## North Carolina Biotechnology Center

## **Ophthalmic Drugs** Indications and Market Landscape

(focus on glaucoma as example indication)

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## **Market & Forecasts**

NOTE: The NCBiotech Life Science Intelligence unit has access to full published reports from two publishers, BCC Research and Kalorama. However, for many markets, other data may be available from press releases, company presentations, etc. Since these market sizes are all estimations, it can be helpful to see multiple projections.



Source: Visualization by NCBiotech Library, see individual market forecasts below.

Global revenues for the ophthalmology market are forecast to grow at a compound annual growth rate of 9.48%, from \$13.7 billion in 2015 to \$26 billion in 2022.<sup>1</sup>

The global ophthalmic drugs market was valued at US\$16 bn in 2012 and is estimated to reach a market value of US\$21.6 bn by 2018, rising at a CAGR of 5.2% from 2013 to 2018.<sup>2</sup>

The global ophthalmic drugs market is projected to grow with a CAGR between 5.2% and 5.5% over the forecast period of 2016 - 2022 and surpass USD 21 billion by 2022.<sup>3</sup>

The ophthalmic drugs market was valued at USD 17.2 Bn in 2015, and is expected to reach USD 27.6 Bn by 2022, expanding at a CAGR of 7.0% from 2016 to 2022.<sup>4</sup>

<sup>&</sup>lt;sup>1</sup> "Global Ophthalmology Drugs market to 2022." *GBI Research report summary*, August 2016. <u>http://www.gbiresearch.com/report-store/market-reports/therapy-analysis/global-ophthalmology-drugs-market-to-</u>2022-angiogenesis-modulators-and-gene-therapies-to-boost-overall-revenue-within-the-fore

<sup>&</sup>lt;sup>2</sup> "Global Ophthalmic Drugs Market to Reach US\$21.6 bn by 2018." *Transparency Market Research*, 25 March 2016. <u>http://www.transparencymarketresearch.com/pressrelease/ophthalmic-drugs-market.htm</u>

<sup>&</sup>lt;sup>3</sup> "Global Ophthalmic Drugs Market: Trend Analysis and Forecast to 2022." *Research and Markets report summary*, Accessed 26 January 2017 (report date is future, December 2017).

http://www.researchandmarkets.com/research/w374zp/global\_ophthalmic

<sup>&</sup>lt;sup>4</sup> "Ophthalmic drugs market is expected to grow at the CAGR of 7.0% during 2016-2023." *Credence Research press release*, accessed 26 January 2017. <u>http://www.m2.com/m2/web/story.php/20166063788</u>

The ophthalmology drug market was valued at \$12.3 billion in 2014, growing at a compound annual growth rate (CAGR% from 2014 to 2019) of 9.1% (see table below).

				CAGR%
Segment	2013	2014	2019	2014-2019
AMD	5,129	5,395	7,857	7.8
Glaucoma	4,023	3,812	6,438	11.1
DES	1,685	1,686	2,276	6.2
Uveitis	1,450	1,447	2,460	11.2
Total	12,287	12,340	19,031	9.1

#### GLOBAL OPHTHALMIC THERAPEUTIC DRUG MARKET BY SEGMENT, THROUGH 2019 (\$ MILLIONS)

Source: "Ophthalmic Therapeutic Drugs." BCC Research, July 2015.

NOTE: Other ways to estimate the market size and activity/growth may be through deal trends, incidence/prevalence of disease (see next section), and/or development pipeline. Best sources and availability of that data depend a lot on the type and the scope of your market of interest.



Source: Pharmadeals database, accessed 26 January 2017.

Searched for deals involving therapeutic products used to treat diseases of the eye in the last 10 years.

