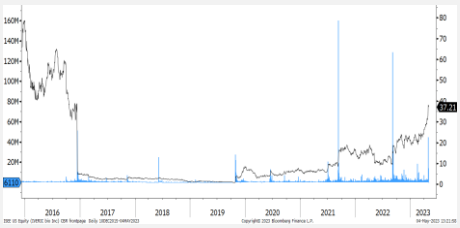
Iveric Bio (ISEE) / Astellas Pharma (4503 JT)
Merger

We don't see serious antitrust issues, however we note that pipeline-related events are not carved out of MAE and the deal might not close before the August 19 PDUFA date.

Deal Terms
1 ISEE = $40

Target: Iveric Bio	
Country	US
Bloomberg	ISEE
Sector	Biotech
Share price (USD)	38.05
Market cap (USD mn)	5,221.8
Free float %	~99
Acquirer: Astellas Pharma	
Country	Japan
Bloomberg	4503 JT
Sector	Large Pharma
Share price (JPY)	2080
Market cap (JPY bn)	3,764.1
Free float %	~98

ISEE Price Chart



Deal status: HSR, proxy filing by May 19.

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Regulatory:

- HSR approval is required
- We note that there is no divestiture obligation set out in the DMA.
- Parties are required to litigate in case of a regulatory challenge.
- **Iveric's key asset is avacincaptad pegol (ACP), currently in trials for treating geographic atrophy**, the advanced stage of macular degeneration, a common cause of vision loss in the elderly.
- ACP, branded as Zimura, **targets the C5 protein** suspected in causing the growth of scarring associated with the disease.
- **Iveric competes with Apellis Pharmaceuticals, which in February received the first-ever FDA approval for a GA therapy, Syfovre (pegcetacoplan injection, C3 inhibitor); and the duo of Lineage Cell Therapeutics and Roche, which are developing OpRegen® (RG6501), a retinal pigment epithelial cell therapy that has generated positive Phase I/IIa results in GA**
- **Most of Astellas' ophthalmology pipeline is in early, preclinical stage**.
- According to Astellas' website, only one candidate in the company's Blindness & Regeneration pipeline is in clinical phases—**ASP7317, a cell therapy consisting of human embryonic stem cell-derived retinal pigment epithelial cells.**
- **Like ACP, ASP7317 targets GA secondary to AMD, though it is also in development for Stargardt disease. ASP7317 is under study in a Phase Ib trial** (NCT03178149), whose estimated primary completion date is August 31, 2014.
- **In addition to Astellas' already approved treatment, there are several other companies with product candidates for GA (and Stargardt disease) in more advanced stages, therefore, we believe that antitrust risk is manageable.**
- **We don't expect an extended review, however a pull and refile might not be ruled out.**

Business risk

- **Product/pipeline related issues are not carved out of MAE.**
- Upcoming catalysts:
    - "FDA accepted the filing of our new drug application for ACP for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD), granting the NDA priority review and a **PDUFA goal date of August 19, 2023."**
    - If approved, the treatment could be commercialised by the end of this year.
- We note that the deal might not close before the PDUFA date.

Counter bid

- Parties interested in the field have an alternative in Iveric competitor Apellis.
- Bloomberg reported early last month that Apellis (APLS) had attracted takeover interest from large pharmaceutical companies. Apellis.
- APLS's GA treatment is already approved by the FDA, however we note that the company's market cap is almost 10b.

Valuation

- The purchase price represents a premium of 64% to Iveric Bio's unaffected closing share price of US$24.33 on March 31, 2023, and a premium of 75% to Iveric Bio's 30 trading day volume weighted average price as of March 31, 2023. The Boards of Directors of both companies have unanimously approved the transaction
- Several analysts estimate a $2b peak sales for ACP, which translates into a cca 3x peak sales multiple.
- Larger deals, where targets already had marketed products, were struck at higher multiples (HZNP >4x, SGEN >5x), while smaller acquisitions with pipeline assets only were cheaper at 2-3x.

