
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 15, 2020

IVERIC bio, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36080
(Commission
File Number)

20-8185347
(IRS Employer
Identification No.)

One Penn Plaza, 35th Floor
New York, NY 10119
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: **(212) 845-8200**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|-------------------|---|
| Common Stock, \$0.001 par value per share | ISEE | The Nasdaq Global Select Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Forward-Looking Statements

This Form 8-K and Exhibit 99.1 attached hereto contain forward-looking statements of Iveric bio, Inc. (the "Company") that involve substantial risks and uncertainties. Any statements in this Form 8-K and Exhibit 99.1 about the Company's future expectations, plans and prospects constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include any statements about the Company's strategy, future operations and future expectations and plans and prospects for the Company, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "goal," "may," "might," "plan," "predict," "project," "seek," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. In this Form 8-K and Exhibit 99.1, the Company's forward looking statements include statements about the impact of the COVID-19 pandemic on the Company's research and development programs, operations and financial position, its expectations to initiate enrollment in its second Phase 3 trial (ISEE2008) of Zimura in geographic atrophy secondary to AMD and to use its previously announced clinical trial of Zimura for the treatment of geographic atrophy (OPH2003) as a Phase 3 trial, its development and regulatory strategy for Zimura, the potential clinical meaningfulness of the results of clinical trials, the implementation of its business plan, the projected use of cash and cash balances, the timing, progress and results of clinical trials and other research and development activities, the potential utility of its product candidates, and the potential for its business development strategy. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to the progression and duration of the COVID-19 pandemic and responsive measures thereto and related effects on the Company's research and development programs, operations and financial position, the initiation and the progress of research and development programs and clinical trials, availability of data from these programs, reliance on university collaborators and other third parties, establishment of manufacturing capabilities, expectations for regulatory matters, need for additional financing and negotiation and consummation of business development transactions and other factors discussed in the "Risk Factors" section contained in the quarterly and annual reports that the Company files with the Securities and Exchange Commission. Any forward-looking statements represent the Company's views only as of the date of this Form 8-K. The Company anticipates that subsequent events and developments will cause its views to change. While the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so except as required by law.

Item 8.01. Other Events.

On June 15, 2020, the Company issued a press release announcing the 18 month results of its Phase 3 clinical trial of Zimura[®] (avacincaptad pegol), the Company's complement factor C5 inhibitor, in patients with geographic atrophy ("GA") secondary to age-related macular degeneration (the "OPH2003 trial"). A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In addition, the Company's management team will host a conference call with webcast at 8:00 a.m. Eastern Time to discuss the 18-month results. Details for the conference call and webcast are in the press release incorporated by reference as Exhibit 99.1. On the conference call and in discussions with investors, the Company may refer to the following additional and supportive data from the OPH2003 trial:

Supportive 18-Month GA Data

18-Month Zimura 2 mg GA Data by Part

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, the Company enrolled patients for the OPH2003 trial in two different parts, Part 1 and Part 2, with different dosages and randomization ratios in each Part. Twenty-five patients receiving Zimura 2 mg were enrolled in Part 1 of the trial and 42 patients receiving Zimura 2 mg were enrolled in Part 2 of the trial. Consistent with the analysis performed at 12 months, the analysis of the mean change in GA growth for Zimura 2 mg as compared to the corresponding sham control group at 18 months was adjusted for the fact that this dose of Zimura was tested in both parts of the trial, each of which had different randomization ratios.

The least squares mean changes in GA in Part 1 and Part 2 at month 18 are shown separately in the following table:

Mean Rate of Change in GA Area from Baseline to Month 18
(MRM Analysis) (Square Root Transformation)

| Cohort | | Zimura 2 mg (N = 25) | Sham (N = 26) | Difference | % Difference |
|--------|---------------------------------------|-------------------------|------------------|------------|--------------|
| Part 1 | Mean Change in GA ^(a) (mm) | 0.464 | 0.635 | 0.170 | 26.84% |

(a) = based on the least squares mean from the MRM model

| Cohort | | Zimura 2 mg (N = 42) | Sham (N = 84) | Difference | % Difference |
|--------|---------------------------------------|-------------------------|------------------|------------|--------------|
| Part 2 | Mean Change in GA ^(a) (mm) | 0.440 | 0.608 | 0.168 | 27.67% |

(a) = based on the least squares means from the MRM model

When the data from the Zimura 2 mg comparisons from each Part of the trial are analyzed using the MRM model, which includes a regression factor by part, the mean difference in GA growth over 18 months between the Zimura 2 mg and sham control groups is 0.168 mm, representing a 28.11% relative benefit in the Zimura 2 mg group as compared to the corresponding sham control group.