# **Trends and Drivers**

The glaucoma category that has experienced generics incursion will be offset by continued growth from new treatment modalities for age-related macular degeneration (AMD) and other retina disorders such as Diabetic Macular Edema (DME) and Retinal Vein Occlusions (RVO).... **Platelet Derived Growth Factor** (PDGF) therapy is expected to be the next frontier for retinal disorders. Regeneron, Novartis, and Allergan are reported to be evaluating combination therapies for the treatment of retinal disorders.<sup>5</sup>

## Growth Influences / Strengths

- New innovations
- Combination therapies
- Growth of glaucoma and uveitis treatments for unmet needs
- Increasing prevalence of diabetes (diabetic macular edema and retinopathy)
- Aging population and rising global population
- Technological advances in drug delivery technology
- Increasing awareness in healthcare spending
- Rapid growth of middle class in emerging markets

## Negative Influences / Threats

- Absence of health insurance in developing countries
- Lack of awareness regarding eye diseases/disorders in underdeveloped and developing countries
- Patent expirations

### **Opportunities**

- High unmet need for patient-friendly formulations
- High unmet need for safer, more efficacious treatments
- Emergence of biosimilars, patent expirations
- Consolidation is expected to continue, M&A landscape is active

### **Unmet Needs**

The key therapeutic segments with large unmet needs include retinal diseases Wet and dry AMD, diabetic retinopathy & diabetic edema, glaucoma, and dry eye (keratoconjunctivitis sicca). Dry AMD represents a strong commercial opportunity as currently there are no approved treatments.<sup>6</sup>

Better formulations to improve adherence and convenience to the patient. One example is topical antiinflammatory therapy for cataract surgery, post-procedure.<sup>7</sup>

<sup>&</sup>lt;sup>5</sup> "The Future of Ophthalmology Drugs Market." *Grand View Research*, accessed 26 January 2017. https://www.grandviewresearch.com/research-insights/future-ophthalmology-drugs-market

<sup>&</sup>lt;sup>6</sup> "The Future of Ophthalmology Drugs Market." *Grand View Research*, accessed 26 January 2017. <u>https://www.grandviewresearch.com/research-insights/future-ophthalmology-drugs-market</u>

<sup>&</sup>lt;sup>7</sup> "Intracanalicular drug depot may fill unmet need for better topical therapy." *Ophthalmology Times*, 15 April 2016. <u>http://ophthalmologytimes.modernmedicine.com/ophthalmologytimes/news/intracanalicular-drug-depot-may-fill-unmet-need-better-topical-therapy</u>

# Key Segments (Glaucoma as one example)

*NOTE: A report could be segmented by indication, product type, delivery method, technology, etc. In this case, glaucoma is given as an example of a report segmented by indication.* 

## Glaucoma

Amongst treatment drugs, the anti-glaucoma drugs segment is leading the global ophthalmic treatment drugs market, with a CAGR of 4.2% expected during the mentioned forecast period.<sup>8</sup>

## **Epidemiology**

The two main types of glaucoma are open-angle (POAG) and angle-closure (PACG). Open-angle glaucoma accounts for at least 90% of all glaucoma cases. Other types include normal-tension glaucoma (NTG) and congenital glaucoma.<sup>9</sup>

It is estimated that over 3 million Americans have glaucoma, but only half of those know they have it. Glaucoma is the second leading cause of blindness in the world. Open-angle glaucoma is the most common form, resulting in increased eye pressure.<sup>10</sup>



#### 2010 U.S. Prevalence Rates for Glaucoma by Age and Race

Source: "Glaucoma, Open-angle." National Eye Institute website, accessed 31 January 2017. <u>https://nei.nih.gov/eyedata/glaucoma</u>

<sup>&</sup>lt;sup>8</sup> "Global Ophthalmic Drugs Market to Reach US\$21.6 bn by 2018." *Transparency Market Research*, 25 March 2016. <u>http://www.transparencymarketresearch.com/pressrelease/ophthalmic-drugs-market.htm</u>

<sup>&</sup>lt;sup>9</sup> "Types of Glaucoma." *Glaucoma Research Foundation*, Accessed 31 January 2017. Page last updated 18 August 2016. <u>http://www.glaucoma.org/glaucoma/types-of-glaucoma.php</u>

