



Astellas Enters Into Definitive Agreement to Acquire Iveric Bio

April 30, 2023

-Companies to Create World-Class Ophthalmology Entity-

-Lead Program, Avacincaptad Pegol for the Potential Treatment of Geographic Atrophy with PDUFA Goal Date of August 19, 2023-

-Acquisition advances Astellas' Primary Focus on "Blindness & Regeneration"-

-Acquisition price of US\$40 per share in cash, representing a total equity value of approximately US\$5.9 billion-

TOKYO & PARSIPPANY, N.J.--(BUSINESS WIRE)--Apr. 30, 2023-- Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") and IVERIC Bio, Inc. (NASDAQ: ISEE, CEO: Glenn P. Sblendorio, "Iveric Bio") today announced that on April 29, 2023 (Japan time), the Companies have entered into a definitive agreement under which Astellas through Berry Merger Sub, Inc., a wholly-owned subsidiary of Astellas US Holding, Inc., has agreed to acquire 100% of the outstanding shares of Iveric Bio for US\$40.00 per share in cash for a total equity value of approximately US\$5.9 billion (the "Acquisition"). In the Acquisition, Iveric Bio will become an indirectly wholly-owned subsidiary of Astellas. The total equity value of Iveric Bio in the Acquisition assumes that there are approximately 148.2 million outstanding shares of Iveric Bio common stock on a fully diluted basis. 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.

"We are pleased to reach an agreement with Iveric Bio, a company with exceptional expertise in the R&D of innovative therapeutics in the ophthalmology field," said Naoki Okamura, President and CEO, Astellas. "Iveric Bio has promising programs including Avacincaptad Pegol ("ACP"), an important program for Geographic Atrophy ("GA") secondary to Age-Related Macular Degeneration ("AMD"), and capabilities across the entire value chain in the ophthalmology field. We believe that this acquisition will enable us to deliver greater VALUE to patients with ocular diseases at high risk of blindness."

"This transaction with Astellas, a highly respected pharmaceutical company, demonstrates the significant value that we have built for our stockholders and recognizes the tremendous work by our dedicated team at Iveric Bio," said Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio.

"The opportunity to create a world-class entity with the ophthalmology expertise and capabilities of Iveric Bio and the global reach and resources of Astellas is unique and has the potential to benefit patients worldwide suffering from blinding retinal diseases, including GA," said Pravin U. Dugel, MD, President of Iveric Bio.

1. Strategic Objectives of the Acquisition

Astellas aims to become a cutting-edge, VALUE-driven life science innovator to realize its VISION to be "on the forefront of healthcare change to turn innovative science into VALUE for patients." Through Astellas' R&D strategy, [Focus Area Approach](#), it is working to create innovative drugs for diseases with high unmet medical need by identifying unique combinations of biology and therapeutic modality / technology from multiple perspectives. Currently, 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.

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.

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."

Funds for the acquisition consist of newly procured funds from bank loans and issuing of commercial paper totaling approximately 800 billion yen and existing cash on hand. Astellas expects to repay this debt within the next five to seven years. The completion of the Acquisition is not subject to a financing condition. Astellas does not anticipate making any change in its dividend policy following the Acquisition.

The closing of the proposed Acquisition is subject to approval by Iveric Bio's stockholders and other customary closing conditions, including receipt of required regulatory approvals. The companies expect to complete the Acquisition in the second quarter of Astellas' fiscal year 2023 (third calendar

quarter of 2023). A copy of the merger agreement regarding the proposed Acquisition will be filed with the U.S. Securities and Exchange Commission (“SEC”) and will be publicly available on the SEC’s website at (<http://www.sec.gov>).

2. Overview of Iveric Bio

① Company	IVERIC bio, Inc.
② Address	8 Sylvan Way Parsippany, NJ 07054, US
③ Representative’s Title and Name	CEO, Glenn P. Sblendorio
④ Business Description	R&D of pharmaceuticals
⑤ Stated Capital	US\$ 137 thousand (as of December 31, 2022)
⑥ Consolidated Stockholders’ equity	US\$ 534,657 thousand (as of December 31, 2022)
⑦ Year of Establishment	2007
⑧ Number of Shares Outstanding	137,616,082 (as of April 27, 2023)
⑨ Major shareholders and ownership ratio (*)	Vanguard Group, Inc.: 7.4% BlackRock, Inc.: 7.1% Deep Track Capital, LP: 5.7%

⑩ Relationship between Astellas and Iveric Bio

Capital Relationship:	There is no capital relationship between Astellas and Iveric Bio required to be disclosed.
Personal Relationship:	There is no personal relationship between Astellas and Iveric Bio required to be disclosed.
Business Relationship:	There is no business relationship between Astellas and Iveric Bio required to be disclosed.
Status of A Related Party Iveric Bio is not an affiliated party of Astellas.	