Observed 18-Month GA Data (non-square root transformation)

In addition to analyzing the mean rate of change in GA area at month 18 using the square root transformation method (measured in millimeters (mm)), the Company also analyzed the mean rate of change in GA area using the observed GA areas (measured in square millimeters (mm²)) with the MRM model. The observed mean GA area data are for the Zimura 2 mg and Zimura 4 mg groups as compared to the corresponding sham control groups are summarized in the following table:

Mean Rate of Change in GA Area from Baseline to Month 18
(MRM Analysis) (Observed)

| Cohort | Zimura 2 mg (N = 67) | Sham 2 (N = 110) | Difference | % Difference |
|---|-------------------------|----------------------|------------|--------------|
| Mean Change in GA ^(a) (mm ²) | 2.431 ^(b) | 3.587 ^(b) | 1.156 | 32.24% |

| Cohort | Zimura 4 mg (N = 83) | Sham (N = 84) | Difference | % Difference |
|---|-------------------------|------------------|------------|--------------|
| Mean Change in GA ^(a) (mm ²) | 2.460 | 3.486 | 1.026 | 29.44% |

(a) = based on the least squares mean from the MRM model.

(b) = these least squares means are estimates from the MRM model, drawing on all available data, including data from groups with different randomization ratios in Part 1 and Part 2, and should not be interpreted as directly observed data.

18-Month Visual Acuity Data

In addition to analyzing mean change in GA area, the Company also performed pre-specified analyses of the mean change in best corrected visual acuity ("BCVA") from baseline to month 18 and the mean change in low luminance best corrected visual acuity ("LL BCVA") from baseline to month 18, both as measured by Early Treatment Diabetic Retinopathy Study ("ETDRS") letters. Testing for visual acuity serves as an important safety assessment to assure that the decrease in visual acuity in the Zimura treatment groups was not significantly different from the sham control groups.

The OPH2003 trial was not designed to reliably assess differences in mean changes in BCVA or LL BCVA with statistical significance. Data for the mean changes in BCVA and LL BCVA are summarized in the following tables:

Mean Change in BCVA from Baseline to Month 18
(MRM Analysis) (ETDRS letters)

| Cohort | Zimura 2 mg (N = 67) | Sham (N = 110) | Difference |
|------------------------------------|-------------------------|----------------------|-------------------|
| Mean Change in BCVA ^(a) | -12.7 ^(b) | -15.1 ^(b) | 2.37 |

| Cohort | Zimura 4 mg (N = 83) | Sham (N = 84) | Difference |
|------------------------------------|-------------------------|------------------|-------------------|
| Mean Change in BCVA ^(a) | -4.27 | -7.07 | 2.80 |

(a) = based on the least squares mean from the MRM model

(b) = these least squares means are estimates from the MRM model, drawing on all available data, including data from groups with different randomization ratios in Part 1 and Part 2, and should not be interpreted as directly observed data.

Mean Change in LL BCVA from Baseline to Month 18
(MRM Analysis) (ETDRS letters)

| Cohort | Zimura 2 mg (N = 67) | Sham (N = 110) | Difference |
|---------------------------------------|-------------------------|----------------------|-------------------|
| Mean Change in LL BCVA ^(a) | -2.72 ^(b) | -3.10 ^(b) | 0.37 |

| Cohort | Zimura 4 mg (N = 83) | Sham (N = 84) | Difference |
|---------------------------------------|-------------------------|------------------|-------------------|
| Mean Change in LL BCVA ^(a) | 2.85 | 1.68 | 1.17 |

(a) = based on the least squares mean from the MRM model

(b) = these least squares means are estimates from the MRM model, drawing on all available data, including data from groups with different randomization ratios in Part 1 and Part 2, and should not be interpreted as directly observed data.

Zimura 1 mg 18-Month Efficacy Data

The Company performed descriptive analyses on the 18 month data for patients in the Zimura 1 mg group as compared to the patients in the sham control group in Part 1 of the trial to aid an assessment of whether a dose response relationship was present across treatment groups included in the clinical trial.