Key terms of the merger

Transaction Details	
Deal announcement	May 1, 2023
Offer terms	1 ISEE = $40
Deal size	$5.9b
Offer structure	All cash merger
Target's Board Recommendation	Yes
Voting Agreement	No
ISEE incorp.	US (DE)
Deal announcement	Click here for the announcement
DMA	Click here for the DMA
Synergies	N/A

Indicated Closing Date

- Deal to close in 2Q of Astellas' fiscal year 2023 or 3Q of 2023 on calendar year basis

Timetable	
DMA	April 28, 2023
Deal announcement	May 1, 2023
HSR filing (15BD)	May 19, 2023
Proxy filing deadline (15BD)	May 19, 2023
HSR initial wp expires	June 18, 2023
Proxy effective	Late-June / July 2023
Shareholder meeting	August 2023
PDUFA goal date	August 19, 2023
Deal close (Co est)	3Q2023
Outside Date	October 27, 2023
Extended Outside Date I	January 25, 2023
Extended Outside Date II	April 21, 2023

Dividends

- ISEE does not pay any dividends.

Key offer conditions

- Shareholder vote (ISEE) - a majority of the outstanding shares
- Regulatory (HSR, foreign approvals)
- No injunctions
- Reps and warranties
- Performance of obligations
- No Company MAE

Governing Law

- Delaware

Break Fee

- Upon termination of the Merger Agreement, under specified circumstances, the Company will be required to pay Parent a termination fee of $222,370,000. Such circumstances include where the Merger Agreement is terminated (i) in connection with the Company accepting a Superior Offer approved by the Board of Directors, (ii) due to the Board of Directors' change or withdrawal of, or failure to reaffirm, its recommendation of the Merger, or (iii) because the Board of Directors or the Company intentionally breach their non-solicit obligations under the Merger Agreement in any material respects. This termination fee will also be payable if the Merger Agreement is terminated because the Company's stockholders did not vote to adopt the Merger Agreement, the Merger is not consummated before the End Date, or the Company breaches its representations, warranties or covenants in a manner that would cause the related closing conditions to not be met, and prior to any such termination, a proposal to acquire at least 50% of the Company's stock or assets is communicated to the Board of Directors or publicly disclosed and the Company enters into an agreement for, or consummates, a transaction contemplated by such proposal within one year of termination.

MAE Definition

- "Company Material shall mean any event, development, occurrence, circumstance, change or effect which, individually or when taken together with all other events, developments, occurrences, circumstances, changes or effects which have occurred in the applicable determination period for a Material Adverse Effect, has had or would reasonably be expected to have a material adverse effect on (a) the ability of the Company to (x) perform any of its material obligations under this Agreement required to consummate the Transactions on or before the End Date, or (y) to

consummate the Transactions on or before the End Date, or (b) the business, assets, financial condition or results of operations of the Acquired Corporations, taken as a whole;

- **Carve-outs**
- (i) any change in the market price or trading volume of the Company's stock or change in the Company's credit ratings; provided that the underlying causes of any such change may be considered in determining whether a Material Adverse Effect has occurred to the extent not otherwise excluded by another exception herein;
- (ii) any event, development, occurrence, circumstance, change or effect directly resulting from the announcement, pendency or performance of the Transactions; provided that this clause
    - (ii) shall not apply to any representation or warranty (or condition to the consummation of the Merger relating to such representation or warranty) to the extent the purpose of such representation and warranty is to address the consequences resulting from the execution and delivery of this Agreement or the pendency, performance or consummation of the Transactions (including the Merger), including any representations or warranties contained in Section 2.8(j), Section 2.17(i), Section 2.21 or Section 2.23 and the condition set forth in Section 6.2(a) solely as such condition relates to Section 2.8(j), Section 2.17(i), Section 2.21 or Section 2.23;
- (iii) any event, development, occurrence, circumstance, change or effect generally affecting the industries in which the Acquired Corporations operate or in the economy generally or other general business, financial or market conditions;
- (iv) any event, development, occurrence, circumstance, change or effect arising from fluctuations in the value of any currency or interest rates; provided that the underlying causes of such event, development, occurrence, circumstance, change or effect may be considered in determining whether a Material Adverse Effect has occurred to the extent not otherwise excluded by another exception herein;
- (v) any event, development, occurrence, circumstance, change or effect arising from any act of terrorism, war, national or international calamity, natural disaster, acts of god, epidemic, pandemic or any other similar event;
- (vi) the failure of the Company to meet internal or analysts' expectations or projections; provided that the underlying causes of such failure may be considered in determining whether a Material Adverse Effect has occurred to the extent not otherwise excluded by another exception herein;
- (vii) any event, development, occurrence, circumstance, change or effect resulting or arising from the identity of, or any facts or circumstances relating to, Parent, Merger Sub or any of their respective Affiliates; or
- (viii) any event, development, occurrence, circumstance, change or effect arising from any change in, or any compliance with or action taken solely for the purpose of complying with any change in, any Legal Requirement or GAAP (or interpretations of any Legal Requirement or GAAP) after the date of the Agreement;

