at room temperature or cooler, but turns into a gel when warmed. It contains ciprofloxacin microparticles that are slowly released after administration. In clinical trials, treatment with Otiprio resulted in fewer treatment failures compared to tube placement alone. While antibiotic ear drops are routinely used after tympanostomy tube placement procedures, the current antibiotic ear drops require multiple doses over several days for efficacy. These products are also not indicated for this use. Otonomy plans to launch Otiprio during the first quarter of 2016. Full prescribing information is at: [www.Otiprio.com](http://www.Otiprio.com)