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): September 20, 2022

Biomea Fusion, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	001-40335	82-2520134
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

900 Middlefield Road, 4th Floor Redwood City, CA	94063
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: (650) 980-9099

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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:

☐ 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, $0.0001 par value	**BMEA**	**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. ☐

Item 8.01. Other Events.

On September 20, 2022, Biomea Fusion, Inc. (the "Company") issued a press release titled, "Biomea Fusion Presents New Preclinical Data at the European Association for the Study of Diabetes (EASD) Annual Meeting Describing BMF-219's Potential as a Novel, Oral, Long-Acting Treatment for Type 2 Diabetes." The information described in the press release was also presented in a presentation at the 58th European Association for the Study of Diabetes (EASD) Annual Meeting, which is taking place September 19-23, 2022 in Stockholm, Sweden.

Copies of the press release and the Company's presentation are attached to this Current Report on Form 8-K as Exhibits 99.1 and 99.2 and incorporated herein by reference.

Forward-Looking Statements

Statements made or incorporated by reference in this Current Report on Form 8-K may include statements which are not historical facts and are considered forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact, including statements regarding the clinical and therapeutic potential of the Company's product candidates and development programs, including BMF-219, the potential of BMF-219 as a treatment for various types of cancer and diabetes, the Company's research, development and regulatory plans, including the Company's pursuit of BMF-219 in metabolic diseases, its plans to submit an IND application for BMF-219 in type 2 diabetes, and the timing of such events, may be deemed to be forward-looking statements. The Company intends these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act and is making this statement for purposes of complying with those safe harbor provisions.

Any forward-looking statements made or incorporated by reference in this Current Report on Form 8-K are based on the Company's current expectations, estimates and projections only as of the date of this Current Report on Form 8-K are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements, including the risk that the Company may encounter delays in patient enrollment and in the initiation, conduct and completion of its planned clinical trials and other research and development activities. These risks concerning the Company's business and operations are described in additional detail in its periodic filings with the U.S. Securities and Exchange Commission (the "SEC"), including its most recent periodic report filed with the SEC and subsequent filings thereafter. The Company explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release titled, "Biomea Fusion Presents New Preclinical Data at the European Association for the Study of Diabetes (EASD) Annual Meeting Describing BMF-219's Potential as a Novel, Oral, Long-Acting Treatment for Type 2 Diabetes."
99.2	Presentation titled, "Oral Menin Inhibitor, BMF-219, displays a significant and durable reduction in HbA1c in a Type 2 Diabetes Rat Model."
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 thereunto duly authorized.

BIOMEA FUSION, INC.

Date: September 21, 2022

By: /s/ Thomas Butler

Thomas Butler
Principal Executive Officer

Exhibit 99.1

Biomea Fusion Presents New Preclinical Data at the European Association for the Study of Diabetes (EASD) Annual Meeting Describing BMF-219's Potential as a Novel, Oral, Long-Acting Treatment for Type 2 Diabetes

September 20, 2022, at 2:45 AM PDT

- Menin, a transcriptional scaffold protein, regulates pancreatic beta cell homeostasis; inhibiting menin function with BMF-219 increased beta cell function in a preclinical animal model, driving an improvement in glycemic control and insulin sensitivity.
- New data presented in a Short Oral Discussion, at EASD in Stockholm, Sweden, highlights the ability of BMF-219, a covalent menin inhibitor, to restore normal HOMA-B, a measure of pancreatic beta cell function, over 4-weeks of treatment in the Zucker Diabetic Fatty (ZDF) Rat model of type 2 diabetes
- BMF-219 significantly lowered HbA1c compared to active control, liraglutide, -3.5% vs -1.7%, respectively. BMF-219 also outperformed liraglutide in reducing fasting glucose, fasting insulin, total cholesterol and triglycerides; furthermore, BMF-219 treatment resulted in a substantive weight loss
- Biomea remains on track to file an IND to study BMF-219 in patients with Type 2 Diabetes in the second half of 2022

REDWOOD CITY, California, September 20, 2022 (GLOBE NEWSWIRE) — Biomea Fusion, Inc. (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to discovering and developing novel covalent small molecules to treat and improve the lives of patients with genetically defined cancers and metabolic diseases, presented today "Oral menin inhibitor, BMF-219, displays a significant and durable reduction in HbA1c in a type 2 diabetes rat model", the first of two oral presentations at the EASD Annual Meeting.