provided that any event, development, occurrence, circumstance, change or effect referred to in the foregoing clauses (iii), (iv), (v) and (viii) may be taken into account in determining whether there is, or would be reasonably expected to be, a Material Adverse Effect to the extent such event, development, occurrence, circumstance, change or effect disproportionately affects the Acquired Corporations relative to other participants in the industries in which the Acquired Corporations operate.

Antitrust related clauses

- Litigation obligation: Yes
- Regulatory break fee: No
- Divestiture obligation: No

Specific performance

- Yes

Key ISEE Shareholders

Vanguard 7.4%

BlackRock 7.1%

Deep Track Capital 5.7%

Company Description

IVERIC BIO DESCRIPTION

- Iveric Bio is a science-driven biopharmaceutical company focused on the discovery and development of novel treatments for retinal diseases with significant unmet medical needs. The Company is committed to having a positive impact on patients' lives by delivering high-quality, safe, and effective treatments designed to address debilitating retinal diseases including earlier stages of age-related macular degeneration.

- Iveric Bio focuses on the discovery and development of novel treatments in the field of ophthalmology.
- The company announced in February 2023 that the U.S. Food and Drug Administration ("FDA") accepted for filing a New Drug Application ("NDA") for ACP for the treatment of GA secondary to AMD. The NDA has been granted priority review with a Prescription Drug User Fee Act **("PDUFA") goal date of August 19, 2023.**
- **ACP, a complement C5 inhibitor, is an investigational drug for GA secondary to AMD** and has significant potential to deliver value to a large and underserved patient base. ACP met its primary efficacy endpoint (reduction of the rate of GA progression) with statistical significance across two pivotal clinical trials (GATHER Clinical Trials) and has received breakthrough therapy designation*1 from the FDA for this indication.
- **Iveric pipeline:**

Clinical & Nonclinical Pipelines

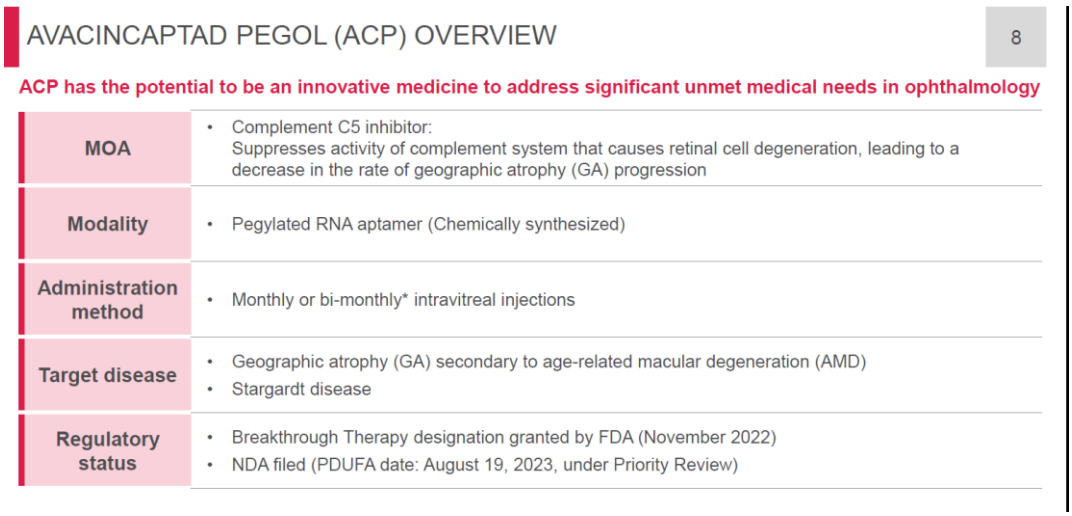
Clinical Asset	MOA / modality	Target disease	Stage
Avacincaptad Pegol (ACP)	C5 inhibitor / RNA aptamer	Geographic Atrophy (GA) secondary to age-related macular degeneration (AMD)	NDA (US; PDUFA date: August 19, 2023)
		Stargardt disease	Phase 2b

