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): April 27, 2026

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.)**

1599 Industrial Road **San Carlos, CA** **(Address of Principal Executive Offices)**	**94070** **(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 7.01 Regulation FD Disclosure

On April 28, 2026, Biomea Fusion, Inc. (the "Company") hosted a conference call and live webcast to discuss topline data for its Phase 2 COVALENT-112 study. The Company has made available a slide presentation to accompany the call, a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liabilities of that section and shall not be incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01. Other Events

On April 27, 2026, the Company reported positive 52-week results from its Phase 2 COVALENT-112 trial evaluating the efficacy, safety, and tolerability of icovamenib in patients with type 1 diabetes ("T1D").

Results

The COVALENT-112 trial demonstrated encouraging results in patients with T1D. In patients diagnosed within 0–3 years, treatment with icovamenib 200 mg once daily for 12 weeks resulted in a 52% increase in mean C-peptide area under the curve (AUC) at Week 12 ($p<0.001$; $n=5$), representing a magnitude of improvement that is not commonly reported in published studies of T1D.

Importantly, the effect was durable following only 12 weeks of dosing, mean C-peptide AUC was largely preserved through Week 52, representing approximately a 7% decline from baseline. A dose response was observed, with the 200 mg dose demonstrating greater activity compared to 100 mg. Published natural history data suggest that patients with Stage 3 T1D typically experience substantial declines in C-peptide over time, underscoring the significance of preserved C-peptide following only a 12-week dosing period.

In patients with longer-standing disease (3-15 years since diagnosis), C-peptide levels were generally preserved through Week 52 (12-week treatment period + 40-week follow-up), with only a modest decline from baseline. A comprehensive dataset will be presented at the upcoming American Diabetes Association's (ADA) Scientific Sessions in June.

Icovamenib was generally well tolerated, with no new or unexpected safety signals identified throughout the 52-week observation period. Unlike investigational approaches in T1D that rely primarily on immune suppression or cellular transplantation, icovamenib is designed as a short course, orally administered therapy targeting beta cell biology, with effects that appear to persist beyond the treatment period.

Planned Next Steps

Based on these data, the Company, in collaboration with four U.S. academic centers, is planning a Phase 2 trial in patients with T1D diagnosed within the past 3 years. The study will evaluate whether extended dosing (up to 6 or 12 months) at 200 mg further improves C-peptide and whether the addition of an immunosuppressive agent enhances clinical outcomes. This study is planned to be initiated within the second half of this year at the Barbara Davis Center for Diabetes, Joslin Diabetes Center, UT Health San Antonio Diabetes Center, and the University of Miami Diabetes Research Institute.

Study Design

COVALENT-112 (NCT06152042) was an open-label Phase 2 trial evaluating icovamenib in adult patients with T1D. The study enrolled patients aged 18 to 60 years with Stage 3 T1D, including those diagnosed within 0–3 years with residual beta cell function at baseline, defined by a screening C-peptide level ≥0.2 nmol/L (Cohort 1), as well as a broader population with disease duration of 3–15 years and residual beta cell function at baseline, defined by a screening C-peptide level ≥0.08 nmol/L (Cohort 2). Participants were assigned to receive icovamenib at 100 mg or 200 mg once daily for 12 weeks, followed by a 40-week post-treatment follow-up to assess durability of effect. Study enrollment and dosing were interrupted in May 2024 due to an FDA clinical hold, which was subsequently resolved. As a result, these data reflect approximately half of the originally intended patient population. A planned placebo-controlled Part 2 of the study was not completed.

The primary endpoint was the mean change from baseline in stimulated C-peptide area under the curve (AUC), measured during a mixed-meal tolerance test (MMTT), to evaluate endogenous insulin secretion. Secondary endpoints included additional measures of beta cell function, glycemic control, insulin use, and safety.

