Specialty Pipeline **Update**

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**New indications**

- **Humira® (adalimumab):** AbbVie’s Humira was recently approved for adults with non-infectious intermediate, posterior and panuveitis.

- **Xolair® (omalizumab):** Genentech and Novartis’ Xolair is now approved for patients six years and older with uncontrolled moderate to severe persistent allergic asthma. Xolair was previously approved to treat allergic asthma in patients 12 years of age and older.

- **Repatha® (evolocumab):** Amgen’s Repatha is now approved with a new device that provides the 420 mg monthly dose as a single injection. Previously, the 420 mg, once-monthly dosing regimen required three injections. Repatha is approved for treatment of high low-density lipoprotein (LDL) cholesterol in patients with heterozygous familial hypercholesterolemia (HeFH), homozygous familial hypercholesterolemia (HoFH), or clinical atherosclerotic cardiovascular disease who are taking maximally tolerated statin therapy and require additional lowering of LDL cholesterol.

- **Prezista® (darunavir):** Janssen’s Prezista is now approved in combination with Norvir® (ritonavir) to treat human immunodeficiency virus (HIV) infection in pregnant women.

- **Berinert® (C1 esterase inhibitor [human]):** CSL Bering’s Berinert is now approved to treat hereditary angioedema (HAE) attacks in pediatrics patients. Berinert is the first and only approved HAE treatment for patients under 12 years old.

*continued*
July news

“In a blow to biosimilar developers and consumers, the federal appeals court has again ruled that biosimilar makers must wait until they have an FDA approval in hand before giving the drugmakers a 6-month heads up that they intend to launch a knockoff.”

“Differin® Gel 0.1% is the first in a class of drugs known as retinoids to be made available over-the-counter (OTC) for the treatment of acne, and contains the first new active ingredient for acne treatment for OTC use since the 1980s. Differin Gel 0.1% was originally approved in 1996 as a prescription product for the treatment of acne vulgaris in patients 12 years of age and older.”

“The FDA advisory panel that endorsed biosimilar Humira® recommended the agent’s approval in a 26–0 vote for many, but not all of the indications currently assigned to Humira itself: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis in patients at least 4 years old, plaque psoriasis, adult Crohn’s disease, and adult ulcerative colitis. A slightly different group of 20 advisory panel members (without any gastroenterologists) voted 20–0 in favor of the FDA granting biosimilar Enbrel® all five of the indications now held by Enbrel: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, and plaque psoriasis.

3. http://www.amjorthopedics.com/index.php?id=25548&tx_ttnews%5Btt_news%5D=523697&cHash=9032750a8f1cf38f9935994d0e6416

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