GA area data for the Zimura 1 mg group and the sham group from Part 1 of the trial at month 18 are summarized in the following table:

Summary of GA Area (mm) and Mean Percentage Change from Baseline to Month 18
(Square Root Transformation)

| Cohort | Zimura 1 mg (N = 26) | Sham (N = 26) |
|--------------------------------|-------------------------|------------------|
| Mean Sq. Root of GA at BL, mm | 2.591 | 2.623 |
| Mean Sq. Root of GA at M18, mm | 3.258 | 3.230 |
| Difference | 0.667 | 0.607 |
| Mean % Change ^(a) | 21.91% | 23.87% |

BL = Baseline; M18 = Month 18

(a) Mean % Change in GA area is an average of the percentage change in GA area observed for each patient.

Although the sample size for the Zimura 1 mg group is small, the Company believes the apparent reduction in mean percentage change in GA area from baseline to month 18 in the Zimura 1 mg group as compared to the sham control group in Part 1, when combined with the results observed in the Zimura 2 mg and Zimura 4 mg groups as compared to their corresponding sham control groups, suggest a potential dose response relationship across treatment groups.

18-Month Safety Data

Based on the Company's review of the safety data in the trial, Zimura was generally well tolerated after 18 months of administration. During the trial, there were no Zimura-related adverse events, no Zimura-related intraocular inflammation, no Zimura-related increased intraocular pressure, no cases of endophthalmitis, and no discontinuations attributed by investigators to Zimura in the trial. The numbers below are based on investigator-reported adverse events occurring during the 18-month duration of the trial for all patients.

The number of patients with one or more serious treatment emergent adverse events ("TEAEs"), organized by MedDRA system organ class, a standard method of reporting adverse events, are set forth in the table below:

Patients with One or More Serious TEAEs in Any Organ Class

| | Part 1 | | | Part 2 | | |
|--|----------------------------|----------------------------|------------------|----------------------------|----------------------------|-----------------------|
| | Zimura 1 mg (N = 26) | Zimura 2 mg (N = 25) | Sham (N = 26) | Zimura 2 mg (N = 42) | Zimura 4 mg (N = 83) | Sham 4 mg (N = 84) |
| Blood and lymphatic system disorders | 0 | 0 | 0 | 0 | 1 (1.2%) | 0 |
| Cardiac disorders | 1 (3.8%) | 0 | 1 (3.8%) | 1 (2.4%) | 2 (2.4%) | 3 (3.6%) |
| Eye disorders | 0 | 0 | 0 | 1 (2.4%) | 1 (1.2%) | 0 |
| Gastrointestinal disorders | 1 (3.8%) | 1 (4.0%) | 2 (7.7%) | 0 | 2 (2.4%) | 6 (7.1%) |
| General disorders and administration site conditions | 0 | 0 | 0 | 1 (2.4%) | 0 | 0 |
| Hepatobiliary disorders | 0 | 1 (4.0%) | 1 (3.8%) | 0 | 1 (1.2%) | 0 |
| Infections and infestations | 0 | 1 (4.0%) | 0 | 2 (4.8%) | 8 (9.6%) | 2 (2.4%) |
| Injury, poisoning and procedural complications | 0 | 1 (4.0%) | 1 (3.8%) | 1 (2.4%) | 3 (3.6%) | 2 (2.4%) |
| Metabolism and nutrition disorders | 0 | 0 | 2 (7.7%) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 1 (3.8%) | 0 | 0 | 0 | 0 | 3 (3.6%) |
| Benign, malignant and unspecified neoplasms (including cysts and polyps) | 0 | 0 | 1 (3.8%) | 1 (2.4%) | 1 (1.2%) | 3 (3.6%) |
| Nervous system disorders | 1 (3.8%) | 1 (4.0%) | 2 (7.7%) | 2 (4.8%) | 3 (3.6%) | 2 (2.4%) |
| Psychiatric disorders | 0 | 0 | 1 (3.8%) | 0 | 0 | 1 (1.2%) |
| Respiratory, thoracic and mediastinal disorders | 0 | 1 (4.0%) | 0 | 0 | 2 (2.4%) | 5 (6.0%) |
| Vascular disorders | 0 | 0 | 0 | 0 | 0 | 1 (1.2%) |

Of the reported serious TEAEs that were eye disorders, one TEAE was an optic ischaemic neuropathy (in the Zimura 2 mg group) and one TEAE was a retinal detachment (in the Zimura 4 mg group). Neither of these TEAEs were reported as related to Zimura.

