Macular Degeneration Therapeutics Market in Asia-Pacific to 2019
Existing Angiogenics Retain Dominance Though High Unmet Need Remains
GBI Research Report Guidance

- Chapter two provides an overview of the disease, its symptoms, etiology, pathophysiology, diagnosis, classification, epidemiology, prognosis, staging and treatment options.

- Chapter three provides a detailed profiling and comparative heat map analysis in terms of safety and efficacy for currently marketed products in the Macular Degeneration market in APAC.

- Chapter four presents a detailed pipeline analysis for the disease including individual product profiles, analysis of the pipeline products on the distribution of molecule types across macular degeneration developmental pipeline, the molecular targets of pipeline and the developmental program types. In addition, detailed analyses of the clinical trial failure rates, the clinical trial durations by phase and clinical trial sizes by participant numbers are also provided.

- Chapter five provides market forecasts across the globe and in APAC countries such as India, Australia, China and Japan. The multiple scenario forecasts take a range of factors that are likely to vary into account and provide a clear perspective on the level of the potential degree of variance in the market sizes.

- Chapter six covers the major deals that have taken place in the macular degeneration market in recent years. Coverage includes Mergers and Acquisitions (M&As) as well as co-development and licensing agreements, which are segmented on the basis of geography and total value. A concomitant analysis of the licensing deal values for products by molecule types and molecular target is also provided.
Executive Summary

Macular Degeneration Therapeutics Market is set to Witness Modest Growth over Forecast Period

The market for macular degeneration has witnessed tremendous growth over the last decade due to the launch of various promising drugs. The market is expected to experience a modest growth rate over the forecast period, due to the absence of promising products in the pipeline or expected launches (excluding Eylea’s (aflibercept) launch in China). The macular degeneration sector in the Asia-Pacific (APAC) markets of India, Australia, China and Japan was estimated to be worth $XXm in 2012, and is expected to grow at a Compound Annual Growth Rate (CAGR) of XX% over the forecast period to reach $XXm by 2019. The Japanese market represented XX% of the APAC market in 2012, followed by Australia, which represented XX%. Regardless of there being no prominent drug launches scheduled, the market is set to grow moderately due to an increase in the region’s aging population, which is in turn responsible for the increase in the prevalence populations of the countries studied.

Anti-angiogenic Drugs Entrenched as First-line Therapies

Laser coagulation was considered the standard treatment for wet Age-related Macular Degeneration (AMD) prior to the approval of anti-angiogenic drugs. The launch of Vascular Endothelial Growth Factor (VEGF) inhibitors as macular degeneration treatments resulted in the reduction of laser coagulation to a niche market role. The inhibition of angiogenesis is now globally accepted as the most effective treatment option for wet AMD. The wet AMD treatment paradigm has evolved over the past decade, following the launch of Eyetech’s Macugen (pegaptanib sodium), the first anti-angiogenic therapy for wet AMD. The product achieved outstanding commercial success following its release, however, the introduction of Roche/Novartis’s Lucentis (ranibizumab) has since set a new standard for wet AMD therapies, relegating Macugen to a product with only niche applications. In spite of its better efficacy and safety, Lucentis is facing stiff competition from retinal specialists’ off-label usage of the cancer drug Avastin (bevacizumab), primarily due to the latter’s low cost of therapy compared to Lucentis. Eylea, the latest anti-angiogenic therapy which gained FDA approval in November 2011, has experienced a strong commercial start. The reason for its rapid uptake is its dosing convenience over the existing gold-standard treatment, Lucentis. The confirmatory Phase III trial results of Eylea proved efficacy of bimonthly dose of Eylea after the first three monthly doses was comparable to Lucentis dosed monthly. Based on the fast uptake of Eylea since its launch, it is expected that it will offer strong competition to Lucentis in the coming years. However, the off-label usage of Avastin is expected to continue relatively undisturbed due to its cheap price.
1 Table of Contents