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 Current Report 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 icovamenib and the potential of icovamenib as a treatment for Type 1 and Type 2 diabetes, and the Company's expectations regarding the optimal dose and target patient population; the Company's research, development and regulatory plans; the mechanism of action of the Company's product candidates and development programs; the progress and initiation of the Company's ongoing and upcoming clinical trials, including its Phase 2 COVALENT-112 trial; the anticipated availability of data from the Company's clinical trials; the Company's planned interactions with regulators; 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 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 preliminary or interim results of preclinical studies or clinical trials may not be predictive of future or final results in connection with ongoing or future clinical trials and the risk that the Company may encounter delays in preclinical or clinical development, patient enrollment and in the initiation, conduct and completion of the Company's ongoing and 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	Presentation titled "Icovamenib in Type 1 Diabetes: COVALENT-112 Topline Results," dated April 28, 2026, furnished herewith.
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: April 28, 2026

By: /s/ Michael J.M. Hitchcock

Michael J.M. Hitchcock
Interim Chief Executive Officer, Director
(Principal Executive Officer)

Icovamenib in Type 1 Diabetes

COVALENT-112 Topline Results

BIOMEA FUSION CONFERENCE CALL
28 APRIL 2026

biomea FUSION

Legal disclaimer & forward-looking statements

Certain statements in this presentation and the accompanying oral commentary are forward-looking statements. These statements relate to future events or the future business and financial performance of Biomea Fusion, Inc. (the "Company") and involve known and unknown risks, uncertainties, and other factors that may cause the actual results, levels of activity, performance or achievements of the Company or its industry to be materially different from those expressed or implied by any forward-looking statements. In some cases, forward-looking statements can be identified by terminology such as "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "potential" or other comparable terminology. All statements other than statements of historical fact could be deemed forward-looking, including any projections of financial information or profitability, the initiation, timing and results of pending or future preclinical studies and clinical trials, the actual or potential actions of the U.S. Food and Drug Administration (FDA), the status and timing of ongoing research, development and corporate partnering activities, any statements about historical results that may suggest trends for the Company's business; any statements of the plans, strategies, and objectives of management for future operations and any statements of expectation or belief regarding future events, potential markets or market size, or technology developments. The Company has based these forward-looking statements on its current expectations, assumptions, estimates, and projections. While the Company believes these expectations, assumptions, estimates and projections are reasonable, such forward-looking statements are only predictions and involve known and unknown risks and uncertainties, many of which are beyond the Company's control. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent annual report on Form 10-K filed with the Securities and Exchange Commission (the SEC), as well as discussions of potential risks, uncertainties, and other important factors in our other subsequent filings with the SEC. The forward-looking statements in this presentation are made only as of the date hereof. Except as required by law, the Company assumes no obligation and does not intend to update these forward-looking statements or to conform these statements to actual results or to changes in the Company's expectations. This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

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Type 1 diabetes at-a-glance

biomea FUSION

~9.5M

People live with T1D globally in 2025[1]

- **~1.8M in the US[2]**

~513K

New diagnoses per year globally in 2025[1]

- **~64K new diagnoses/year in the US[3]**

T1D is caused by autoimmune destruction of insulin-producing pancreatic islet beta cells

- **T1D is considered a lifelong chronic disease and carries substantial acute risk** (severe hypoglycemia, DKA) as well as long-term complications including kidney disease, nerve damage, vision loss, and cardiovascular issues[4]
- **Patients with symptomatic T1D (Stage 3) typically lose yearly ~50%** of their beta cell capacity over the first 7 years[5]
- **There are no approved therapies** other than exogenous insulin that address the dysglycemia associated with the progressive decline of C-peptide in Stage 3 T1D[6]

1. *Ogle, et al. Diabetes Research and Clinical Practice 2025, 225, 112277*
2. *Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2023*
3. *Mayer-Davis et al., NEJM / CDC updates*
4. *American Diabetes Association. Standards of Care in Diabetes–2025*
5. *Diabetes Care. 2018 Jun 7;41(7):1486–1492*
6. *Front. Endocrinol., 05 November 2024*

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Lowering menin is a natural biological process that drives beta cell expansion and is expected to reduce diabetes risk