The number of patients with one or more TEAEs, including serious TEAEs, identified by the investigator as related to the study drug (Zimura or sham) are set forth in the table below:

Reported TEAEs Related to Zimura or Sham

| | Part 1 | | | Part 2 | | |
|---------------------------------|----------------------------|----------------------------|------------------|----------------------------|----------------------------|-----------------------|
| | Zimura 1 mg (N = 26) | Zimura 2 mg (N = 25) | Sham (N = 26) | Zimura 2 mg (N = 42) | Zimura 4 mg (N = 83) | Sham 4 mg (N = 84) |
| Subjects with at least one TEAE | 0 | 0 | 0 | 0 | 0 | 0 |

The number of patients with one or more ocular TEAEs in the study eye are set forth in the table below:

Reported Ocular TEAEs in Study Eyes

| | Part 1 | | | Part 2 | | |
|--|----------------------------|----------------------------|------------------|----------------------------|----------------------------|-----------------------|
| | Zimura 1 mg (N = 26) | Zimura 2 mg (N = 25) | Sham (N = 26) | Zimura 2 mg (N = 42) | Zimura 4 mg (N = 83) | Sham 4 mg (N = 84) |
| Eye disorders | 12 (46.2%) | 11 (44.0%) | 6 (23.1%) | 28 (66.7%) | 61 (73.5%) | 39 (46.4%) |
| Eye disorders related to injection procedure | 4 (15.4%) | 5 (20.0%) | 2 (7.7%) | 18 (42.9%) | 46 (55.4%) | 24 (28.6%) |

All of the above TEAEs that were not related to the injection procedure were also not related to the study drug. The number of patients with one or more ocular TEAEs in the study eye, identified by the investigator as related to the study drug (Zimura or sham) is set forth in the table below:

Reported Ocular TEAEs in the Study Eye Related to Zimura or Sham

| | Part 1 | | | Part 2 | | |
|---------------------------------|----------------------------|----------------------------|------------------|----------------------------|----------------------------|-----------------------|
| | Zimura 1 mg (N = 26) | Zimura 2 mg (N = 25) | Sham (N = 26) | Zimura 2 mg (N = 42) | Zimura 4 mg (N = 83) | Sham 4 mg (N = 84) |
| Subjects with at least one TEAE | 0 | 0 | 0 | 0 | 0 | 0 |

In addition to the Company collecting investigator-reported adverse events, the independent masked reading center performed multi-modal imaging analysis. Multi-modal imaging analysis is a process used to assess patient retinal findings by reviewing different image types, in this case fluorescein angiograms and optical coherence tomography images, to provide a more comprehensive view of the patient's retinal tissue. In this trial, the reading center's multi-modal imaging analysis identified one additional case of macular choroidal neovascularization ("CNV") for a patient in the Zimura 4 mg group at month 12. As the investigator following the patient did not detect the CNV, the patient remained in the trial through month 18.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

[99.1 Press Release dated June 15, 2020](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

IVERIC bio, Inc.

Date: June 15, 2020

By: /s/ David F. Carroll

David F. Carroll

Senior Vice President, Chief Financial Officer and Treasurer



IVERIC bio Announces Positive Zimura 18 Month Data Supporting the 12 Month Efficacy Findings: Continuous Positive Treatment Effect with Favorable Safety Profile in Geographic Atrophy Secondary to Age-Related Macular Degeneration in a Phase 3 Trial