1 Table of Contents .................................................................................................................. 6
1.1 List of Tables ....................................................................................................................... 9
1.2 List of Figures ..................................................................................................................... 10
2 Macular Degeneration Asia-Pacific Market to 2019 – Introduction ........................................ 11
2.1 Symptoms .......................................................................................................................... 11
2.2 Etiology ............................................................................................................................. 12
2.3 Pathophysiology ............................................................................................................... 12
2.3.1 Disease Initiation .......................................................................................................... 13
2.3.2 Disease Propagation ..................................................................................................... 13
2.4 Classification .................................................................................................................... 15
2.4.1 Early AMD .................................................................................................................. 15
2.4.2 Intermediate AMD ...................................................................................................... 15
2.4.3 Advanced AMD ......................................................................................................... 16
2.5 Co-morbidities and Complications .................................................................................. 17
2.6 Diagnosis .......................................................................................................................... 18
2.6.1 History ....................................................................................................................... 18
2.6.2 Examination ............................................................................................................... 18
2.6.3 Diagnostic Tests ......................................................................................................... 19
2.7 Epidemiology .................................................................................................................... 21
2.8 Prognosis and Disease Staging ....................................................................................... 23
2.9 Treatment Options .......................................................................................................... 23
2.9.1 Pharmacological ......................................................................................................... 23
2.9.2 Treatment Algorithms and Prescribing Habits ......................................................... 25
2.9.3 Non-pharmacological Care ...................................................................................... 27
3 Macular Degeneration Asia-Pacific Market to 2019 – Marketed Products .............................. 29
3.1 Therapeutic Landscape ...................................................................................................... 30
3.1.1 Lucentis (ranibizumab) – Novartis AG/Roche (Genentech) ........................................... 30
3.1.2 Eylea (aflibercept) – Regeneron Pharmaceuticals/Bayer Healthcare ............................ 31
3.1.3 Avastin (bevacizumab) – Genentech (Roche) ............................................................... 33
3.1.4 Macugen (pegaptanib sodium) – Valeant Pharmaceuticals/Pfizer ............................... 33
3.1.5 Visudyne (verteporfin injection) – Novartis AG ........................................................ 34
3.1.6 Triamcinolone Acetonide ............................................................................................ 35
3.2 Comparative Efficacy and Safety .................................................................................... 36
4 Macular Degeneration Asia-Pacific Market to 2019 – Pipeline for Disease ............................ 38
4.1 Overall Pipeline ................................................................................................................ 38
4.2 Pipeline Analysis by Molecule Type ................................................................................ 40
4.3 Pipeline Analysis by Mechanism of Action ..................................................................... 42
4.4 Clinical Trials .................................................................................................................... 44
4.4.1 Failure Rate ................................................................................................................ 44
4.4.2 Clinical Trial Duration ............................................................................................... 45
4.4.3 Clinical Trial Size ....................................................................................................... 46
4.5 Promising Drug Candidates in the Pipeline .................................................................... 47
4.5.1 MC-1101 – MacuCLEAR, Inc. .................................................................................. 47
4.5.2 KH902 (Fumitidine) – Chengdu Kanghong Pharmaceuticals Group Co., Ltd. ............ 47
5 Macular Degeneration Asia-Pacific Market to 2019 – Market Forecast to 2019 .................... 49
# Table of Contents

5.1 Geographical Markets.................................................................................49
  5.1.1 APAC Market .........................................................................................49
  5.1.2 Australia .................................................................................................51
  5.1.3 China ......................................................................................................53
  5.1.4 India .......................................................................................................55
  5.1.5 Japan ......................................................................................................57
5.2 Drivers and Barriers for the Disease Market........................................59
  5.2.1 Drivers ....................................................................................................59
  5.2.2 Barriers..................................................................................................60
6  Macular Degeneration Asia-Pacific Market to 2019 – Deals and Strategic Consolidations........61
  6.1 Deals Analysis............................................................................................61
  6.2 Major Co-development Deals.................................................................63
    6.2.1 Shionogi Enters into Co-development Agreement with OncoTherapy Science ........................................................................67
    6.2.2 Alcon Enters into Collaboration with AstraZeneca .........................64
    6.2.3 X-Body BioSciences Enters into Co-development Agreement with Hengrui Medicine for AMD .................................................64
    6.2.4 Acucela Enters into Co-Development Agreement with Otsuka Pharma for ACU-4429.................................................................64
  6.3 Major Licensing Deals ............................................................................65
    6.3.1 Allegro Ophthalmics Enters into Licensing Agreement with Senju Pharma to Develop Integrin Peptide Therapy .................................................66
    6.3.2 Allergan Enters into Co-development Agreement with Molecular Partners ..................................................................................66
    6.3.3 PanOptica Enters into Licensing Agreement with OSI Pharma ......................................................................................66
    6.3.4 Lpath Enters into Licensing Agreement with Pfizer .................................................66
    6.3.5 Shionogi Enters into Licensing Agreement with OncoTherapy Science ..................................................................................67
7  Macular Degeneration Asia-Pacific Market to 2019 – Appendix................68
  7.1 All Pipeline Drugs by Phase ....................................................................68
    7.1.1 Discovery ..............................................................................................68
    7.1.2 Preclinical .............................................................................................69
    7.1.3 IND-filed and Phase 0 ..........................................................................70
    7.1.4 Phase I ..................................................................................................70
    7.1.5 Phase II................................................................................................71
    7.1.6 Phase III................................................................................................71
    7.1.7 Undisclosed ..........................................................................................72
  7.2 Market Forecasts to 2019 ........................................................................72
    7.2.1 Asia-Pacific ..........................................................................................72
    7.2.2 Australia ...............................................................................................72
    7.2.3 China......................................................................................................73
    7.2.4 India ......................................................................................................73
    7.2.5 Japan ......................................................................................................73
  7.3 Market Definitions ....................................................................................74
  7.4 Abbreviations ...........................................................................................74
  7.5 References ................................................................................................75
  7.6 Research Methodology ............................................................................78
    7.6.1 Coverage ................................................................................................78
    7.6.2 Secondary Research ............................................................................78
    7.6.3 Primary Research ................................................................................78

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<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.6.4</td>
<td>Therapeutic Landscape</td>
<td>79</td>
</tr>
<tr>
<td>7.6.5</td>
<td>Geographical Landscape</td>
<td>81</td>
</tr>
<tr>
<td>7.6.6</td>
<td>Pipeline Analysis</td>
<td>82</td>
</tr>
<tr>
<td>7.7</td>
<td>Expert Panel Validation</td>
<td>82</td>
</tr>
<tr>
<td>7.8</td>
<td>Contact Us</td>
<td>82</td>
</tr>
<tr>
<td>7.9</td>
<td>Disclaimer</td>
<td>82</td>
</tr>
</tbody>
</table>
1.1 List of Tables