- **Physiologic evidence**
  Natural states such as pregnancy and lactation reduce menin, enabling beta cell expansion and increased insulin output

- **Preclinical and translational validation**
  Across animal models and human islet studies, reduced menin is consistently linked to improved beta-cell mass and function

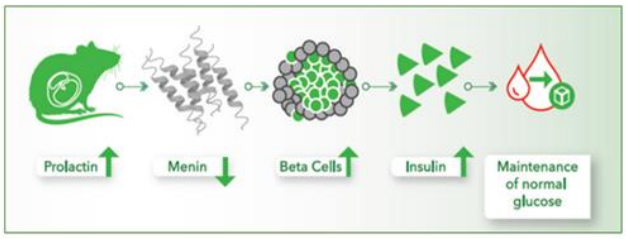
- **Icovamenib MOA**
  Icovamenib reduced menin levels to replicate a validated biological process and restore beta cell function

Science
AAAS

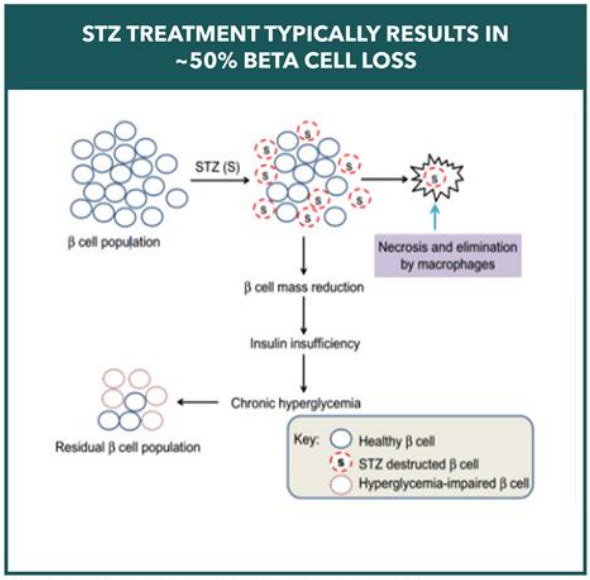
Menin Controls Growth of Pancreatic β-Cells in Pregnant Mice and Promotes Gestational Diabetes Mellitus

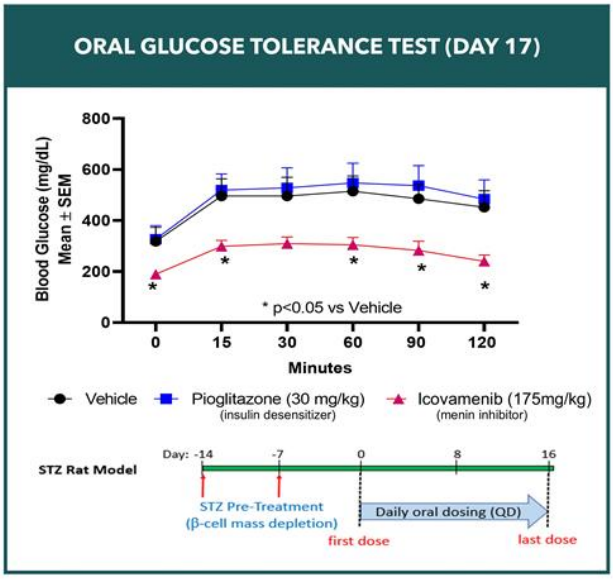
Satyajit K. Karnik,[1] Hainan Chen,[1*] Graeme W. McLean,[1*] Jeremy J. Heit,[1*] Xueying Gu,[1] Andrew Y. Zhang,[1] Magali Fontaine,[2] Michael H. Yen,[1,3] Seung K. Kim[1,3]†

Karnik SK, et al. Science. 2007;318:806-809



Icovamenib significantly reduced blood glucose in STZ rats (a model in which only insulin decreases blood glucose levels)