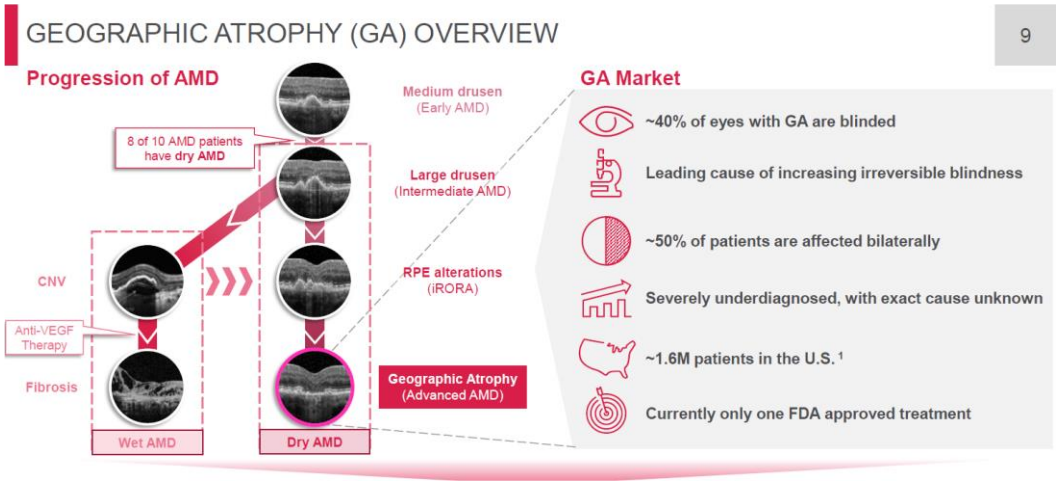
Nonclinical Asset	MOA / modality	Target disease	Stage
IC-500	HtrA1 inhibitor / small molecule	GA secondary to AMD	Preclinical
Mini-CEP290	miniCEP290 gene replacement (AAV)	Leber's congenital amaurosis 10	Research
Mini-ABCA4	miniABCA4 gene replacement (AAV)	Stargardt disease type 1	Research
Mini-USH2A	miniUSH2A gene replacement (AAV)	Usher syndrome type 2	Research

Source: Iveric Bio

AMD, GA and ACP:

- Age-related macular degeneration (AMD) is the major cause of moderate and severe loss of central vision in aging adults, affecting both eyes in the majority of patients. The macula is a small area in the central portion of the retina responsible for central vision. As AMD progresses, the loss of retinal cells and the underlying blood vessels in the macula results in marked thinning and/or atrophy of retinal tissue. Geographic atrophy secondary to AMD, leads to irreversible loss of vision in patients and has a high unmet medical need. It is estimated that approximately 1.6 million people in the U.S. have GA in at least one eye.
- Avacincaptad pegol (ACP) is an investigational drug that is currently under evaluation for safety and efficacy by the U.S. FDA. ACP is a novel complement C5 protein inhibitor. Overactivity of the complement system and the C5 protein are suspected to play a critical role in the development and growth of scarring and vision loss associated with geographic atrophy (GA) secondary to age-related macular degeneration (AMD). By targeting C5, ACP has the potential to decrease activity of the complement system that causes the degeneration of retinal cells and potentially slow the progression of GA.
- ACP met its primary endpoint in the completed GATHER1 clinical trial and the ongoing GATHER2 clinical trial both of which are randomized, double-masked, sham-controlled, multicenter Phase 3 clinical trials. These clinical trials evaluated the safety and efficacy of monthly 2 mg intravitreal administration of ACP in patients with GA secondary to AMD. For the first 12 months in both trials, patients were randomized to receive either ACP 2 mg or sham monthly. There were 286 participants enrolled in GATHER1 and 448 participants enrolled in GATHER2. The primary efficacy endpoints in both pivotal studies were based on GA area measured by fundus autofluorescence at three time points: Baseline, Month 6, and Month 12. The mean rate of growth (slope) in GA area from baseline to month 12 using observed data was 35% in GATHER 1 and 18% in GATHER2. In GATHER1 and GATHER2 combined, the most frequently reported treatment emergent adverse events in the 2 mg recommended dose were related to injection procedure. The most common adverse reactions (≥ 5% and greater than sham) reported in patients who received avacincaptad pegol 2 mg were conjunctival hemorrhage (13%), increased IOP (9%), and CNV (7%). After 18 months of treatment in GATHER1 and 12 months of treatment in GATHER2, there were no events of serious intraocular inflammation, vasculitis, or endophthalmitis.