Table 1: Macular Degeneration Market, Classification of AMD .................................................................15
Table 2: Macular Degeneration Market, Treatment Recommendations and Follow-up for Non-neovascular AMD ..........................................................................................................................26
Table 3: Macular Degeneration Market, Treatment Recommendations and Follow-up for Neovascular AMD .................................................................................................................................26
Table 4: Macular Degeneration Market, Global, Pharmaceutical Pipeline (Discovery), 2013 .....................68
Table 5: Macular Degeneration Market, Global, Pharmaceutical Pipeline (Preclinical), 2013 ....................69
Table 6: Macular Degeneration Market, Global, Pharmaceutical Pipeline (IND/CTA-filed), 2013 ...............70
Table 7: Macular Degeneration Market, Global, Pharmaceutical Pipeline (Phase I), 2013 .......................70
Table 8: Macular Degeneration Market, Global, Pharmaceutical Pipeline (Phase II), 2013 .......................71
Table 9: Macular Degeneration Market, Global, Pharmaceutical Pipeline (Phase III), 2013 .....................71
Table 10: Macular Degeneration Market, Global, Pharmaceutical Pipeline (Undisclosed), 2013 ..............72
Table 11: Macular Degeneration Market, Asia-Pacific, Market Forecast, 2012–2019 ..............................72
Table 12: Macular Degeneration Market, Australia, Market Forecast, 2012–2019 .................................72
Table 13: Macular Degeneration Market, China, Market Forecast, 2012–2019 .........................................73
Table 14: Macular Degeneration Market, India, Market Forecast, 2012–2019 ........................................73
Table 15: Macular Degeneration Market, Japan, Market Forecast, 2012–2019 ........................................73
1.2 List of Figures

Figure 1: Macular Degeneration Market, Pathophysiology of AMD ................................................. 14
Figure 2: Macular Degeneration Market, Types of Dry AMD .............................................................. 16
Figure 3: Macular Degeneration Market, Classification of AMD .......................................................... 17
Figure 4: Macular Degeneration Market, Amsler Grid Test ................................................................. 19
Figure 5: Macular Degeneration Market, Asia-Pacific, Epidemiology, 2012–2019 ............................... 22
Figure 6: Macular Degeneration Market, Photodynamic Therapy ....................................................... 24
Figure 7: Macular Degeneration Market, Treatment Algorithm by Type and by Stage ....................... 25
Figure 8: Macular Degeneration Market, Fluorescein Angiogram Showing Laser Photocoagulation Images .......................................................... 27
Figure 9: Macular Degeneration Market, Global, Annual Sales (§m), 2012 .......................................... 29
Figure 10: Macular Degeneration Market, Lucentis, Global, Annual Sales (§m), 2006–2012 .................. 30
Figure 11: Macular Degeneration Market, Eylea, Global, Annual Sales (§m), 2011–2012 ..................... 32
Figure 12: Macular Degeneration Market, Visudyne, Global, Annual Sales (§m), 2005–2012 ............. 35
Figure 13: Macular Degeneration, Global, Heat Map of Safety and Efficacy for Marketed Products .... 36
Figure 14: Macular Degeneration Market, Global, Pipeline, 2013 ....................................................... 39
Figure 15: Macular Degeneration Market, Global, Pipeline, 2013 ....................................................... 41
Figure 16: Macular Degeneration Market, Global, Pipeline, 2013 ....................................................... 43
Figure 17: Macular Degeneration Market, Global, Clinical Trial Failure Rate, 2013 ......................... 44
Figure 18: Macular Degeneration Market, Global, Pipeline, Clinical Trial Duration, 2013 ................. 45
Figure 19: Macular Degeneration Market, Global, Pipeline, Clinical Trial Size, 2013 ......................... 46
Figure 20: Macular Degeneration Market, Global, Annual Sales (§bn), 2012–2019 ......................... 50
Figure 21: Macular Degeneration Market, Australia, Annual Sales (§m), 2012–2019 ......................... 52
Figure 22: Macular Degeneration Market, China, Annual Sales (§m), 2012–2019 ............................... 54
Figure 23: Macular Degeneration Market, India, Annual Sales (§m), 2012–2019 ............................... 56
Figure 24: Macular Degeneration Market, Japan, Annual Sales (§m), 2012–2019 ............................... 58
Figure 25: Macular Degeneration Market, Global, Deals, 2007–2013 .............................................. 62
Figure 26: Macular Degeneration Market, Global, Co-development Deals, 2007–2013 ....................... 63
Figure 27: Macular Degeneration Market, Global, Licensing Deals, 2007–2013 ................................. 65
Figure 28: GBI Research Market Forecasting Model ........................................................................... 81
Age-related Macular Degeneration (AMD), commonly known as macular degeneration, is a chronic ophthalmic disorder that leads to the deterioration of the center of the retina, the macula, leading to loss of central vision. Globally, AMD occupies the third position among the global causes of visual impairment, with a blindness prevalence of XX%, after glaucoma and cataracts (WHO, 2013). The disease usually manifests after 50 years of age, thus it is referred to as ‘age-related’ macular degeneration. Since it impairs only the central vision, people rarely go blind from AMD. However, this impairment can make it difficult to perform daily activities that require acute central vision.