<sup>&</sup>lt;sup>10</sup> "Don't let glaucoma steal your sight!" *CDC website*, accessed 31 January 2017. Page last updated 11 January 2017. https://www.cdc.gov/features/glaucoma-awareness/index.html

In 2013, the number of people (aged 40–80 years) with glaucoma worldwide was estimated to be 64.3 million, increasing to 76.0 million in 2020 and 111.8 million in 2040, disproportionally affecting people residing in Asia and Africa.<sup>11</sup>

Globally 57.5 million people (95% CI 46.4 to 73.1 million) were affected by POAG in 2015, rising to 65.5 million (95% CrI 52.8, 83.2 million) by 2020.<sup>12</sup>



PGA: Prostaglandin Analogue; BE Source: IMS MIDAS. IMS NPA

Major drugs in pipeline<sup>13</sup>



http://bjo.bmj.com/content/100/1/86.abstract

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<sup>&</sup>lt;sup>11</sup> Tham, Y-C. et al. "Global prevalence of glaucoma and projections of glaucoma burden through 2040." *Ophthalmology*, 2014, 121(11): 2081-2090. <u>http://www.aaojournal.org/article/S0161-6420(14)00433-3/abstract</u>

<sup>&</sup>lt;sup>12</sup> Kapetanakis, V.V. et al. "Global variations and time trends in the prevalence of primary open angle glaucoma (POAG): a systematic review and meta-analysis." *Br J Ophthalmol*, 2016; 100: 86-93.

<sup>&</sup>lt;sup>13</sup> Biopharm Insight database, Glaucoma Indication profile, accessed 26 January 2017.

NOTE: data below was summarized in published BCC Research report, but if not already available through a published source could also be gathered from company websites, drug pipeline databases and clinicaltrials.gov

#### ENV515 (Envisia)

Envisia, the USA-North Carolina based company, completed a Phase IIa study (NCT02371746) with ENV515 extended-release travoprost product for the treatment of glaucoma in late 2015. The firm has decided to amend the protocol, add an additional cohort and extend the trial for 12 months. The next cohort will be starting soon and will enroll approximately 10 patients. The first cohort studied was glaucoma patients that underwent cataract surgery, while the second cohort will be exclusively glaucoma patients that have not had the surgery.

#### Latanoprost punctal plug (Mati Therapeutics)

Mati Therapeutics has enrolled 75 out of approximately 145 planned patients in a Phase IIb for glaucoma, and is amending trial protocol to overcome recruitment hurdles. The Austin, Texas-based company initiated the Phase IIb efficacy comparison study of its latanoprost punctal plug delivery system with active comparator timolol maleate ophthalmic gel forming solution in patients with glaucoma in December 2013 and has faced enrollment challenges.

#### **OTX-TP (Ocular Therapeutics)**

Ocular Therapeutix's OTX-TP has experts divided over the likelihood of it reaching its primary endpoint in a Phase IIb glaucoma study. Some maintained that Ocular's punctum plug technology and travoprost, which is the API in OTX-TP, are both tried and true. Others noted the risk associated with inserting the plug, uncertainty surrounding dose release and the likelihood of the punctum plugs simply falling out without patients' awareness. The Phase IIb OTX-TP study was expected by YE15. It will test 0.36 mg of sustained-release travoprost against timolol.

#### NCBiotech-subscribed drug pipeline databases

*NOTE:* data from the pipeline databases can be searched and filtered by many different criteria, and can be exported in Excel format for further analysis. The Biopharm Insight database also has a Devices module.

- **Biopharm Insight** database currently shows 56 glaucoma drugs in clinical trials, and 52 in discovery or pre-clinical stages. (accessed 26 January 2017) see also example "Indication Profile" report
- Adis Insight database currently shows 50 glaucoma drugs in clinical trials, and 41 in preclinical or research stages. (*accessed 26 January 2017*)

# **Key Companies**

NOTE: Lists of companies can be pulled from market reports (those subscribed and table of contents from others online); drug development pipeline databases; PharmaDeals database; Factiva news database; trade journals; etc. Details about key products on the market can also be gathered from similar sources.

