# FDA clears XEN gel stent for refractory glaucoma

The Food and Drug Administration (FDA) granted regulatory approval to the XEN Glaucoma Treatment System (consisting of the Xen45 Gel Stent and the Xen Injector) for the management of refractory glaucomas, where previous surgical treatment has failed or in patients with primary open angle glaucoma, and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy. Marketer Allergan (Dublin, Ireland) said the Xen is implanted through an ab interno approach and reduces IOP by creating a new drainage channel with a permanent implant that becomes flexible. In the U.S. pivotal trial, the device reduced IOP from a mean medicated baseline of 25.1 (±3.7) mm Hg to 15.9 (±5.2) mm Hg at the 12-month visit (n=52). The mean baseline number of IOP-lowering medications was 3.5 (±1.0) versus an average use of 1.7 (±1.5) medications at 12 months. Allergan plans to launch the XEN Glaucoma Treatment System in the U.S. in early 2017