AMD is characterized by the deposition of material in the choroid layer of the eye, which lies below the retina. It causes damage to the macular or the center portion of the retina. AMD affects the outer retina, the Retinal Pigment Epithelium (RPE), Bruch’s membrane and the choroid, culminating in the death of macular photoreceptors and a reduction in visual function. The resultant visual impairment has been shown to result in reduced quality of life, impaired ability to perform activities of daily living, increased risk of falls, and a higher risk of depression. AMD often affects both eyes although it may affect one eye before the other.

AMD is divided into two main classes – non-exudative or dry AMD and exudative or wet AMD. The latter is considered to be the more severe form of AMD. Dry AMD is the most common type, and occurs due to the gradual breakdown of macular cells. Small yellowish-white spots called drusen are the key identifiers for the dry type. This condition is asymptomatic and people with these spots may have excellent vision. Advanced dry macular degeneration, known as Geographic Atrophy (GA), is the culmination of prolonged, progressive wasting changes in the nerves and sensory retina. GA is the main cause of vision loss in dry AMD, not the drusen. Dry AMD affects around nine out of 10 people with AMD. Approximately XX% of patients with dry AMD eventually progress to wet AMD. (Synowiec et al., 2012).

Wet AMD occurs when new blood vessels, Choroidal Neovascular Membranes (CNVMs), develop under the retina. CNVMs cause leakage of fluid and blood and, if left untreated, ultimately cause a centrally blinding disciform scar. It can cause rapid and severe loss of central vision. Although wet AMD affects only about 10–XX% of late-stage AMD patients, it accounts for XX% of vision loss due to AMD (Macular Degeneration Partnership, 2013).

Macular degeneration treatments are primarily limited to the wet form of macular degeneration, and include anti-VEGF medication injections, such as Macugen (pegaptanib sodium), Lucentis (ranibizumab), Eylea (aflibercept), off-label Avastin (bevacizumab), and other treatment options such as thermal laser treatment and Photodynamic Therapy (PDT). No proven treatment options are available for the dry form of macular degeneration. However, a large scientific study, Age-Related Eye Disease Study (AREDS), has shown that antioxidants, vitamins and zinc may reduce the impact of macular degeneration in some people by slowing its progression toward more advanced stages.

### 2.1 Symptoms

In the early stages, AMD can be asymptomatic. When symptoms are present, they commonly include reduced central visual acuity; image distortion, referred to as metamorphopsia; and central scotoma, which is a blind spot in the visual field. Also, since AMD rarely affects both eyes simultaneously, symptoms from the affected eye may go unnoticed by patients until the fellow eye is also affected. This is because the eye with good vision compensates for impaired vision in the affected eye.

AMD symptoms and associated syndromes include:

- **Blurred vision**: Those with dry AMD may be asymptomatic or notice a gradual loss of central vision, whereas those with the wet form often notice a rapid onset of vision loss.

- **Reduced visual acuity**: Reduction in visual acuity is due to damaged photoreceptors. The degree of reduction is a factor of the size, type, location, and age of neovascular lesion.

- **Central scotoma**: Usually appears as the disease reaches the progression stage and is caused by the leakage of blood and fluid under the retina.

- **Metamorphopsia (distortion of images)**: Image distortion could be considered the first indication of wet AMD. Straight line distortion is the first sign of fluid under the retina.

- **Decreased color vision**: Patients usually complain of a difference in the size and color of objects with each eye.
Macular Degeneration Asia-Pacific Market to 2019 – Marketed Products

Currently, four anti-angiogenic drugs – Lucentis, Eylea, Macugen and off-label Avastin – and a photosensitizing drug, Visudyne, are available in the market for the treatment of wet-AMD. Apart from these, there are a few corticosteroids such as Triamcinolone Acetonide (TA) that can be used as adjuvant therapy. Many publications have confirmed the synergistic role of combining TA and PDT therapy for the treatment of all types of CNV: classic or predominantly classic, occult or minimally classic, and Retinal Angiomatous Proliferation (RAP) lesions (Becerra et al., 2011). In contrast to wet AMD, no standard drug therapy is currently available in the market for dry AMD. However, several vitamin and mineral supplements are available for maintaining eye health. All the available treatment options are meant to halt the further aggravation of the disease. However, these options cannot cure the disease completely.

Out of the currently available drugs, Lucentis is considered a gold standard for the treatment of wet AMD. The recent entrant Eylea, which was launched in 2012 in Japan and Australia, is providing a stiff competition to the other existing therapies. None the less, the off-label usage of Avastin also plays an imperative role as a treatment option in developing countries such as India and China because of its cost-efficiency.

The three approved VEGF inhibitors – Lucentis, Eylea and Macugen, together generated global sales of about $XX billion in 2012. More than 80% of the share is generated by the gold standard therapy Lucentis and approximately XX% of the estimated sale value is generated by the newly launched drug, Eylea. The share of Macugen is almost negligible compared to other drugs. The photosensitive drug Visudyne generated revenue of $XXm in 2012. However, except for Macugen all the other drugs are approved for multiple indications such as Diabetic Macular Edema (DME), myopia, Retinal Vein Occlusion (RVO). Reported sales are therefore an aggregate for all indications treated by each drug.