These data further support BMF-219's potential as an oral, long-acting, disease-modifying treatment for type 2 diabetes. The short oral discussion presentation can be viewed on Biomea's website at https://biomeafusion.com/publications.

"Today we reported new data demonstrating BMF-219's ability to improve HOMA-B scores to the range of normal pancreatic beta cell function with 4-week oral treatment in the ZDF rat model of type 2 diabetes. This data provides mechanistic support that the durable glycemic control and significant reduction of HbA1c achieved by BMF-219 is the result of improved beta cell function," said Priyanka Somanath, Biomea's Associate Director of Translational Research.

“Our approach with BMF-219 represents a potential paradigm shift in the way patients with Type 2 Diabetes are treated. By reestablishing the pool of beta cells, BMF-219 could provide patients with durable glycemic control with a short-term oral treatment. We believe the preclinical results presented today highlight two features of BMF-219’s novel mechanism, reactivation and preservation of beta cells in an insulin resistant diabetes model. We are excited by the translational possibility of BMF-219 to reverse beta cell depletion and potentially restore the body’s own ability to produce insulin and elicit beneficial weight loss in the setting of type 2 diabetes.”, said Thomas Butler, Chief Executive Officer and Chairman of the Board.

Biomea’s second accepted abstract “Oral long-acting menin inhibitor normalizes type 2 diabetes in two rat models” will be presented during the session ‘OP 33 Therapy Outside the Box’ on Thursday, September 22 at 15:30-15:45 CEST.

About Menin in Diabetes

Loss of functional beta-cell mass is a core component of the natural history in both types of diabetes — type 1 diabetes (mediated by autoimmune dysfunction) and type 2 diabetes (mediated by metabolic dysfunction). Beta-cells are found in the pancreas and are responsible for the synthesis and secretion of insulin. Insulin is a hormone that helps the body use glucose for energy and helps control blood glucose levels. In patients with diabetes, beta-cell mass and function are diminished, leading to insufficient insulin secretion and hyperglycemia. Menin is thought to act as a brake on beta-cell turnover / beta-cell growth, supporting the notion that inhibition of menin could lead to the regeneration of normal healthy beta-cells. Based on these and other scientific findings, Biomea is exploring the potential for menin inhibition as a viable therapeutic approach to permanently halt or reverse progression of type 2 diabetes.

About Biomea Fusion

Biomea Fusion is a clinical stage biopharmaceutical company focused on the discovery and development of covalent small molecules to treat patients with genetically defined cancers and metabolic diseases. A covalent small molecule is a synthetic compound that forms a permanent bond to its target protein and offers a number of potential advantages over conventional non-covalent drugs, including greater target selectivity, lower drug exposure, and the ability to drive a deeper, more durable response. The company is utilizing its proprietary FUSION™ System to advance a pipeline of covalent-binding therapeutic agents against key oncogenic drivers of cancer and metabolic diseases. Biomea Fusion’s goal is to utilize its capabilities and platform to become a leader in developing covalent small molecules in order to maximize the clinical benefit when treating various cancers and metabolic diseases.

Forward-Looking Statements

Statements we make in this press release may include statements which are not historical facts and are considered forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact, including statements regarding our cash runway, the clinical and therapeutic potential of our product candidates and development programs, including BMF-219, the potential of BMF-219 as a treatment for various types of cancer and diabetes, our research, development and regulatory plans, including our pursuit of BMF-219 in metabolic diseases, our plans to submit an IND application for BMF-219 in type 2 diabetes, and the timing of such events, may be deemed to be forward-looking statements. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act and are making this statement for purposes of complying with those safe harbor provisions.

Any forward-looking statements in this press release are based on our current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements, including the risk that we may encounter delays or unforeseen results in preclinical development, IND-filing and acceptance, patient enrollment and in the initiation, conduct and completion of our planned clinical trials and other research, development and regulatory activities. These risks concerning Biomea Fusion's business and operations are described in additional detail in its periodic filings with the U.S. Securities and Exchange Commission (the "SEC"), including its most recent periodic report filed with the SEC and subsequent filings thereafter. Biomea Fusion explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

Contact:

Sasha Blaug
SVP Corporate Development
sb@biomeafusion.com
(650) 460-7759

Exhibit 99.2

Presentation #590

Oral Menin Inhibitor, BMF-219, displays a significant and durable reduction in HbA1c in a Type 2 Diabetes Rat Model

Priyanka Somanath, Sanchita Mourya, Weiqun Li, Tenley Archer, Brian Law, Daniel Lu, Tripta Rughwani, Lekha Kumar, Taisei Kinoshita, Mini Balakrishnan, Thomas Butler

EASD Annual Meeting 2022
September 20, 2022

biomea FUSION™

Menin: A novel target for beta-cell homeostasis

Potential Mechanism of Menin in Diabetes

- Menin is an epigenetic protein that plays a key role in regulating beta-cell proliferation and function.
- Menin inhibition has previously been shown to improve glycemic control in high fat induced diabetic mice (Ma et al., 2021).
- Inhibition of menin/JunD complex reduces the expression of Cyclin Dependent Kinase Inhibitors (CDKIs), allowing CDKs to drive beta-cell proliferation.