⑪ Iveric Bio’s consolidated operating results and consolidated financial position for the past three years(**)

Accounting Period (in thousands except per share data)	Fiscal year ended December, 2020	Fiscal year ended December, 2021	Fiscal year ended December, 2022
Total Equity	191,563	360,528	534,657
Total Assets	216,754	389,358	666,823
Equity per share (US \$)	2.58	3.54	4.42
Revenue (***)	-	-	-
Operating Loss	(88,736)	(114,757)	(189,906)
Loss before taxes	(88,242)	(114,522)	(185,211)
Net Loss	(84,547)	(114,522)	(185,211)
Net Loss per share (US \$)	(1.14)	(1.12)	(1.53)
Dividend per share (US \$)	-	-	-

* Includes holdings of its subsidiaries and affiliates; based on information from Iveric Bio’s definitive proxy statement filed on April 5, 2023, with the SEC in connection with Iveric Bio’s planned annual stockholder meeting for 2023

** Excerpt from Iveric Bio’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed by Iveric Bio with the SEC on March 1, 2023

*** There were no sales since these were before the product launch

3. Number of Iveric Bio shares to be acquired by Astellas, acquisition price, and status of shareholdings before and after the Acquisition

① Number of Iveric Bio shares held by Astellas before the Acquisition ⁰ (as of April 27, 2023)	(Number of voting rights: 0) (Ownership ratio of voting rights: 0%)
② Number of Iveric Bio Shares Outstanding as of April 27, 2023	137,616,082 shares
③ Acquisition amount (****)	US\$40 per share (approximately US\$5.9 billion in the aggregate)
④ Percentage of Iveric Bio shares to be held after the Acquisition	100% (Number of voting rights: 100%) (Ownership ratio of voting rights: 100%)

**** Acquisition amount includes the full amount required to purchase all outstanding options and restricted stock units

4. Schedule

① Date of Definitive Agreement	April 29, 2023 (Japan time)
② Estimated Date of stockholder meeting to be held by Iveric Bio	second quarter of Astellas’ fiscal year 2023 (third calendar quarter of 2023)

**** Subject to applicable regulatory approvals

5. Financial Impact of the Acquisition

The impact of the consummation of the Acquisition on Astellas' financial results is not reflected in Astellas' consolidated financial forecasts for the fiscal year ending March 31, 2024, that were announced on April 27, 2023. Astellas is still reviewing the impact and will promptly announce any events that are to be publicly reported.

6. Financial and Legal Advisors

J.P. Morgan Securities LLC, acting through its affiliate JPMorgan Securities Japan Co., Ltd., is acting as exclusive financial advisor to Astellas and Jones Day is acting as Astellas' legal counsel. BofA Securities, Inc. and Centerview Partners LLC are serving as Iveric Bio's exclusive financial advisors and Skadden, Arps, Slate, Meagher & Flom LLP is serving as Iveric Bio's legal counsel, with Wilmer Cutler Pickering Hale and Dorr LLP advising on general corporate and licensing matters.

*1: The FDA's breakthrough therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for breakthrough therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. FDA will review the full data submitted to support approval of drugs designated as breakthrough therapies to determine whether the drugs are safe and effective for their intended use before they are approved for marketing.

About Astellas' Primary Focus "Blindness & Regeneration"

The Primary Focus' mission is to identify, develop and deliver next generation treatments to restore sight for patients with retinal diseases. Astellas is passionate about R&D to increase productivity and creativity and deliver innovative treatments to patients as quickly as possible by combining optimal internal and external capabilities. For more information, please visit our website at <https://www.astellas.com/en/innovation/primary-focus-blindness-regeneration>.

About Geographic Atrophy (GA) secondary to Age-related Macular Degeneration (AMD)

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 eye¹.

About Avacincaptad Pegol (ACP)

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.

About GATHER Clinical Trials

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.

About Astellas

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. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+[®] healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into VALUE for patients. For more information, please visit our website at <https://www.astellas.com/en>.

About Iveric Bio

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. For more information on the Company, please visit www.ivericbio.com.

Cautionary Notice Regarding Forward-Looking Statements

All statements in this press release, other than statements of historical fact, are statements that could be deemed "forward-looking statements." In some cases, forward-looking statements may be identified by terminology such as "believe," "may," "will," "should," "predict," "goal," "strategy," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect," "seek" and similar expressions and variations thereof. Iveric Bio intends these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements in the U.S.

This press release contains “forward-looking statements” relating to, among other things, the proposed acquisition of Iveric Bio by Astellas and the objectives of such proposed acquisition, Astellas’ and Iveric Bio’s beliefs and expectations regarding the potential benefits sought to be achieved by Astellas’ proposed acquisition of Iveric Bio, the potential effects of the proposed acquisition on both Astellas and Iveric Bio, the expected benefits and success of Iveric Bio’s product candidates, the potential for and anticipated timing for approval of ACP, the anticipated financing of the proposed acquisition, and the anticipated timing of completion of the proposed acquisition, each of which involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements.