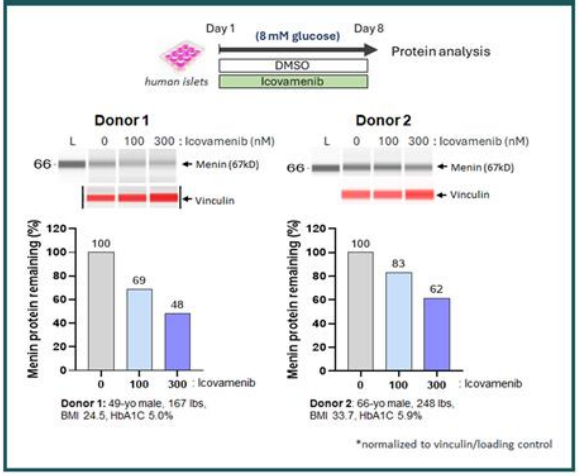


Butler, eta al. Diabetologia 65 (Suppl 1), 1–469 (2022) presentation #197

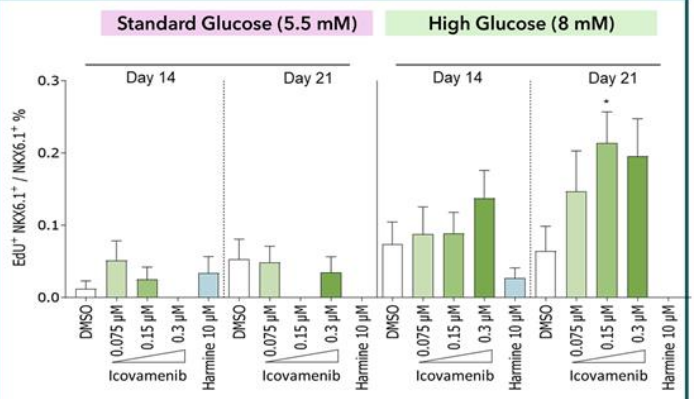
STZ=Streptozotocin, an antibiotic that produces pancreatic islet beta cell destruction and is widely used experimentally to produce a model in diabetes

Icovamenib decreased menin protein levels & promoted beta cell proliferation in ex vivo human islet cultures

MENIN LEVELS DECREASED



ICOVAMENIB CONDITIONALLY PROMOTED BETA CELL PROLIFERATION ONLY UNDER HYPERGLYCEMIC CONDITIONS



Somanath, et al. Diabetologia 68 (Suppl 1), 1-754 (2025). Oral presentation #66

Frias, et al. Metabolism,Vol153, Supplement,2023,#88

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Treatment Landscape: Limitations of current approaches in stage 3 T1D

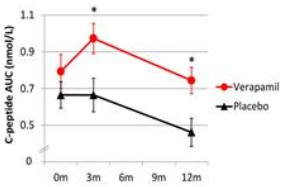
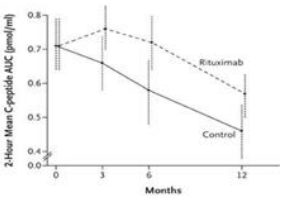
- Most investigational therapies in T1D focus on immune modulation to slow autoimmune destruction or on preserving residual beta cell function[1]
- C-peptide area under the curve (AUC) has become the accepted endpoint, driving enrollment early after diagnosis (<90 days, new-onset T1D) to preserve residual beta-cell function[2]
- To date, most investigational therapies have not demonstrated durable restoration of beta cell function or sustained increases in C-peptide, outside of cell-based transplantation approaches[3]

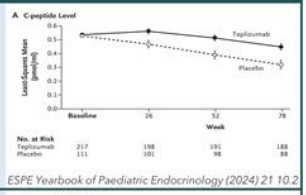
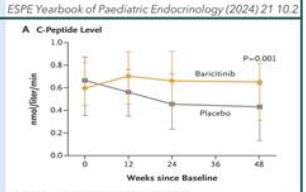
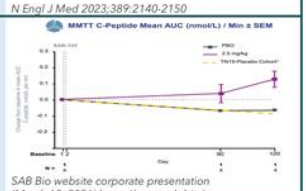
The Next Frontier:

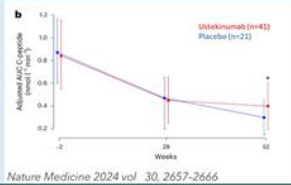
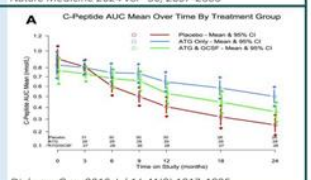
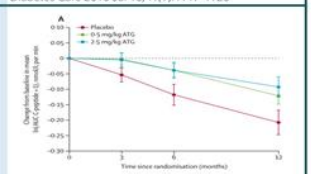
- Restoring beta cell function and mass, beyond only slowing the decline of C-peptide
- Expanding the treatment window beyond early, new onset T1D populations
- Enabling persistence of newly generated beta cells despite autoimmune pressure

1. *Zarei M et al. Diabetes Epidemiology and Management 2025;17*
2. *Diabetes Care 2025*
3. *NIDDK. Diabetes in America, 2024*

Most therapies in development for stage 3 T1D show limited and non-durable C-peptide impact

DRUG	Mean C-PEPTIDE AUC VS PLACEBO
Verapamil	 *Nature. 2018 Aug;24(8):1108-1112*
Rituximab	 *NEJM. 2009 361:2143-2152*

DRUG	Mean C-PEPTIDE AUC VS PLACEBO
Teplizumab (Tzield)	 *ESPE Yearbook of Paediatric Endocrinology (2024) 21 10.2*
Baricitinib	 *N Engl J Med 2023;389:2140-2150*
SAB-142	 *SAB Bio website corporate presentation (March 10, 2026) https://www.sab.bio/*

DRUG	Mean C-PEPTIDE AUC VS PLACEBO
Ustekinumab	 *Nature Medicine 2024 vol 30, 2657-2666*
ATG (TrialNet)	 *Diabetes Care 2018 Jul 16;41(9):1917-1925*
MELD-ATG	 *Lancet 2025 Sep 27;406(10510):1375-1388*

**Ladarixin and Diamyd,* both Immune modulating, not mentioned here as they demonstrated no meaningful difference compared to placebo

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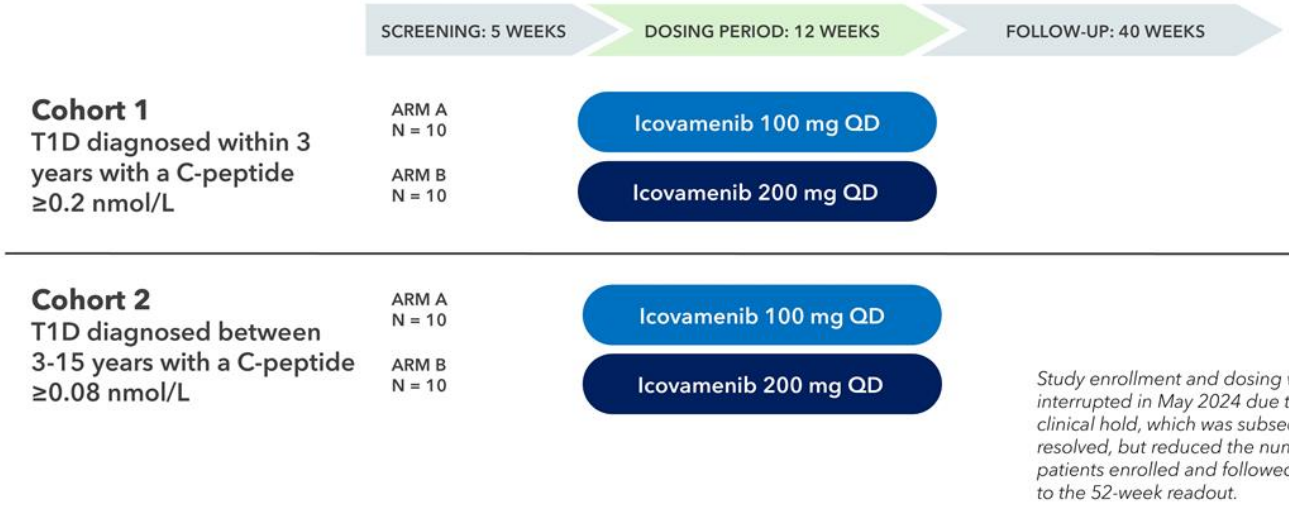
COVALENT-112 | Study Design