Menin regulates beta-cell quiescence

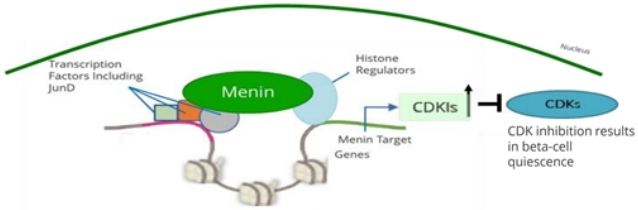
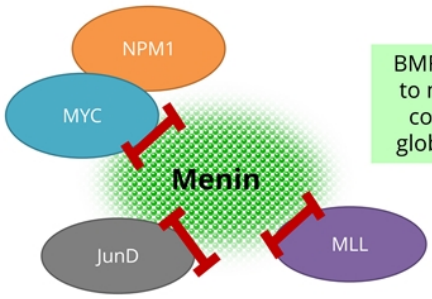


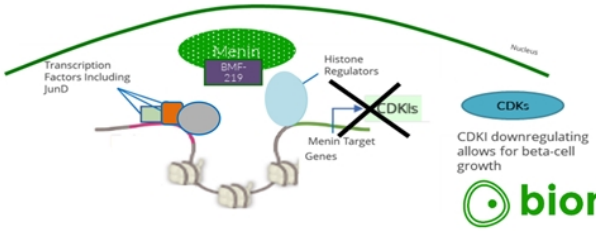
Figure adapted from Issa et al. *Leukemia* **35**, 2482–2495 (2021).

BMF-219: A selective covalent menin inhibitor



BMF-219 covalent binding to menin disrupts menin complexes, resulting in global change of function

Menin inhibition by BMF-219 allows for beta-cell restoration and glucose homeostasis



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Study Design: Zucker Diabetic Fatty (ZDF) rat model of T2DM

THE ZDF RAT

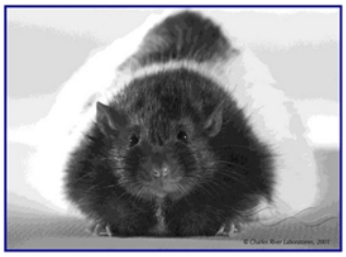
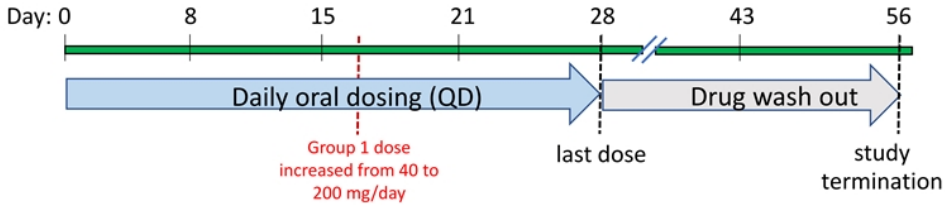


Image Source: Charles River Laboratories, 2001.

- The ZDF rat is a model of pancreatic exhaustion and insulin resistance, thus mimicking some aspects of human diabetes.
- The ZDF rat is a translatable model for studying the development of T2D.

Treatment Scheme of ZDF Rat Model



Treatment groups (n=10/group):

1. Vehicle
2. BMF-219 40 mg/kg days 1-16, 200 mg/kg days 17-28 (QD, PO)
3. BMF-219 85 mg/kg (QD, PO)
4. BMF-219 170 mg/kg (QD, PO)
5. Liraglutide 0.2 mg/kg (BID, SC)

Rats monitored through dosing and washout phases:
Fasting blood glucose, insulin, OGTT, HbA1c, body weight, blood lipemic levels

Study Objective

Measure the ability of BMF-219 in restoring glycemic control in Zucker Diabetic Fatty (ZDF) Rat over a 4-week dosing study.