Risks and uncertainties include, among other things, risks related to the ability of Iveric Bio and Astellas to complete the transactions contemplated by the merger agreement; the satisfaction or waiver of the conditions to closing the proposed acquisition set forth in the merger agreement (including the failure to obtain necessary regulatory approvals and failure to obtain the requisite vote by Iveric Bio stockholders) in the anticipated timeframe or at all, including the possibility that the proposed acquisition does not close; the timing and nature of regulatory filings for Iveric Bio’s product candidates, and the possibility of a termination of the merger agreement; the possibility that competing offers to acquire Iveric Bio may be made; risks related to the ability to realize the anticipated benefits of the proposed acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period; the risk that Iveric Bio’s business and products will not be integrated with those of Astellas successfully; the effects of disruption from the transactions contemplated by the merger agreement on Iveric Bio’s business and the fact that the announcement and pendency of the transactions may make it more difficult to establish or maintain relationships with employees, suppliers and other business partners; negative effects of this announcement or the consummation of the proposed acquisition on the market price of Astellas’ or Iveric Bio’s common stock and/or operating results; significant transaction costs; unknown liabilities; the risk of litigation and/or regulatory actions related to the proposed acquisition or Iveric Bio’s business; risks related to the financing of the acquisition; other business effects and uncertainties, including the effects of industry, market, business, economic, political or regulatory conditions; future exchange and interest rates; changes in tax and other laws, regulations, rates and policies; future business combinations or disposals; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data is subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when drug applications may be filed in any jurisdictions for Iveric Bio’s pipeline products; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product’s benefits outweigh its known risks and determination of the product’s efficacy and, if approved, whether any such products will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety or other matters that could affect the availability or commercial potential of such products; expectations regarding personnel and human capital matters; and competitive developments.

Moreover, Astellas and Iveric Bio operate in very competitive and rapidly changing environments, and new risks emerge from time to time. Astellas and Iveric Bio have based these forward-looking statements on their current expectations and projections about future events and trends that they believe may affect the financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs of Astellas and Iveric Bio, but they cannot guarantee future events, results, actions, levels of activity, performance or achievements, business and market conditions, the timing and results of biotechnology development and potential regulatory approval. The foregoing factors are not exhaustive. You should also carefully consider other risks and uncertainties that may affect the business of Iveric Bio, including those described in the “Forward-Looking Statements”, “Summary of Principal Risk Factors”, and “Risk Factors” sections of Iveric Bio’s Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other documents filed from time to time with the SEC, all of which are available on the SEC’s website at www.sec.gov. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements and Astellas and Iveric Bio assume no obligation to, and do not intend to, update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise, unless required by applicable law.

Additional Information and Where to Find It

In connection with the proposed acquisition, Iveric Bio will be filing documents with the SEC, including preliminary and definitive proxy statements relating to the proposed acquisition. This press release is not a substitute for the proxy statement or any other document which Iveric Bio may file with the SEC. The definitive proxy statement will be mailed to Iveric Bio’s stockholders in connection with the proposed acquisition. **BEFORE MAKING ANY VOTING DECISION, IVERIC BIO’S INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PRELIMINARY AND DEFINITIVE PROXY STATEMENTS AND ANY OTHER DOCUMENTS TO BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED TRANSACTION OR INCORPORATED BY REFERENCE IN THE PROXY STATEMENT WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED ACQUISITION.** Any vote in respect of resolutions to be proposed at Iveric Bio’s stockholder meeting to approve the proposed transaction or other responses in relation to the proposed transaction should be made only on the basis of the information contained in Iveric Bio’s proxy statement. Investors and security holders may obtain free copies of these documents (when they are available) and other related documents filed with the SEC at the SEC’s web site at www.sec.gov, and all documents filed by Iveric Bio with the SEC are available to all stockholders of Iveric Bio free of charge at <https://investors.ivericbio.com/financial-information/sec-filings>.

Participants in the Solicitation

Iveric Bio, and its directors, executive officers and other members of management and certain other people may be deemed to be participants in the solicitation of proxies in connection with the proposed acquisition. Information about Iveric Bio’s directors and executive officers is included in the proxy statement for Iveric Bio’s annual meeting of stockholders for 2023, filed with the SEC on April 5, 2023. Additional information regarding these persons and their interests in the merger will be included in the proxy statement relating to the proposed acquisition when it is filed with the SEC. These documents, when available, can be obtained free of charge from the sources indicated above.

Important Additional Information

This communication is for informational purposes only and is not intended to and does not constitute, or form part of, an offer, invitation or the solicitation of an offer or invitation to purchase, otherwise acquire, subscribe for, sell or otherwise dispose of Iveric Bio common stock or any other securities, or the solicitation of any vote or approval in any jurisdiction, pursuant to the proposed acquisition or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law.

Reference

¹ Klein, et al. JAMA Ophthalmology. 2011.

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