Source: Iveric Bio

ASTELLAS PHARMA DESCRIPTION

- Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality.
- The Primary Focus' mission is to identify, develop and deliver next generation treatments to restore sight for patients with retinal diseases.
- Astellas' main products
    - Notable products in our lineup include XTANDI® (treatment for prostate cancer), mirabegron (treatment for overactive bladder), and Prograf® (immunosuppressant). We expect future growth of key strategic products such as PADCEV® (treatment for urothelial cancer), XOSPATA® (treatment for acute myeloid leukemia) and EVRENZO® (treatment for chronic kidney disease).
        - XTANDI® (enzalutamide): XTANDI is a treatment for prostate cancer.
        - XOSPATA® (gilteritinib): XOSPATA is a treatment for patients who have relapsed or refractory acute myeloid leukemia (AML) with a *FLT3* mutation.
        - PADCEV® (enfortumab vedotin): PADCEV is a treatment for patients with locally advanced or metastatic urothelial cancer who have previously received other treatments.
        - Evrenzo® (roxadustat): Evrenzo is a treatment for anemia associated with chronic kidney disease (CKD).
        - Betanis®/Myrabetriq™/BETMIGA™ (mirabegron): Betanis/Myrabetriq/BETMIGA is a treatment for overactive bladder (OAB).
        - Prograf® and Advagraf™/Graceptor®/ASTAGRAF XL™ (tacrolimus): Prograf and Advagraf/Graceptor/ASTAGRAF XL are immunosuppressants.

Deal rationale

- Astellas has identified five Primary Focuses, including "Blindness & Regeneration", and is prioritizing investment resources in these areas. As such, this transaction is a key step in building Astellas' product portfolio in this important area.
- Astellas expects that the acquisition of Iveric Bio will not only contribute to Astellas' FY2025 revenue targets set in its Corporate Strategic Plan 2021, but also, that ACP in conjunction with fezolinetant and PADCEV, is anticipated to be a revenue-generating pillar to help compensate for the decline in sales of XTANDI due to anticipated patent expiration later this decade.
- In addition, the acquisition of Iveric Bio will provide a foundation of ophthalmology focused capabilities, including a multi-faceted commercial team, expansive network of experts in the ophthalmology field, established relationships with medical institutions, and the infrastructure and experience to drive our combined ophthalmology business going forward. Furthermore, through acquired capabilities, Astellas will accelerate pre-clinical and clinical development and commercialization activities to positively contribute to the goals of Primary Focus, "Blindness & Regeneration."

Key risks

REGULATORY APPROVALS / TIMING

- HSR, and possibly foreign antitrust approvals are also required.

Overlap:

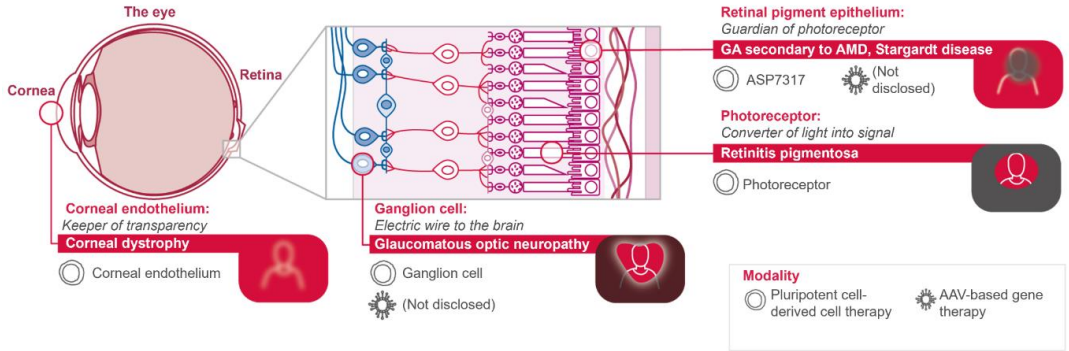
- **Astellas ophthalmology pipeline:**
- Most of Astellas' ophthalmology pipeline is in early, preclinical stage.
- According to Astellas' website, only one candidate in the company's Blindness & Regeneration pipeline is in clinical phases—**ASP7317**, **a cell therapy** consisting of human embryonic stem cell-derived retinal pigment epithelial cells.
- **Like ACP, ASP7317 targets GA secondary to AMD**, though it is **also in development for Stargardt disease**. **ASP7317 is under study in a Phase Ib trial** (NCT03178149) whose estimated primary completion date is August 31, 2014.
- Last year, screening and enrollment in the Phase Ib trial for ASP7317 was put on hold "due to a manufacturing delay," according to an accompanying presentation. Screening and enrollment were restarted last August, with dosing of patients expected to resume during Astellas' current fiscal year, which ends March 31, 2024.

Blindness and Regeneration	ASP7317	Retinal pigment epithelium cells	Geographic atrophy secondary to age-related macular degeneration, Stargardt disease	In-house (Ocata Therapeutics)

- ASP7317, human embryonic stem cell-derived retinal pigment epithelial cells, is our lead program for geographic atrophy secondary to age-related macular degeneration and Stargardt disease in phase 1b clinical trial.
- ASP2020, a universal donor cell-derived program, has recently entered into the pipeline. We believe universal donor cell technology is a powerful tool to solve or reduce the problem of immune rejection and to realize the ideal cell transplantation.

Program	Modality/Mechanism	Indication	Current phase	Origin/Partner
ASP7317	RPE cell	Geographic atrophy secondary to AMD, Stargardt disease	Phase 1	astellas
ASP1015	Gene therapy (AAV)	Glaucoma	Preclinical	Quethera*
ASP1819	Photoreceptor rescue cell	Retinitis pigmentosa	Preclinical	astellas
ASP2020	Universal donor cell (UDC) RPE	Dry AMD, Other macular degeneration	Preclinical	Universal Cells*
(Not disclosed)	Ganglion rescue cell	Glaucoma, Optic neuropathy	Discovery	astellas
(Not disclosed)	Corneal endothelial cell	Corneal dystrophy	Discovery	astellas
(Not disclosed)	Vascular progenitor cell	Vascular disease	Discovery	astellas

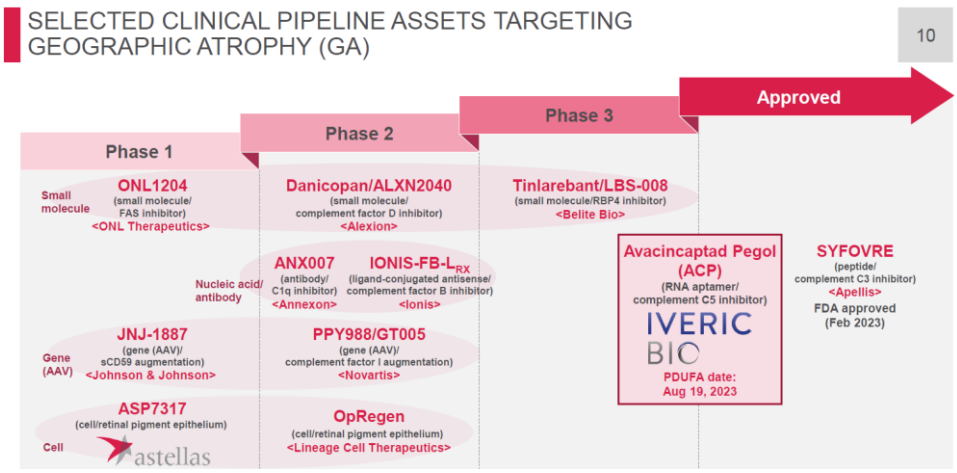
* Acquired (current programs classified as 'in-house')
RPE: Retinal pigment epithelial, AMD: Aged-related macular degeneration, AAV: Adeno-associated virus