- 28% Relative Benefit for Zimura 2 mg at 18 Months -

- Second Phase 3 Clinical Trial to Initiate this Month -

- Conference Call and Webcast Today, June 15, 2020 at 8:00am ET -

NEW YORK, JUNE 15, 2020 – IVERIC bio, Inc. (Nasdaq: ISEE) today announced positive 18 month results from the Company’s first Phase 3 clinical trial (OPH2003) for Zimura® (avacincaptad pegol), a novel complement C5 inhibitor, for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). The 18 month data supports the previously announced 12 month data from this trial, at which time point Zimura met the pre-specified primary efficacy endpoint with statistical significance. The reduction in the mean rate of GA growth over 18 months was 28.11% for the Zimura 2 mg group as compared to the corresponding sham control group and 29.97% for the Zimura 4 mg group as compared to the corresponding sham control group. The pre-specified efficacy analysis for the primary endpoint was performed at month 12 using all of the power in the trial to detect a statistically significant difference. Therefore, the p-values for the 18 month statistical analyses are descriptive in nature. The descriptive p-values for the treatment effects at month 18 were p=0.0014 for the Zimura 2 mg group and p=0.0021 for the Zimura 4 mg group.

In this trial, the treatment effect was observed as early as 6 months, with an increase in the absolute difference of the mean change in GA growth for treatment with either Zimura 2 mg or Zimura 4 mg, as compared to sham, at each subsequent time point, suggesting the progressive benefit of continuous treatment with Zimura. Zimura maintained its favorable safety profile at 18 months with no reported Zimura related adverse events, no cases of endophthalmitis and a lower rate of choroidal neovascularization (CNV) than reported for C3 inhibition. The overall 18 month data may suggest a dose response relationship.

“We are extremely excited by the new 18 month data from this Phase 3 clinical trial, both with respect to efficacy and safety,” stated Glenn P. Sblendorio, Chief Executive Officer and President of IVERIC bio. “In the OPH2003 clinical trial, the 18 month results indicated continuous Zimura treatment benefit with a favorable safety profile in patients with GA secondary to AMD. This is an impressive achievement since we believe OPH2003 is currently the only Phase 3 clinical trial showing suppression of GA growth with continuous treatment for 18 months.”

“We are one step closer to potentially bringing a clinically meaningful therapy to patients with GA who currently do not have any FDA or EMA approved treatments available to them,” stated Kourous A. Rezaei, MD, Chief Medical Officer of IVERIC bio. “We believe the robust 18 month efficacy data further validates the potential role of complement C5 inhibition in GA secondary to AMD and has the potential to differentiate Zimura from other product candidates in development. We are poised to initiate our second pivotal trial, ISEE2008, comparing Zimura 2 mg with sham later this month. We want to thank our patients, our clinical trial investigators and their staffs for their support and participation in this trial.”

The Company previously announced that in the OPH2003 clinical trial, Zimura met its pre-specified primary efficacy endpoint at 12 months and reached statistical significance in the international, multicenter, randomized, double masked, sham controlled clinical trial in GA secondary to AMD. The reduction in the mean rate of GA growth over 12 months was 27.38% (p-value = 0.0072) for the Zimura 2 mg group as compared to the corresponding sham control group and 27.81% (p-value = 0.0051) for the Zimura 4 mg group as compared to the corresponding sham control group. The data for both dose groups were statistically significant.

“I am excited about the efficacy and favorable safety profile observed in the 12 month Zimura Phase 3 data, and now the long term 18 month efficacy and safety data further confirm my belief in the role of complement C5 inhibition in the treatment of GA,” stated Peter K. Kaiser, MD, Chaney Family Endowed Chair in Ophthalmology Research, Cole Eye Institute and Professor of Ophthalmology at the Cleveland Clinic Lerner College of Medicine. “The delta between the Zimura 2 mg and Zimura 4 mg treatment groups and the corresponding sham control groups occurred early in the study and continued over 18 months which means my patients may benefit after only a few injections and maintain this with additional treatments. Moreover, the safety profile remained favorable after 18 months of treatment.”

“We are excited by these 18 month results,” stated Pravin U. Dugel, MD, Executive Vice President and Chief Strategy and Business Officer of IVERIC bio. “In the challenging COVID-19 pandemic era, we believe that we are in an advantageous position as the OPH2003 data is the only positive Phase 3 clinical data in GA secondary to AMD that we are aware of that has been reported to date. We believe that these robust data should increase investigator enthusiasm and confidence for patient recruitment and retention in our ISEE2008 clinical trial.”

OPH2003 18 Month Data

A total of 286 patients were enrolled in this trial.