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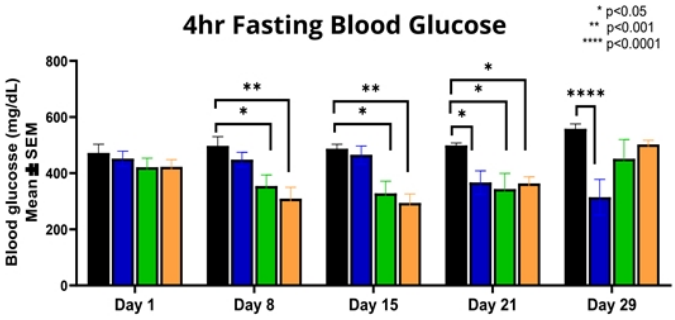
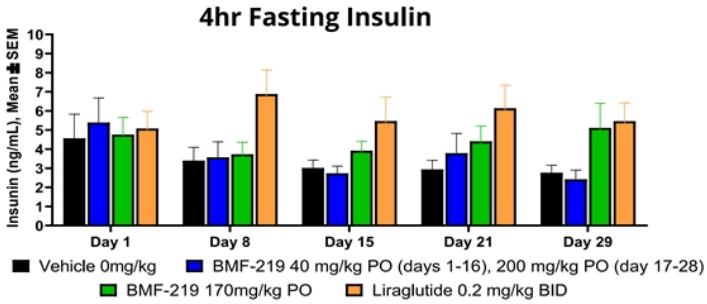
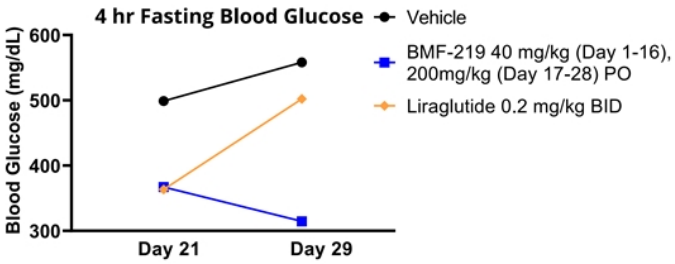
BMF-219 substantially controls blood glucose levels in a 4-week dosing study in ZDF rats







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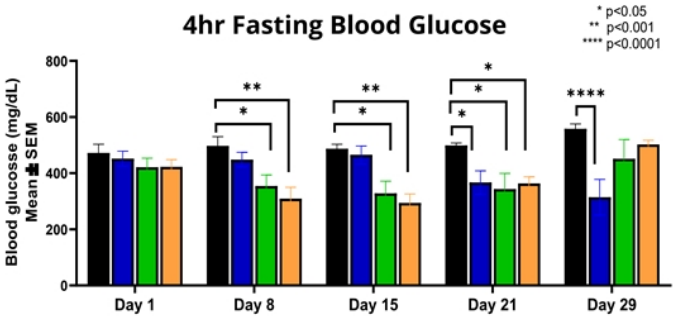
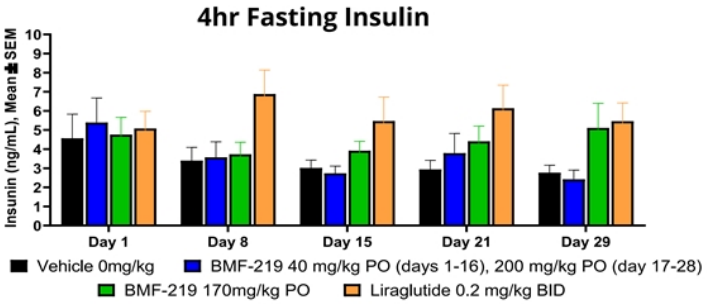
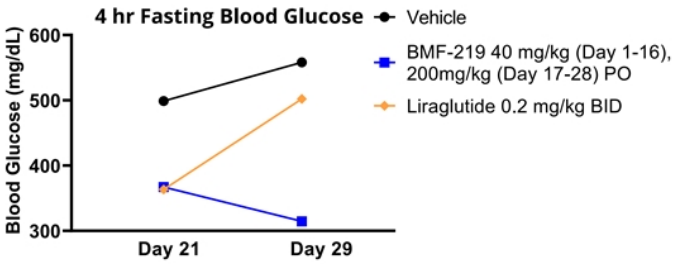
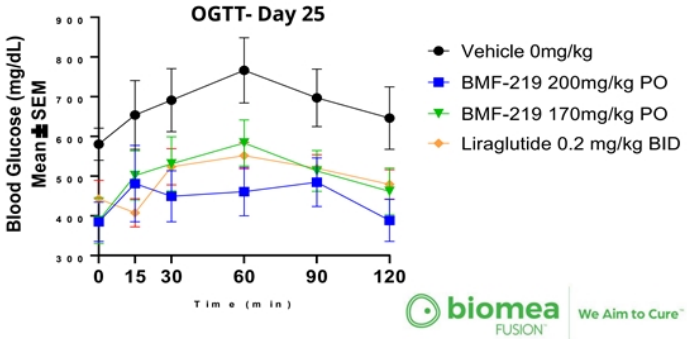
BMF-219 substantially controls blood glucose levels in a 4-week dosing study in ZDF rats