Detailed listings of companies and products is best for projects on more narrow/specific indications or markets. This section can take significantly more time to compile as it often requires looking at each company's website.

## Alcon (a Novartis company)

#### https://www.alcon.com/ OR https://www.myalcon.com/

*from company website:* As a division of Novartis, we offer the broadest portfolio of products to enhance sight and improve people's lives. Our products touch the lives of more than 260 million people each year living with **conditions like cataracts, glaucoma, retinal diseases and refractive errors**, and there are millions more who are waiting for solutions to meet their eye care needs. Our purpose is reimagining eye care, and we do this through innovative products, partnerships with eye care professionals and programs that enhance access to quality eye care.

R&D strategy is built around specific unmet medical needs within these four therapeutic areas:14

- Glaucoma
- Cataract and Refractive Error
- Retina
- External Disease

Alcon is the second-largest division of Novartis and a global leader in eye care with pro-forma sales of \$10.8 billion in 2014. The company has a broad portfolio of products, including several that are due to be filed with regulatory authorities over the next five years, such as Fovista in wet AMD (2016), Lucentis CNV and ME (2016) and for ROP (after 2018). Novartis' medical retina pipeline includes investigational treatments in late-stage clinical development such as RTH258 for wet AMD (next generation anti-VEGF), and LFG316 for the treatment of dry AMD. In May 2014, Novartis obtained exclusive marketing rights for Ophthotech's Fovista (anti-PDGF aptamer) outside the U.S. Fovista is being studied in combination with anti-VEGF agents for patients suffering from wet AMD. Novartis will also develop a co-formulation of Fovista with a Novartis proprietary anti-VEGF treatment, Lucentis.

## Allergan (formerly Actavis)

#### http://www.allergan.com

*from company website*: Allergan markets a portfolio of leading brands and best-in-class products for the central nervous system, eye care, medical aesthetics and dermatology, gastroenterology, women's health, urology and anti-infective therapeutic categories. Allergan has built one of the broadest development pipelines in the pharmaceutical industry with 70+ mid-to-late stage pipeline programs in development.

Allergan's R&D efforts in Eye Care are focused on advancing innovation in the treatment of dry eye disease, glaucoma and conditions that impact the back of the eye, including retinal conditions. Lead programs include Oculeve, new delivery and formulations of Restasis, XEN 45, Bimatoprost SR, Brimonidine SR for dry age-related macular degeneration and the DARPin portfolio of programs.

<sup>&</sup>lt;sup>14</sup> <u>https://www.alcon.com/our-work/research-development/research-areas-pipeline</u>, Accessed 26 January 2017.

Allergan's assets included a rich ophthalmic product pipeline including Restasis (Phase III) and Restasis X (Phase II) for the treatment of ocular surface disease; Novadur (brimonidine; Phase II) and AGN 208397 (Phase II) for retinal diseases; Brimatoprost SR (Phase II) for glaucoma; and AGN-150998, anti VEGF/PDGF-B and TKI in development for AMD. Since 2007, Allergan has forged partnerships with a number of biotechnology companies developing novel ophthalmic medicines, including Taris Biomedical, Voyant Biotherapeutics, Medytox, Spetrum Pharmaceuticals, Molecular Partners, Bioavail, Inspire Pharmaceuticals and QLT.<sup>15</sup>

### Merck & Co.

#### http://www.merck.com/

*from company website:* Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions.



*NOTE:* doesn't show specific eye indications on this current pipeline figure. Biopharm Insight database shows two Phase 1 drugs indicated for Glaucoma and one in discovery for AMD. As well as 7 drugs and drug combinations already approved for market in the ophthalmology space.

<sup>&</sup>lt;sup>15</sup> "Ophthalmic Therapeutic Drugs." *BCC Research*, July 2015.