Mean rate of change in GA growth over 18 months, was measured by fundus autofluorescence (FAF) based on readings at four time points (baseline, month 6, month 12 and month 18) and was calculated using the square root transformation of the GA area. The FAF images were assessed by an independent masked reading center. The prespecified statistical analysis plan used a model of repeated measures (MRM) to compare data for the Zimura 2 mg and Zimura 4 mg groups to the corresponding sham groups. Detailed data are shown below:

Mean Rate of Change in Geographic Atrophy (GA) Area from Baseline to Month 18 (Square Root Transformation)

| Cohort | Zimura 2 mg (N = 67) | Sham (N = 110) | Difference | % Difference | P-Value (Descriptive) |
|-------------------------------------|-------------------------|-------------------|------------|--------------|--------------------------|
| Mean Change in GA ^a (mm) | 0.430 | 0.599 | 0.168 | 28.11% | 0.0014 |

| Cohort | Zimura 4 mg (N = 83) | Sham (N = 84) | Difference | % Difference | P-Value (Descriptive) |
|-------------------------------------|-------------------------|------------------|------------|--------------|--------------------------|
| Mean Change in GA ^b (mm) | 0.391 | 0.559 | 0.167 | 29.97% | 0.0021 |

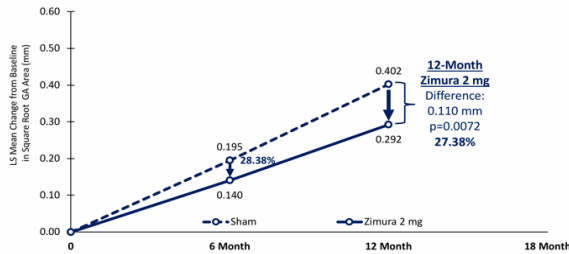
^a Based on least squares means from MRM model, these least square means are from the MRM model, drawing on all available data at the month 18 time point, including data from groups with different randomization ratios in Part 1 and Part 2, and should not be interpreted as directly observed data.

^b These least squares means are estimates of the MRM model, drawing on all available data, at the month 18 time point.

The graphs below illustrate the observed difference in mean rate of GA growth between each of the Zimura 2 mg and Zimura 4 mg treatment groups and their corresponding sham control groups based on the MRM analysis at both 12 months (which was previously reported) and 18 months.

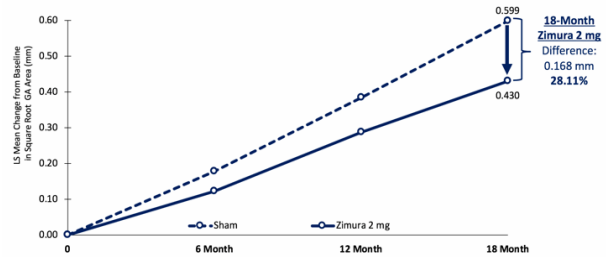
Primary Efficacy Endpoint Met at 12 Months*

Zimura 2 mg vs Sham
(square root transformation)



Decrease in GA Growth Over 18 Months

Zimura 2 mg vs Sham
(square root transformation)

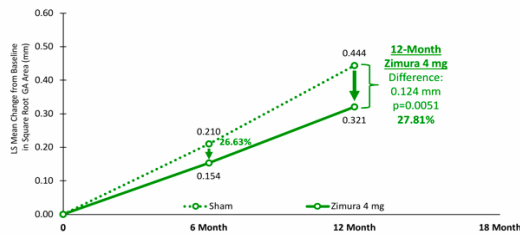


ITT Population; Based on the least squares means from MRM Model drawing on all available data at the respective 12 month and 18 month analysis time points, including data from groups with different randomization ratios in Part 1 and Part 2, and should not be interpreted as directly observed data; Hochberg procedure used for significance testing for 12 month data.

*Previously reported

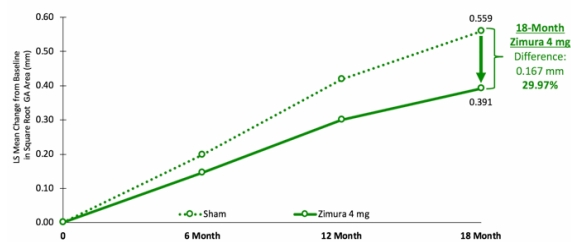
Primary Efficacy Endpoint Met at 12 Months*

Zimura 4 mg vs Sham
(square root transformation)



Decrease in GA Growth Over 18 Months

Zimura 4 mg vs Sham
(square root transformation)



ITT Population; Based on the least squares means from the MRM Model drawing on all available data at the respective 12 month and 18 month analysis time points; Hochberg procedure used for significance testing for 12 months data.