Source: Astellas

Competition

- **In GA, Iveric competes with Apellis Pharmaceuticals, which in February received the first-ever FDA approval for a GA therapy**, Syfovre (pegcetacoplan injection); and the duo of Lineage Cell Therapeutics and Roche, which are developing OpRegen® (RG6501), a retinal pigment epithelial cell therapy that has generated positive Phase I/IIa results in GA, most recently last week at the 2023 Association for Research in Vision and Ophthalmology Annual Meeting (ARVO 2023).
- **The Apellis drug, Syfovre (c3 inhibitor), is the first to win FDA approval for the treatment of geographic atrophy secondary to AMD** and is forecast to generate peak revenue of more than $1 billion, according to analyst estimates.
    - In December 2022, Apellis submitted an MAA to the EMA. Apellis announced that the EMA had validated their MAA and the application was under review, with a decision expected in early 2024.
- LumiThera, Inc. has a medical device using its LT-300 light delivery system, which is approved in the European Union for the treatment of dry AMD.
- There are a number of products in preclinical and clinical development by third parties to treat GA or dry AMD. In general, these product candidates can be categorized based on their proposed mechanisms of action. The mechanisms of action for these product candidates include complement system and inflammation suppression, visual cycle modulators, antioxidants and neuroprotectants, cell and gene therapies and vascular perfusion enhancers.
- According to Apellis, AstraZeneca PLC (which acquired Alexion Pharmaceuticals, Inc. in 2021), Akari Therapeutics, Plc, Annexon Inc., Apellis, Applied Genetic Technologies Corporation, or AGTC, Biogen Inc., Gemini Therapeutics, Inc. (which merged with Disc Medicine, Inc.), Gyroscope Therapeutics (which was acquired by Novartis AG), IONIS Pharmaceuticals, Inc. (in collaboration with Roche AG), Janssen Pharmaceuticals Inc. (which acquired its program through the acquisition of Hemera Biosciences, LLC), Kanaph Therapeutics Inc, NGM Biopharmaceuticals Inc. and Novartis AG **each have complement inhibitors in development for GA or dry AMD**, including, in the cases of Gyroscope Therapeutics and Janssen Pharmaceuticals, complement inhibitor gene therapies and in the cases of AGTC and Gemini Therapeutics, research programs on complement factor H gene therapy.
    - Several other companies, including Allegro Ophthalmics, LLC, Alkeus Pharmaceuticals Inc., Astellas Pharma Inc., Aviceda Therapeutics, Boehringer Ingelheim, Lineage Cell Therapeutics, Inc. (which was acquired by Roche AG), Ocugen, Inc., ONL Therapeutics, Inc., Regenerative Patch Technologies, Roche AG, Stealth BioTherapeutics Corp. and Visus Therapeutics, are pursuing development programs for the treatment GA or dry AMD using different mechanisms of action outside of the complement system, including Genentech, Inc. (an affiliate of Roche AG) and Gemini Therapeutics, which are pursuing HtrA1 inhibition as a mechanism of action. The most advanced HtrA1 inhibitor program in development was Genentech's monoclonal antibody HtrA1 inhibitor, which was being studied in a Phase 2 clinical trial until it was discontinued in October 2022.
    - Several other companies that are actively developing product candidates for the treatment of GA, including the following product candidates that are in clinical development: ANX007, a C1q inhibitor being developed by Annexon Biosciences, Inc. in Phase 2 clinical trials; GT005, a CFI expression subretinal gene therapy being developed by Novartis in Phase 2 clinical trials (Novartis completed its acquisition of Gyroscope Therapeutics in February 2022); IONIS-FB-L(RX), a complement factor B inhibitor being developed by Ionis (in collaboration with Roche/Genentech) in Phase 2 clinical trials; danicopan (ALXN2040), an orally administered factor D inhibitor being developed by AstraZeneca in Phase 2 clinical trials; HMR59, an intravitreal gene therapy targeting CD59 being developed by The Janssen Pharmaceutical Companies of Johnson & Johnson (after acquisition from Hemera Biosciences), which completed and presented Phase 1 results in 2022; and other product candidates that do not target the complement system that are either in a single Phase 3 or in Phase 2 clinical trials, including therapies being developed by Alkeus Pharmaceuticals, Inc., Lineage Cell Therapeutics, Inc. (in collaboration with Roche/Genentech), and Regenerative Patch Technologies, LLC. Novartis has initiated a Phase 2 trial of orally administered iptacopan, a factor B inhibitor, in patients with early or intermediate AMD.