The route of administration of all the currently marketed wet AMD drugs is the same. Visudyne and all VEGF inhibitors are administered intravitreally. Clinical trial data indicates that Lucentis and Eylea produce very similar results. However, the dosing regimen for Eylea is different (MDF Australia, 2012). The clinical trial results of Eylea indicate that the efficacy of a bimonthly dose of Eylea after the first three monthly doses was comparable to Lucentis dosed monthly. Of all the VEGF inhibitors, the safety and efficacy profile Macugen is comparatively weak.
4.2 Pipeline Analysis by Molecule Type

The pipeline of AMD is dominated by small molecules, with 39 drug candidates or XX% of the overall pipeline (Figure 15, Panel A). When segregated on the basis of stage of development, the share of small molecules is highest in the preclinical stage (XX%), followed by Phase II (XX%) and Phase I (XX%). Out of the three product candidates that are currently in Phase III trials, one molecule falls under this category (Figure 15, Panel B).

In the overall pipeline, peptides and proteins occupy a significant share followed by small molecules. Eighteen drug candidates (XX%) are proteins and XX are peptides (XX%) (Figure 15, Panel A). Similar to small molecules the share of proteins is greater in the preclinical phase (XX%), followed by the Phase II stage of development (XX%) (Figure 15, Panel B). Out of the three products in Phase III trial, two molecules are proteins. Similar to other types, peptides have the highest number of molecules in preclinical phase (XX%) followed by Phase II (XX%). The number of peptides in the discovery phase is also similar to Phase II (Figure 15, Panel B). The percentage of monoclonal antibodies is also almost similar to that of proteins (XX%) (Figure 15, Panel A). The share of monoclonal antibodies is highest in the preclinical phase (XX%).

Apart from these molecule types, a substantial portion is occupied by cell therapy segment (XX%, XX molecules). The number of molecules that are categorized as biosimilars, vaccines and antibodies is significantly less in comparison with small molecules, proteins, peptides and monoclonal antibodies.
Figure 15: Macular Degeneration Market, Global, Pipeline, 2013

A  Age-related Macular Degeneration Pipeline by Molecule Type

- Peptide
- Small molecule
- Protein
- Monoclonal antibody
- Biosimilar
- Gene therapy
- Antibody
- Vaccine
- Cell therapy

B  Age-related Macular Degeneration Pipeline by Molecule Type and by Phase

Source: GBI Research Proprietary Pipeline Products Database [Accessed on July 18, 2013]
5.1.2 Australia

5.1.2.1 Treatment Usage Patterns

Data from the Macular Degeneration Foundation Australia indicates that macular degeneration is responsible for XX% of all blindness in the country. Approximately one in seven Australians, over XX per XX people, have some evidence of macular degeneration. In 2010, XX% of people over the age of 50 years (XX) had early signs of the disease and around XX% (XX people) had late-stage AMD. The late-stage prevalence included XX with dry AMD and XX people with the wet form of the disease. The number of people with some evidence of disease is expected to increase by XX% to XX million by 2030, in the absence of effective prevention and treatment measures (MDF Australia, 2012). As depicted in Figure 21, it is estimated that the prevalence population is set to increase from XX in 2012 to 200,250 in 2019. The treatment population is comparatively higher in Australia compared to the markets in Asia. The treatment population is estimated to increase at a CAGR of XX% during the forecast period. The core factor for this is the increased awareness of the disease and better healthcare facilities. Analysis of Medicare data and other measures (such as independent national polls) indicated that the awareness of AMD and the numbers of people requesting a check of their macula have dramatically increased from 2007 to 2011 (Heraghty et al., 2012).

5.1.2.2 Annual Cost of Treatment

The ACOT for macular degeneration is estimated to reach about $XX by 2019, growing at a CAGR of XX% from 2012. Among all the APAC markets, the Australian market is considered to have the highest ACOT for macular degeneration. The key reason for the higher ACOT there is the low penetration of the off-label Avastin, unlike other Asian markets such as India and China. The penetration of Avastin is not significant in the Australian market, as the prescription wet AMD drugs (Lucentis, Eylea and Visudyne) are included in the Pharmaceutical Benefits Scheme (PBS). Following the registration of Lucentis, the off-label usage of Avastin has declined considerably, but it is still used for patients who do not qualify for PBS-reimbursed Lucentis, as it is much cheaper than non-reimbursed Lucentis (MDF Australia, 2011). However, in contrast with India and China, the ACOT is estimated to increase at a slow pace because of their comparatively low inflation rates. The absence of any prominent product approval during the forecast period is also another major reason for the slow growth of the ACOT.

5.1.2.3 Market Size

The market for macular degeneration in Australia is expected to grow from $XXm in 2012 to $XXm in 2019, at a CAGR of XX%. The steady rise in the prevalence population, improvements in diagnostic techniques and greater awareness of the disease are the key factors that are responsible for increasing the market size during the forecast period. In spite of no new prominent drug approvals, the market is set to experience steady growth as the dominant wet-AMD drugs have recently been approved in Australia. Lucentis, which is considered the gold standard AMD drug, obtained approval in 2007, and the latest wet-AMD drug Eylea received approval in 2012 in the Australian market. Hence the market for AMD has no risk of impediment of the generic drugs during the forecast period.
Figure 21: Macular Degeneration Market, Australia, Annual Sales ($m), 2012–2019


B Annual Cost of Therapy ($)

C Revenues ($m)

## Macular Degeneration Asia-Pacific Market to 2019 – Appendix

### 7.1 All Pipeline Drugs by Phase

#### 7.1.1 Discovery

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Source: GBI Research Proprietary Pipeline Products Database [Accessed on July 18, 2013]
### 7.1.2 Preclinical