*Previously reported

Zimura was generally well tolerated after 18 months of administration. There was no Zimura-related inflammation, no Zimura-related discontinuations from the trial, no cases of endophthalmitis and no Zimura-related adverse events. Through month 18, the reported incidence of CNV in the untreated fellow eye was 11 patients (3.8%), and in the study eye was 3 patients (2.7%) in the sham control group, 8 patients (11.9%) in the Zimura 2 mg group, and 13 patients (15.7%) in the Zimura 4 mg group. The most frequently reported ocular adverse events were related to the injection procedure.

The Company plans to make additional supportive information regarding the 18 month results available in its public filings with the Securities and Exchange Commission.

Geographic Atrophy

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, the advanced stage of AMD, leads to further irreversible loss of vision in these patients. There are currently no U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA) approved treatment options available for patients with geographic atrophy.

Zimura

Complement factor C5 is a central component of the complement cascade and is believed to be involved in the development and progression of AMD. Zimura is designed to inhibit complement factor C5 cleavage into C5a and C5b. By inhibiting the formation of complement C5 terminal fragments, Zimura may decrease the activation of inflammasomes and the formation of membrane attack complex (MAC). This mechanism of action could potentially prevent or slow down the degeneration of retinal pigment epithelial (RPE) cells and slow down the progression of GA.

Conference Call/Web Cast Information

IVERIC bio's management team will host a conference call/webcast today at 8:00 a.m. Eastern Time to discuss the positive 18 month Zimura data. To participate in the conference call, dial 800-367-2403 (USA) or 334-777-6978 (International), passcode 7075082. A live, listen-only audio webcast of the conference call can be accessed on the Investors section of the IVERIC bio website at www.ivericbio.com. A replay will be available approximately two hours following the live call for two weeks. The replay number is 888-203-1112 (USA Toll Free), passcode 7075082.

IVERIC bio

IVERIC bio is a science-driven biopharmaceutical company focused on the discovery and development of novel treatment options for retinal diseases with significant unmet medical needs. The Company is currently developing both therapeutic product candidates for age-related retinal diseases and gene therapy product candidates for orphan inherited retinal diseases. Vision is Our Mission. For more information on the Company, please visit www.ivericbio.com.

Forward-looking Statements

Any statements in this press release about the Company's future expectations, plans and prospects constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include any statements about the Company's strategy, future operations and future expectations and plans and prospects for the Company, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "goal," "may," "might," "plan," "predict," "project," "seek," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. In this press release, the Company's forward looking statements include statements about the impact of the COVID-19 pandemic on the Company's research and development programs, operations and financial position, its expectations to initiate enrollment in its second Phase 3 trial (ISEE2008) of Zimura in geographic atrophy secondary to AMD and to use its previously announced clinical trial of Zimura for the treatment of geographic atrophy (OPH2003) as a Phase 3 trial, its development and regulatory strategy for Zimura, the potential clinical meaningfulness of the results of clinical trials, the implementation of its business plan, the projected use of cash and cash balances, the timing, progress and results of clinical trials and other research and development activities, the potential utility of its product candidates, and the potential for its business development strategy. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to the progression and duration of the COVID-19 pandemic and responsive measures thereto and related effects on the Company's research and development programs, operations and financial position, the initiation and the progress of research and development programs and clinical trials, availability of data from these programs, reliance on university collaborators and other third parties, establishment of manufacturing capabilities, expectations for regulatory matters, need for additional financing and negotiation and consummation of business development transactions and other factors discussed in the "Risk Factors" section contained in the quarterly and annual reports that the Company files with the Securities and Exchange Commission. Any forward-looking statements represent the Company's views only as of the date of this press release. The Company anticipates that subsequent events and developments will cause its views to change. While the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so except as required by law.

ISEE-G

Investor Contact:

IVERIC bio

Kathy Galante, 212-845-8231

Vice President, Investor Relations and Corporate Communications

kathy.galante@ivericbio.com

or

Media Contact:

SmithSolve

Alex Van Rees, 973-442-1555 ext. 111

alex.vanrees@smithsolve.com