Evomela Approved
Spectrum Pharmaceuticals was given approval by the U.S. Food and Drug Administration (FDA) for Evomela™ (melphalan) for injection on March 10, 2016. Evomela is indicated to provide palliative care for multiple myeloma patients unable to take oral medication. It also is approved, in high doses, as the first drug for pre-conditioning before a progenitor (stem) cell transplant for multiple myeloma patients. Melphalan, an alkylator which interrupts cell division, was first approved in the United States in 1964 as GlaxoSmithKline’s Alkeran® and is currently available as oral tablet and injectable formulations. However, Evomela is not interchangeable with other injectable melphalan products. All forms of melphalan carry boxed warnings that it may interfere seriously with production of blood cells in bone marrow, possibly resulting in leukemia, infections or excessive bleeding. Approximately 2% of patients receiving injectable melphalan also experience anaphylaxis (severe, potentially life-threatening allergic reactions). As a result, melphalan should be prescribed and supervised only by physicians proficient with using it. Dosage amounts and frequencies differ according to the condition being treated, the patient’s body surface area, and the patient’s ability to tolerate the drug. It will be dispensed in single-use vials that each contain 56mg melphalan equivalent. Unlike Alkeran injection, which needs to be used immediately after it is reconstituted, under specific conditions, Evomela can be kept at room temperature for four to five hours or refrigerated for up to 24 hours without losing effectiveness. No pricing or launch plans have been announced. Full prescribing information is available at http://www.evomela.com.

Generic for Frova
On March 13, 2016, the FDA approved Glenmark Pharmaceuticals’ AB-rated generic to Elan’s Frova® (frovatriptan) 2.5mg tablets, a product used to treat migraine headaches. The recommended dose is one tablet taken at the beginning of migraine pain. If needed, a second tablet may be taken after two hours, with no more than three tablets used in 24 hours. To prevent menstruation-associated migraines, frovatriptan is taken regularly for six days before the period starts. For the 12 months ending on Jan. 31, 2016, Frova sales were approximately $88 million according to IMS Health. Launch and pricing plans are not yet available for the generic.

Generic Azilect Approved (But Not Launched)
Orchid Pharmaceuticals announced on March 17, 2016, that it had received approval from the FDA for rasagiline, the first AB-rated generic for Teva Neuroscience’s Azilect® tablets. For treating Parkinson’s disease, rasagiline is taken once daily either alone or in combination with levodopa, another Parkinson’s medication. Because it blocks the activity of monoamine oxidase-B (MAO-B), an enzyme that breaks down dopamine, rasagiline helps to stabilize blood levels of dopamine. Low dopamine levels may lead to problems with balance, movement, muscle control and other symptoms of Parkinson’s. Orchid, which has a 180-day exclusivity period for rasagiline, plans to introduce it to the U.S. market in the third quarter of 2016. According to Teva’s annual report for 2015, global sales for Azilect were $514 million for the year.
Updated DrugWatch Document Available
The Emerging Therapeutics department has updated DrugWatch, a document that highlights near-term pipeline drugs as well as potential new generic opportunities. Click here for the updated DrugWatch.