Table 5: Macular Degeneration Market, Global, Pharmaceutical Pipeline (Preclinical), 2013

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Source: GBI Research Proprietary Pipeline Products Database [Accessed on July 18, 2013]
### 7.1.3 IND-filed and Phase 0

**Table 6: Macular Degeneration Market, Global, Pharmaceutical Pipeline (IND/CTA-filed), 2013**

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Source: GBI Research Proprietary Pipeline Products Database [Accessed on July 18, 2013]

### 7.1.4 Phase I

**Table 7: Macular Degeneration Market, Global, Pharmaceutical Pipeline (Phase I), 2013**

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Source: GBI Research Proprietary Pipeline Products Database [Accessed on July 18, 2013]
### 7.1.5 Phase II

**Table 8: Macular Degeneration Market, Global, Pharmaceutical Pipeline (Phase II), 2013**

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Source: GBI Research Proprietary Pipeline Products Database [Accessed on July 18, 2013]

### 7.1.6 Phase III

**Table 9: Macular Degeneration Market, Global, Pharmaceutical Pipeline (Phase III), 2013**

<table>
<thead>
<tr>
<th>Drug/project name</th>
<th>Company</th>
<th>Targeted area</th>
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Source: GBI Research Proprietary Pipeline Products Database [Accessed on July 18, 2013]
7.1.7 Undisclosed

Table 10: Macular Degeneration Market, Global, Pharmaceutical Pipeline (Undisclosed), 2013

<table>
<thead>
<tr>
<th>Drug/project name</th>
<th>Company</th>
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Source: GBI Research Proprietary Pipeline Products Database [Accessed on July 18, 2013]

7.2 Market Forecasts to 2019

7.2.1 Asia-Pacific

Table 11: Macular Degeneration Market, Asia-Pacific, Market Forecast, 2012–2019

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7.2.2 Australia

Table 12: Macular Degeneration Market, Australia, Market Forecast, 2012–2019

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### 7.2.3 China

Table 13: Macular Degeneration Market, China, Market Forecast, 2012–2019

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### 7.2.4 India

Table 14: Macular Degeneration Market, India, Market Forecast, 2012–2019

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### 7.2.5 Japan

Table 15: Macular Degeneration Market, Japan, Market Forecast, 2012–2019

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7.3 **Market Definitions**

Market coverage: AMD in four countries in the APAC region: Australia, China, India and Japan.

The prevalence population is the estimated number of people at any given point of time who are affected by AMD.

The prescription rate is the percentage of the AMD-suffering population that has been prescribed any drug therapy.

The prescription population refers to the number of people taking any drug for AMD.

7.4 **Abbreviations**

- **µm**: Micro meter
- **ACOT**: Annual Cost of Therapy
- **AMD**: Age-related Macular Degeneration
- **ANCHOR**: Antibody for the Treatment of Predominantly Classic Choroidal Neovascularization in AMD
- **AAO**: Academy of Ophthalmology
- **APAC**: Asia-Pacific
- **AREDS**: Age-Related Eye Disease Study
- **ATE**: Arterial Thromboembolic Event
- **BCVA**: Best Corrected Visual Acuity
- **CAGR**: Compound Annual Growth Rate
- **CATT**: Comparison of Age-related macular degeneration Treatment Trials
- **CBS**: Charles Bonnet Syndrome
- **CFH**: Complement Factor H
- **CNV**: Choroidal Neovascularization
- **CNVM**: Choroidal Neovascular Membrane
- **COX**: Cyclooxygenase
- **CRVO**: Central Retinal Vein Occlusion
- **CSC**: Central Serous Chorioretinopathy
- **DME**: Diabetic Macular Edema
- **EC**: European Commission
- **EMA**: European Medicines Agency
- **EMEA**: Europe, the Middle East and Africa
- **FDA**: Food and Drug Administration
- **FFA**: Fluorescence angiography
- **FFS**: Form Fill Seal
- **GA**: Geographic Atrophy
- **ICG**: Indocyanine Green
- **IMT**: Implantable Miniature Telescope
- **LDL**: Low-Density Lipoprotein
- **OCT**: Optical Coherence Tomography
- **PBS**: Pharmaceutical Benefits Scheme
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
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<tbody>
<tr>
<td>PARP</td>
<td>Poly Adenosine diphosphate Ribose Polymerase</td>
</tr>
<tr>
<td>PCV</td>
<td>Polypoidal Choroidal Vasculopathy</td>
</tr>
<tr>
<td>PDT</td>
<td>Photodynamic Therapy</td>
</tr>
<tr>
<td>PEDs</td>
<td>Pigment Epithelial Detachments</td>
</tr>
<tr>
<td>PEDF</td>
<td>Pigment Epithelium Derived Factor</td>
</tr>
<tr>
<td>PLGF</td>
<td>Placental Growth Factor</td>
</tr>
<tr>
<td>PDGF</td>
<td>Platelet-Derived Growth Factor</td>
</tr>
<tr>
<td>POC</td>
<td>Proof of Concept</td>
</tr>
<tr>
<td>NADPH</td>
<td>Nicotinamide Adenine Dinucleotide Phosphate</td>
</tr>
<tr>
<td>NEI</td>
<td>National Eye Institute</td>
</tr>
<tr>
<td>M&amp;A</td>
<td>Mergers and Acquisitions</td>
</tr>
<tr>
<td>mg</td>
<td>Milligram</td>
</tr>
<tr>
<td>MMP</td>
<td>Matrix Metalloproteinase</td>
</tr>
<tr>
<td>MPS</td>
<td>Macular Photocoagulation Study</td>
</tr>
<tr>
<td>mTOR</td>
<td>mammalian Target Of Rapamycin</td>
</tr>
<tr>
<td>PDGFR</td>
<td>Platelet-Derived Growth Factor Receptor</td>
</tr>
<tr>
<td>RPE</td>
<td>Retinal Pigment Epithelium</td>
</tr>
<tr>
<td>RAP</td>
<td>Retinal Angiomatous Proliferation</td>
</tr>
<tr>
<td>RVO</td>
<td>Retinal Vein Occlusion</td>
</tr>
<tr>
<td>SOD</td>
<td>Superoxide Dismutase</td>
</tr>
<tr>
<td>TA</td>
<td>Triamcinolone Acetonide</td>
</tr>
<tr>
<td>TFDA</td>
<td>Tanzania Food and Drugs Authority</td>
</tr>
<tr>
<td>TGA</td>
<td>Therapeutic Goods Association</td>
</tr>
<tr>
<td>TGF</td>
<td>Transforming Growth Factor</td>
</tr>
<tr>
<td>TTT</td>
<td>Transpupillary Thermotherapy</td>
</tr>
<tr>
<td>VA</td>
<td>Visual Acuity</td>
</tr>
<tr>
<td>VEGF</td>
<td>Vascular Endothelial Growth Factor</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
7.5 References