#### **Pfizer** http://www.pfizer.com/

*from company website:* We have a leading portfolio of products and medicines that support wellness and prevention, as well as treatment and cures for diseases across a broad range of therapeutic areas; and we have an industry-leading pipeline of promising new products that have the potential to challenge some of the most feared diseases of our time, like Alzheimer's disease and cancer.

Pfizer is committed to developing novel therapies that improve the lives of patients with ophthalmic diseases. Our in-line medicines in this area include Xalatan® (latanoprost ophthalmic solution), Xalacom® (latanoprost and timolol), and Macugen® (pegaptanib injection). http://www.pfizer.com/partnering/areas of interest/ophthalmology

## Roche

#### http://www.roche.com/

*from company website:* Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Our ophthalmic research programs are focused on addressing the leading causes of blindness, including geographic atrophy secondary to age-related macular degeneration (AMD), neovascular AMD, diabetic macular edema and other retinal diseases.

### Other

Smaller companies are making headway with niche products including Acucela, Aerie Pharmaceuticals, Inotek Pharmaceuticals Corporation, Lux Biosciences, Molecular Partners AG, Optherion, pSivida Corporation, Regeneron Pharmaceuticals, Resolvyx Pharmaceuticals, Santen Pharmaceutical Co., Sylentis S.A. and Valeant Pharmaceuticals.<sup>16</sup>

**Pfizer Inc**, Hoya Corporation, Bayer, Novartis International AG, Abbott Medical Optics Inc., Ziemer Ophthalmic Systems AG, Regeneron, Johnson & Johnson Vision Care Inc., Bausch & Lomb Inc., Topcon Corporation, Ellex Medical Lasers Ltd., **Alcon Inc., Merck & Co. Inc,** Spark Therapeutics, Insight Vision Inc., **Roche Holding Ltd**, Ophthotech, Novagali Pharma S A, **Allergan Inc.,** Carl-Zeiss AG, Santen, Essilor International S.A.<sup>17</sup>

The companies covered in the report include Abbott Healthcare, **Allergan Plc**, Johnson & Johnson, Bayer, Valeant Pharmaceuticals, Inc., **Pfizer, Inc., Merck & Co.**, **Novartis AG**, Renegeron, and Santen Pharmaceuticals Company Ltd.<sup>18</sup>

<sup>&</sup>lt;sup>16</sup> "Ophthalmic Therapeutic Drugs." *BCC Research*, July 2015.

<sup>&</sup>lt;sup>17</sup> "Global Ophthalmology Drugs Market Research and Projections 2016-2021."*medGadget press release*, 18 November 2016. <u>http://www.medgadget.com/2016/11/global-ophthalmology-drugs-market-research-and-projections-2016-2021-on-consumer-needs-pricing-strategy-revenue-and-growth-rate.html</u>

<sup>&</sup>lt;sup>18</sup> "Global Ophthalmic Drugs Market: Trend Analysis and Forecast to 2022." *Research and Markets report summary*, Accessed 26 January 2017 (report date is future, December 2017).

http://www.researchandmarkets.com/research/w374zp/global\_ophthalmic

# **Review Articles**

*NOTE: Scientific literature searches can be provided, and a limited selection of articles can be ordered through interlibrary loan at \$20/article. This focus was recent articles on innovation in glaucoma treatment.* 

Donegan RK, Lieberman RL. <u>Discovery of Molecular Therapeutics for Glaucoma: Challenges, Successes, and</u> <u>Promising Directions.</u> J Med Chem. 2016 Feb 11;59(3):788-809. doi: 10.1021/acs.jmedchem.5b00828. Review. PubMed PMID: 26356532.

Lusthaus JA, Goldberg I. <u>Emerging drugs to treat glaucoma: targeting prostaglandin F and E receptors.</u> Expert Opin Emerg Drugs. 2016;21(1):117-28. doi: 10.1517/14728214.2016.1151001. Review. PubMed PMID: 26854598.

Hoy SM. <u>Tafluprost/Timolol: A Review in Open-Angle Glaucoma or Ocular Hypertension</u>. Drugs. 2015 Oct;75(15):1807-13. doi: 10.1007/s40265-015-0476-9. Review. PubMed PMID: 26431840.