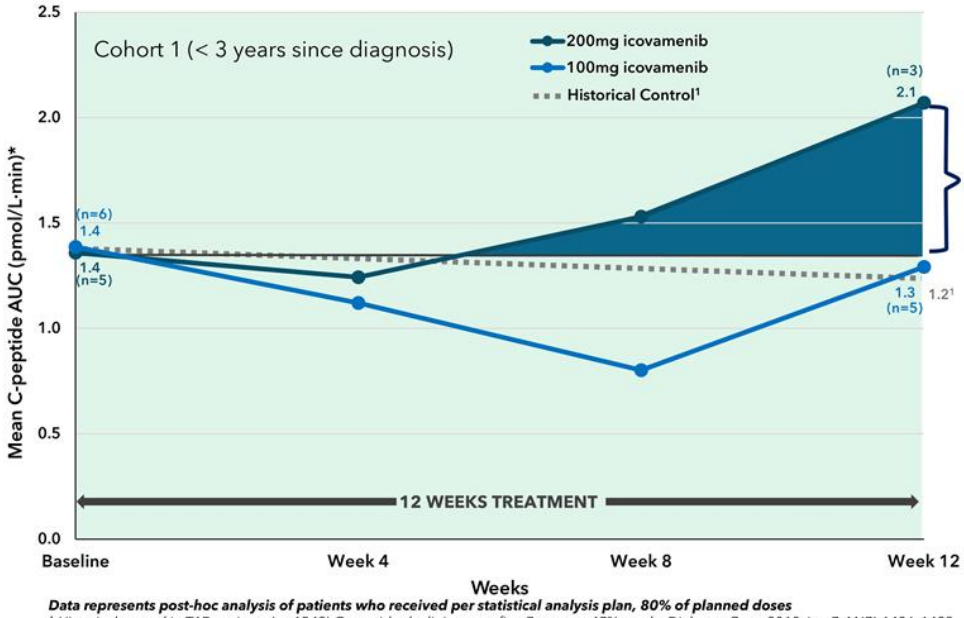
COVALENT-112 (NCT06152042) was a Phase 2 trial designed to examine beta cell function (as measured by C-peptide change and the change of exogenous insulin usage) and glucose and lipid metabolism in participants with T1D treated with standard of care insulin and icovamenib.



Study enrollment and dosing were interrupted in May 2024 due to an FDA clinical hold, which was subsequently resolved, but reduced the number of patients enrolled and followed through to the 52-week readout.

Readout at Week 12

52% mean increase in C-peptide during the 12 weeks treatment period of icovamenib