- Bressler, N.M et al. (2002). Photodynamic Therapy of Subfoveal Choroidal Neovascularization in Age-Related Macular Degeneration with Verteporfin: additional information regarding baseline lesion composition's impact on vision outcomes-TAP report No. 3. Archives of Ophthalmology, Vol. 120, pp: 1,443–1,454


7.6 **Research Methodology**

GBI Research’s dedicated research and analysis teams consist of experienced professionals with marketing, market research and consulting backgrounds in the pharmaceutical industry as well as advanced statistical expertise.

GBI Research adheres to the codes of practice of the Market Research Society ([www.mrs.org.uk](http://www.mrs.org.uk)) and the Strategic and Competitive Intelligence Professionals ([www.scip.org](http://www.scip.org)).

All GBI Research databases are continuously updated and revised.

7.6.1 **Coverage**

The objective of updating GBI Research coverage is to ensure that it represents the most up-to-date vision of the industry possible.

Changes to the industry taxonomy are built on the basis of extensive research of company, association and competitor sources.

Company coverage is based on three key factors: market capitalization, revenues and media attention/innovation/market potential.

An exhaustive search of 56 member exchanges is conducted and companies are prioritized on the basis of their market capitalization.

The estimated revenues of all major companies, including private and governmental, are gathered and used to prioritize coverage.

Companies which is making the news, or which are of particular interest due to their innovative approach, are prioritized.

GBI Research aims to cover all major news events and deals in the pharmaceutical industry, updated on a daily basis.

The coverage is further streamlined and strengthened with additional inputs from GBI Research’s expert panel (see below).

7.6.2 **Secondary Research**

The research process begins with exhaustive secondary research on internal and external sources in order to source qualitative and quantitative information relating to each market.

The secondary research sources that are typically referred to include, but are not limited to:

- Company websites, annual reports, financial reports, broker reports, investor presentations and US Securities and Exchanges Commission (SEC) filings
- Industry trade journals, scientific journals and other technical literature
- Internal and external proprietary databases
- Relevant patent and regulatory databases
- National government documents, statistical databases and market reports
- Procedure registries
- News articles, press releases and web-casts specific to the companies operating in the market

7.6.3 **Primary Research**

GBI Research conducts hundreds of primary interviews a year with industry participants and commentators in order to validate its data and analysis. A typical research interview fulfills the following functions:

- It provides first-hand information on the market size, market trends, growth trends, competitive landscape and future outlook
- It helps in validating and strengthening the secondary research findings
- It further develops the analysis team’s expertise and market understanding
Primary research involves email and telephone interviews as well as face-to-face interviews for each market, category, segment and sub-segment across geographies.

The participants who typically take part in such a process include, but are not limited to:

- **Industry participants:** CEOs, VPs, marketing/product managers, market intelligence managers and national sales managers
- **Hospital stores, laboratories, pharmacies, distributors and paramedics**
- **Outside experts:** Investment bankers, valuation experts, research analysts specializing in specific medical equipment markets
- **Key opinion leaders:** Physicians and surgeons specializing in different therapeutic areas corresponding to different kinds of medical equipment.

### 7.6.4 Therapeutic Landscape

Revenues for each indication, geography-wise, are arrived at by utilizing the GBI Research market forecasting model. The global revenue for each indication is the sum value of revenues of all seven regions.

The annual cost of therapy for each indication is arrived at by considering the cost of the drugs, dosage of the drugs and the duration of the therapy.

The generic share of the market for each indication is obtained by calculating the prescription share for generic drugs and the respective cost of treatment.

The treatment usage pattern which includes quantitative data on the diseased population, treatment-seeking population, diagnosed population and treated population for an indication, is arrived at by referring to various sources as mentioned below.