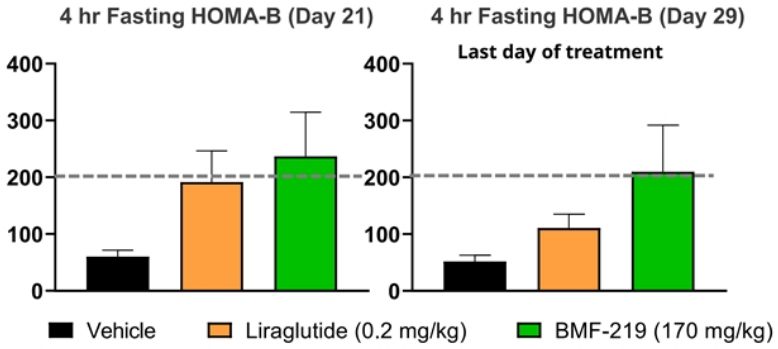








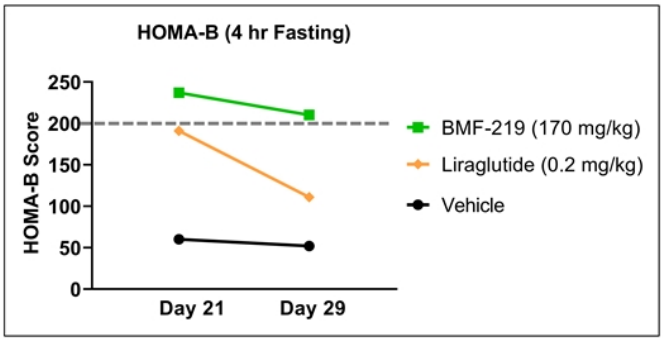
BMF-219 restores beta-cell function over 4 weeks of treatment



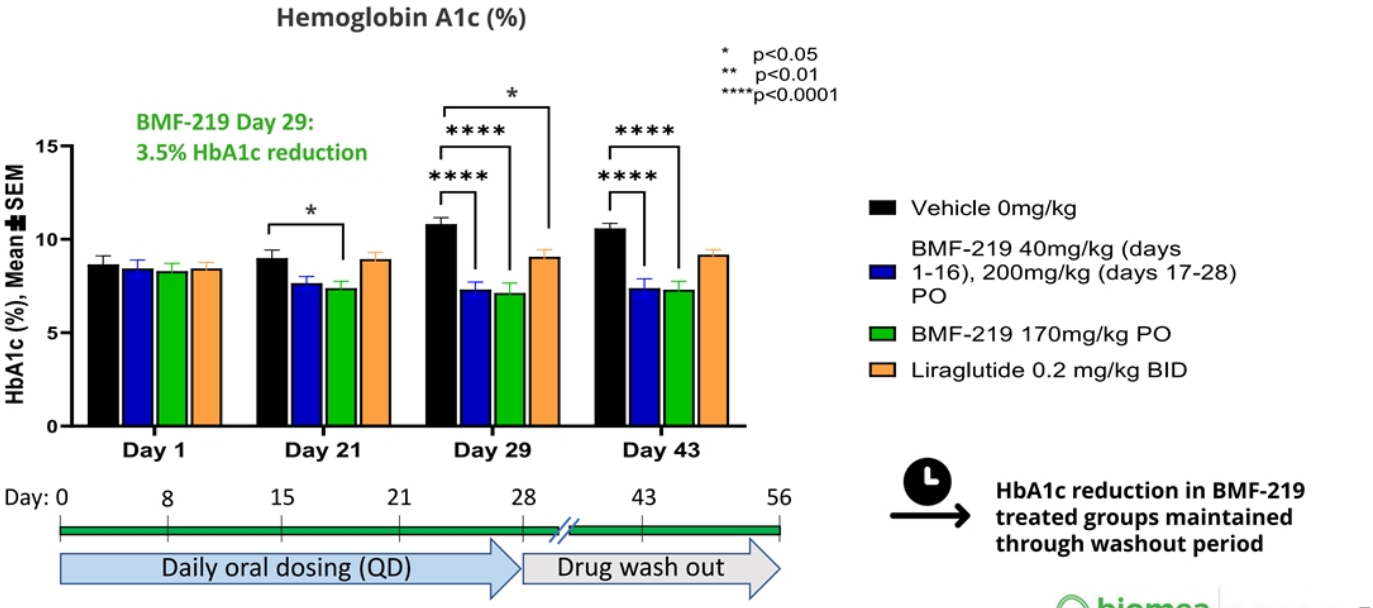
Severity Grading Assessment for Pancreatic Beta-Cell Function	HOMA-B Index
Adequate (normal state)	≥ 201.00
Mild deficiency	134.00 to 200.99
Moderate deficiency	67.00 to 133.99
Severe deficiency	0.00 to 66.99