Chen YS, Green CR, Danesh-Meyer HV, Rupenthal ID. <u>Neuroprotection in the treatment of glaucoma--A focus</u> on connexin43 gap junction channel blockers. Eur J Pharm Biopharm. 2015 Sep;95(Pt B):182-93. doi: 10.1016/j.ejpb.2015.01.031. Review. PubMed PMID: 25676338.

Carvalho IM, Marques CS, Oliveira RS, Coelho PB, Costa PC, Ferreira DC. <u>Sustained drug release by contact</u> <u>lenses for glaucoma treatment-a review.</u> J Control Release. 2015 Mar 28;202:76-82. doi: 10.1016/j.jconrel.2015.01.023. Review. PubMed PMID: 25617723.

Cholkar K, Trinh HM, Pal D, Mitra AK. <u>Discovery of novel inhibitors for the treatment of glaucoma</u>. Expert Opin Drug Discov. 2015 Mar;10(3):293-313. doi: 10.1517/17460441.2015.1000857. Review. PubMed PMID: 25575654; PubMed Central PMCID: PMC4589152.

Tanna AP, Lin AB. <u>Medical therapy for glaucoma: what to add after a prostaglandin analogs?</u> Curr Opin Ophthalmol. 2015 Mar;26(2):116-20. doi: 10.1097/ICU.00000000000134. Review. PubMed PMID: 25594765.

Greig SL, Deeks ED. <u>Brinzolamide/brimonidine: a review of its use in patients with open-angle glaucoma or ocular hypertension</u>.Drugs Aging. 2015 Mar;32(3):251-60. doi: 10.1007/s40266-015-0250-4. Review. PubMed PMID: 25732405.

Bucolo C, Platania CB, Reibaldi M, Bonfiglio V, Longo A, Salomone S, Drago F. <u>Controversies in Glaucoma:</u> <u>Current Medical Treatment and Drug Development.</u> Curr Pharm Des. 2015;21(32):4673-81. Review. PubMed PMID: 26350532.

# **Recent News**

NOTE: The following are lead paragraph excerpts from news articles found in Factiva (Dow Jones) database or online trade journals.

#### Stem cell secretions may protect against glaucoma 30 January 2017

National Eye Institute News

NEI scientists find that stem cell exosomes promote survival of retinal ganglion cells in rats. A new study in rats shows that stem cell secretions, called exosomes, appear to protect cells in the retina, the light–sensitive tissue in the back of the eye. The findings, published in the journal Stem Cells Translational Medicine, point to potential therapies for glaucoma, a leading cause of blindness in the United States. The study was conducted by researchers at the National Eye Institute (NEI), part of the National Institutes of Health.

# Otsuka launches a new treatment for glaucoma and ocular hypertension

11 January 2017 Company Reports, CHPR © 2017 Elsevier Engineering Information

Otsuka Pharmaceutical Co Ltd announced the launch of Mikeluna combination ophthalmic solution for glaucoma and ocular hypertension. The drug is to be co-promoted with Senju Pharmaceutical Co Ltd. Mikeluna combination ophthalmic solution is an Otsukadeveloped eye drop containing a combination of the non-selective beta-blocker cartelol hydrochloride and the prostaglandin analogue latanoprost.

Usually glaucoma is treated initially with a single therapeutic agent and if intraocular pressure is not controlled sufficiently then additional agents are prescribed. However, the requirement to wait between applications of each eye drop may reduce the efficacy of the treatment as dose adherence often decreases. A combination of the two into one formulation would improve adherence.

# Sun Pharma dry eye drug gets positive results in clinical trials

5 January 2017 Nikkei Report, NKRP © Copyright 2017. Nihon Keizai Shimbun, Inc. All rights reserved.

Sun Pharmaceutical Industries said its new ophthalmic drug for dry eye disease met its primary endpoint in a phase three study, giving a shot in the arm for India's largest drug maker that aims to strengthen its specialty pharmaceutical products.