GBI Research uses the epidemiology-based treatment flow model to forecast market size for therapeutic indications.

#### 7.6.4.1 Epidemiology-based Forecasting

The forecasting model used at GBI Research makes use of epidemiology data gathered from research publications and primary interviews with physicians to represent the treatment flow patterns for individual diseases and therapies. The market for any disease segment is directly proportional to the volume of units sold and the price per unit.

\[
\text{Sales} = \text{Volume of Units sold} \times \text{Price per Unit}
\]

The volume of units sold is calculated on the average dosage regimen for that disease, duration of treatment and number of patients who are prescribed drug treatment (prescription population). Prescription population is calculated as the percentage of population diagnosed with a disease (diagnosis population). Diagnosis population is the population diagnosed with a disease expressed as a percentage of the population that is seeking treatment (treatment-seeking population). Prevalence of a disease (diseased population) is the percentage of the total population who suffer from a disease/condition.

Data on the treatment seeking rate, diagnosis rate and prescription rate, if unavailable from research publications, are gathered from interviews with physicians and are used to estimate the patient volumes for the disease under consideration. Therapy uptake and compliance data are fitted in the forecasting model to account for patient switching and compliance behavior.

To account for the differences in patient affordability of drugs across various geographies, macroeconomic data such as inflation and GDP; and healthcare indicators such as healthcare spending, insurance coverage and average income per individual are used.

Annual cost of treatment is calculated using product purchase frequency and the average price of the therapy. Product purchase frequency is calculated from the dosage data available for the therapies and drug prices are gathered from public sources. The sources for the price of drugs are RxUSA, ZenRx and the British National Formulary.

The epidemiology-based forecasting model uses a bottom-up methodology and it makes use of estimations in the absence of data from research publications. Such estimations may result in a final market value that is different from the actual value. To correct this ‘gap’ the forecasting model uses ‘triangulation’ with the help...
of base-year sales data (from company annual reports, internal and external databases) and sales estimations.

**Analogous Forecasting Methodology**

Analogous forecasting methodology is used to account for the introduction of new products, patent expiries of branded products and the subsequent introduction of generics. Historic data for new product launches and generics penetration are used to arrive at robust forecasts. An increase or decrease of prevalence rates, treatment seeking rate, diagnosis rate and prescription rate are fitted into the forecasting model to estimate the market growth rate.

GBI Research’s proprietary model enables it to account for the impact of individual drivers and restraints in the growth of the market. The year of impact and the extent of impact are quantified in the forecasting model to provide close-to-accurate data sets.

**Diseased Population**

The diseased population for any indication is the prevalence. The prevalence population for this report is taken from articles published in various journals including the Investigative Ophthalmology & Visual Science, Journal of Ophthalmology and Archives of Ophthalmology.

**Prescription Population**

Treatment options for AMD depend upon the stage of the disease and the type of lesion. Options for the treatment of AMD include surgical intervention, non-biologic drug therapy and biologic drug therapy. The prescription population is defined as the number of patients who are prescribed biologic drug therapy. This is calculated as a percentage of the diagnosis population. The prescription population proportion is taken from articles published in various journals including the Journal of Ocular Biology, Diseases, Informatics, Retina.
7.6.4.2 Market Size by Geography

The treatment usage pattern and annual cost of treatment in each country has been factored in while deriving the individual country market size.

Forecasting Model for Therapeutic Areas

The figure above represents a typical forecasting model followed in GBI Research. As discussed previously, the model is built on the treatment flow patterns. The model starts with the general population, then the diseased population as a percentage of the general population and then follows the treatment seeking population as a percentage of the diseased population and diagnosed population as a percentage of the treatment seeking population. Finally, the total volume of units sold is calculated by multiplying the treated population by the average dosage per year per patient.
7.6.5 Geographical Landscape

GBI Research analyzed four geographies: Australia, China, India and Japan. The total market size for each country is provided, which is the sum value of the market sizes of all the indications for that particular country.

Articles from research journals and agency publications such as the Journal of Ophthalmology, Investigative Ophthalmology & Visual Science, National Institute of Health and ClinicalTrials.gov are the sources of data for the estimation of market sizes and making forecasts.

7.6.6 Pipeline Analysis

This section provides a list of molecules at various stages in the pipeline for various indications. The list is sourced from an internal database and validated for the accuracy of its phase and mechanism of action data at ClinicalTrials.gov and through company websites. The section also includes a list of promising molecules that is narrowed down based on the results of the clinical trials at various stages and the novelty of mechanism of action. A heat map, sourced from relevant clinical trials, is provided in order to compare these products to one another in addition to currently marketed products. The latest press releases issued by the relevant companies and news reports are also sources of information for the status of the molecule in the pipeline. This list of pipeline molecules, in conjunction with a list of ongoing and completed clinical trials, is analyzed in this section, and a full breakdown of pipeline molecules and clinical trials by phase, molecule type and molecular target is provided.

7.7 Expert Panel Validation

GBI Research uses a panel of experts to cross-verify its databases and forecasts.

GBI Research’s expert panel comprises marketing managers, product specialists, and international sales managers from pharmaceutical companies, academics from research universities and key opinion leaders from hospitals.

Historic data and forecasts are relayed to GBI Research’s expert panel for feedback and are adjusted in accordance with their feedback.

7.9 Disclaimer

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