Source: Astellas

- **Competitive considerations for Stargardt disease:**
- There are a number of products in preclinical research and clinical development by third parties to treat Stargardt disease.
- AGTC, Alkeus Pharmaceuticals, Inc., Beam Therapeutics Inc., Biogen, Generation Bio Co., Kubota Vision Inc. (formerly Acucela), Lin BioScience, Inc., ProQR Therapeutics N.V., or ProQR, and Spark Therapeutics (a subsidiary of Roche AG) each have research or development programs in Stargardt disease.
- Three of these programs, Alkeus, Kubota and Lin BioScience, are exploring the use of oral therapeutics, while AGTC, Nightstar and Spark are each using a gene therapy approach, Beam is using a base editing approach, and ProQR is using an RNA-based approach. **Kubota's product candidate, to which the FDA and the EMA granted orphan drug designation in August 2020, is in Phase 3 development while Alkeus's product candidate is in Phase 2 development.** In addition, several academic organizations have early stage programs in Stargardt disease.
- Nanoscope has a gene therapy in Phase 1/2. Phase 2 fully enrolled, key 6-month data due in 1H2023.
- Belite Bio (Phase 3): "Developed from our RBP4 intellectual property portfolio, our lead candidate, LBS-008, has initiated its phase 3 for Stargardt disease, an inherited juvenile form of macular degeneration, and expects to initiate its phase 3 for dry age-related macular degeneration in 2022. LBS-008 has obtained Orphan Drug Designation in the United States and Europe and has been granted a Rare Pediatric Disease (RPD) designation and Fast Track Designation in the US."
    - "We recruited 41 subjects out of the 90 subjects into our global Phase 3 Stargardt study. And we are expecting interim readouts by the mid 2024 next year"

CBR summary

- **Astellas' overlapping ophthalmology pipeline is in early, preclinical stage.**
- **In addition to Astellas' already approved treatment, there are several other companies with product candidates for GA (and Stargardt disease) in more advanced stages, therefore, we believe that antitrust risk is manageable.**
- **We don't expect an extended review, however a pull and refile might not be ruled out.**

BUSINESS RISK

- **Product/pipeline related issues are not carved out of MAE.**
- Upcoming catalysts:
    - "FDA accepted the filing of our new drug application for ACP for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD), granting the NDA priority review and a PDUFA goal date of August 19, 2023."
    - If approved, the treatment could be commercialised by the end of this year.

COUNTER BID

- Parties interested in the field have an alternative in Iveric competitor Apellis.
- Bloomberg reported early last month that Apellis (APLS) had attracted takeover interest from large pharmaceutical companies. Apellis.
    - Deliberations are ongoing and there's no certainty they will lead to a transaction, the people said.
    - The company currently prefers to stay independent, two of the people said.
- **APLS's GA treatment is already approved by the FDA, however we note that the company's market cap is almost 10b.**

Valuation

PREMIUM

- The purchase price represents a premium of 64% to Iveric Bio's unaffected closing share price of US$24.33 on March 31, 2023, and a premium of 75% to Iveric Bio's 30 trading day volume weighted average price as of March 31, 2023. The Boards of Directors of both companies have unanimously approved the transaction.

DEAL MULTIPLE

- Several analysts estimate a $2b peak sales for ACP, which translates into a cca 3x peak sales multiple.
    - Larger deals, where targets already had marketed products, were struck at higher multiples (HZNP >4x, SGEN >5x), while smaller acquisitions with pipeline assets only were cheaper at 2-3x.
- The deal marks the fifth major overseas acquisition by Astellas, Japan's third biggest drugmaker by sales, since 2019 in a push to shore up its pipeline as its main sellers lose patent protection.

Disclosures:

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