Table Source: Fasipe JO et al. 2020. Can J Diabetes 44 (2020) 663e669.

BMF-219 restores and maintains HOMA-B index to normal state (>201) over 4 weeks of treatment



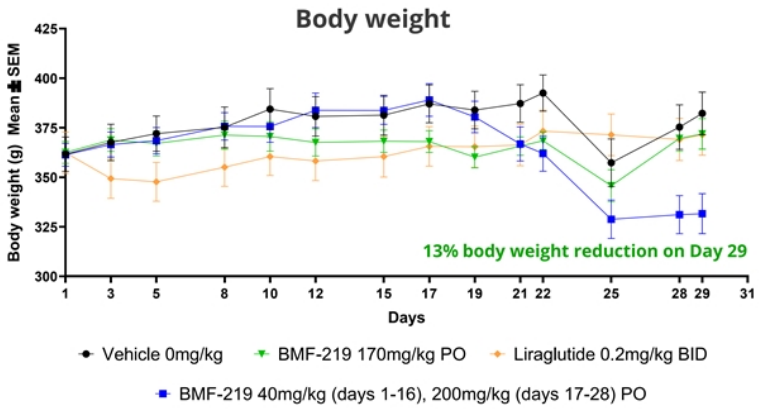
BMF-219 significantly reduces HbA1c (-3.5%) during treatment and maintains lowering effect during 2 weeks of drug washout



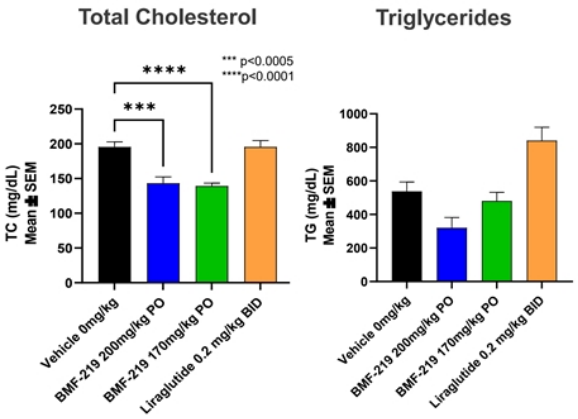
HbA1c reduction in BMF-219 treated groups maintained through washout period

BMF-219 treated groups display body weight and cholesterol reduction

BMF-219 200 mg/kg group reduces body weight during treatment in ZDF rats



BMF-219 reduces blood lipemic levels measured on Day 29



Summary and Conclusions

- **BMF-219 displays significant glycemic control in ZDF rats, outperforming liraglutide in reduction of fasting blood glucose by Day 29 and by OGTT on day 25.**
- **BMF-219 significantly reduces HbA1c levels (-3.5%) during treatment and drug washout.**
- **BMF-219 treatment restores HOMA-B scores to normal state indicating restored beta-cell function.**
- **BMF-219 treated groups have significant reductions in body weight (13% at 4 weeks of treatment) and reduced blood lipemic levels.**

Collectively, these data demonstrate the novel long-acting potential of BMF-219 as an orally administered short-term treatment in achieving and maintaining glycemic control in T2DM.


THANK YOU
#EASD2022
EASD 2022
58th ANNUAL MEETING
European Association for the Study of Diabetes
19-23 September 2022
Stockholm & Online
easd.org
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FUSION