The company, backed by billionaire Dilip Shanghvi, last year got exclusive global rights for the drug Seciera through the acquisition of Ocular Technologies. Sun bought Ocular from Auven Therapeutics, a private equity firm focused on drug development, for an initial payment of \$40 million. The company is developing the drug to sell in the U.S., Europe, and Japan, as well as in several emerging markets.

#### Using Genetics to guide AMD therapy: Are we there yet? 1 January 2017

Retinal Physician

There are several commercially available genetic tests for AMD. In the United States, Macula Risk PGx (ArcticDx, Toronto) can be ordered by a provider. RetnaGene (Sequenom, San Diego) is no longer available. Asper Biotech based in Tartu, Estonia, offers direct-to-consumer genetic testing worldwide. ...

AMD is a multifactorial disease with many genetic and environmental risk factors. Over the past decade, much insight has been gained regarding AMD risk variants, but at this time there is no convincing evidence that genetic testing is beneficial in the routine management of AMD patients. Data from future large, prospective trials may provide validation for the pharmacogenetics of AMD. At the present time, genetic testing is more useful as a research tool than in clinical management.

# Dexamethasone implant as first line therapy for DME

December 2016 EyeWorld

# New German study substantiates long-acting effects of implant

Intravitreal therapy has become the first line treatment option for the management of diabetic macular edema (DME). Dexamethasone implants have matched the visual and macular- slimming results attained through the use of anti-vascular endothelial growth factor (VEGF) injections, with the added advantage of longer steroid effects, meaning fewer injections and happier patients.

# Aerie Surges on Glaucoma treatment trial results

14 September 2016 Dow Jones Institutional News © 2016, Dow Jones & Company, Inc.

Aerie Pharmaceuticals (AERI) shares pop after the company posted favorable results from a late-stage study of its new glaucoma treatment Roclatan. The study met its primary efficacy endpoint, demonstrating statistical superiority over each of its components, including Aerie product candidate Rhopressa and market-leading prostaglandin analogue latanoprost. The trial "clearly reconfirms the potential for Roclatan to become the most efficacious" intraocular pressure-lowering therapy to enter the market, if approved, said CEO Vicente Anido. Aerie expects to file an NDA at the end of next year.

#### Allergan to Buy Eye-Care Company ForSight Vision5 for \$95 Million

By Emma Court 11 August 2016 Dow Jones Newswires © 2016, Dow Jones & Company, Inc.

Allergan Plc said Thursday that it had agreed to acquire the private eye-care biotechnology company ForSight Vision5 for \$95 million. The deal also includes a launch milestone payment for the biotech's lead product, which is inserted on the surface of the eye and allows for the extended release of glaucomamedication. The product completed mid-stage clinical trials last year. The purchase is expected to be completed within 60 days.

# FDA approves new medication for dry eve disease

12 July 2016 FDA News Release

The U.S. Food and Drug Administration approved Xiidra (lifitegrast ophthalmic solution) for the treatment of signs and symptoms of dry eye disease, on Monday, July 11, 2016. Xiidra is the first medication in a new class of drugs, called lymphocyte function-associated antigen 1 (LFA-1) antagonist, approved by the FDA for dry eye disease.

"Normal tear production is needed for clear vision and eye health," said Edward Cox, M.D., director of the Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research. "This approval will provide a new treatment option for patients with dry eye disease."

#### Statins may show promise as a treatment for Dry Age-Related Macular Degeneration

By Maureen Duffy 23 February 2016 <u>VisionAware</u>

This month, researchers from Harvard Medical School and the University of Crete in Greece have published findings from a small phase 1/2 clinical trial in which 10 out of 23 subjects with dry AMD who were given high doses of the cholesterollowering drug Lipitor showed regression of drusen deposits (a buildup of waste materials beneath the retina, explained below) and demonstrated some improvements in visual acuity. Although this research was conducted with a small number of subjects and is in its earliest stages, the results show promise as a potential treatment for dry AMD.