52% mean increase from baseline

+0.7
P<0.001

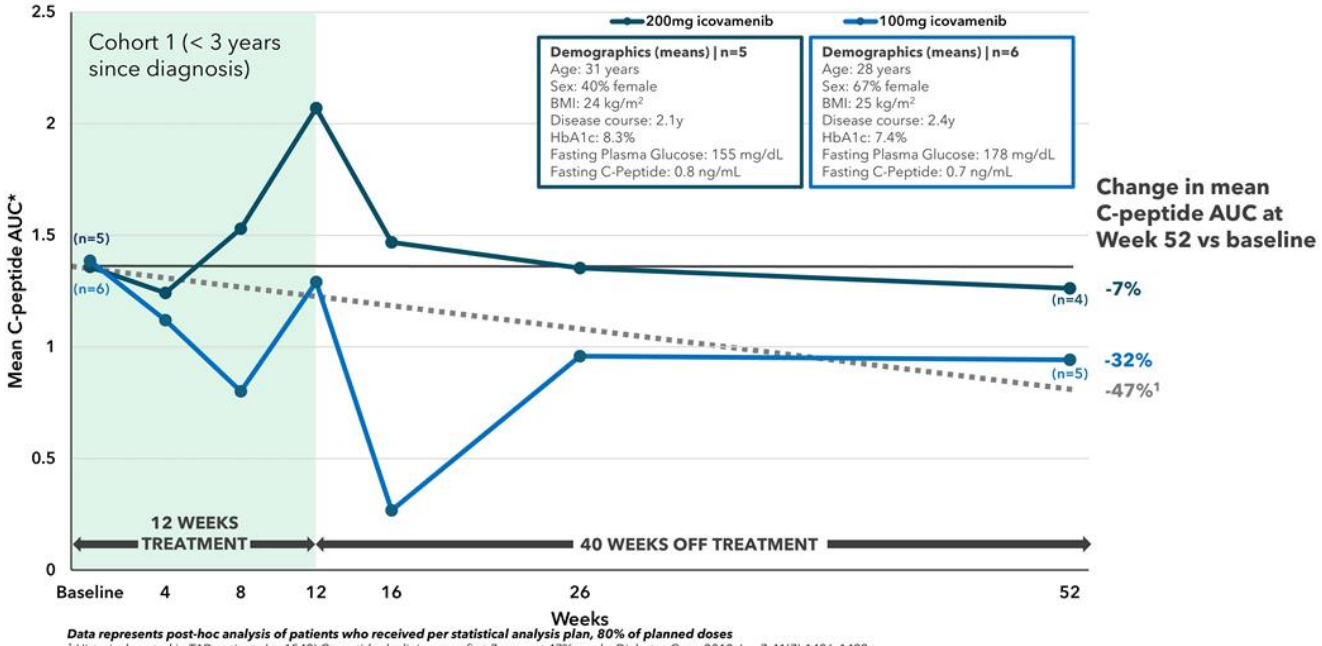
Data represents post-hoc analysis of patients who received per statistical analysis plan, 80% of planned doses

[1] Historical control in T1D patients (n=1549) C-peptide declining over first 7 years at 47% yearly. Diabetes Care. 2018 Jun 7;41(7):1486–1492

** 4-hour Mixed Meal Tolerance Test (MMTT)*

Readout at week 52

Baseline C-peptide levels sustained through week 52 with minimal decline (only -7.1%) observed post 12 weeks of 200mg daily icovamenib



Data represents post-hoc analysis of patients who received per statistical analysis plan, 80% of planned doses

[1] Historical control in T1D patients (n=1549) C-peptide declining over first 7 years at 47% yearly. Diabetes Care. 2018 Jun 7;41(7):1486-1492

** 4-hour Mixed Meal Tolerance Test (MMTT)*

Topline results of icovamenib demonstrated marked C-peptide increase in T1D with observed persistence

- **Observed 52% increase in mean C-peptide AUC at Week 12** ($p < 0.001$) in Cohort 1 patients dosed at 200 mg (diagnosed within 0–3 years; n=5), a magnitude of improvement not commonly reported in published T1D studies
- **Mean C-peptide AUC remained largely preserved through Week 52** in Cohort 1 patients dosed at 200 mg (~7% decline from baseline), supporting persistence of effect. Patients dosed in Cohort 2 demonstrated stable AUC during and post dosing.
- **Generally well-tolerated,** with a favorable safety profile throughout the 52-week observation period
- **Validation of menin as a target for diabetes (T1D & T2D)** further supported by these results
- **Presentation at American Diabetes Association's (ADA) Scientific Session,** comprehensive dataset of Cohort 1 and Cohort 2 to be presented (full release on June 5th at 6:30 pm CST)

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Optimal dose and target population identified for T1D phase 2 program

ICOVAMENIB

T1D insights:

- ✓ Dose response: 200 mg demonstrated stronger clinical activity vs 100 mg
- ✓ Potential early intervention advantage: T1D patients dosed ≤3 years showed greater response vs those 3-15 years from diagnosis
- ✓ 12-week treatment showed continuous and improved responses, supporting potential for greater benefit with extended dosing
- ✓ Preclinical chronic toxicology studies support longer term dosing
- ✓ Generally well-tolerated, with a favorable safety profile maintained through the 52-week observation period

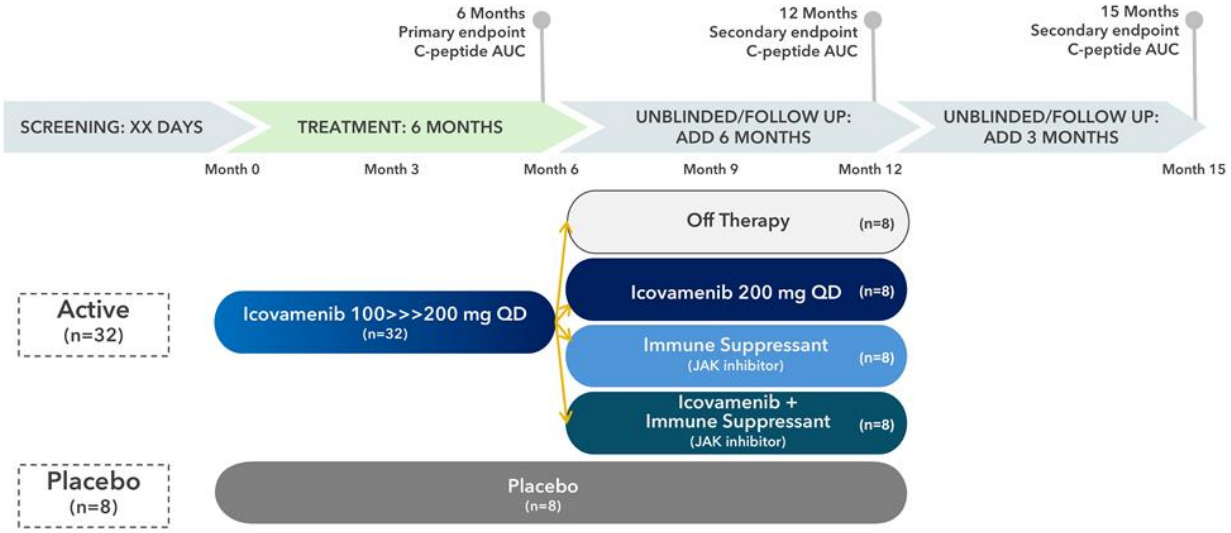
T1D development focus:

- Potential to further increase C-peptide AUC in T1D with extended or continuous dosing
- Opportunity to potentially enhance outcomes through combination with immunomodulation therapies

Proposed phase 2 trial design*

Inclusion Criteria

- Adult participants with T1D diagnosed within 3 years with a C-peptide ≥0.2 nmol/L
- Background therapy maintained unless rescue required



*Subject to regulatory and investigator alignment, and feedback from applicable health authorities.

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Thank you

(NASDAQ: BMEA)

For questions or inquiries, please reach out to Meichiel Weiss at ir@biomeafusion.com

www.biomeafusion.com

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Exhibits

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KOL perspectives across clinical significance, biology, and future development in T1D

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Efforts to intervene against type 1 diabetes (T1D) have historically focused on preserving remaining insulin secretion in people just diagnosed with T1D. These icovamenib data are unique in showing increased C-peptide-reflected insulin secretion in patients with established T1D during dosing and persistence of this effect after treatment was stopped. In people with established T1D, endogenous insulin secretion progressively declines to very low levels.

Any evidence of improvement in endogenous insulin secretion—even among a few T1D individuals—is unprecedented and of immense biologic and clinical significance. These findings warrant rigorous and longer-term evaluation.

G. Alexander "Zan" Fleming, MD
FOUNDER & EXECUTIVE CHAIRMAN, KINEXUM
FORMER FDA SENIOR MEDICAL OFFICER AND DIVISION LEADER FOR METABOLIC & ENDOCRINE DRUGS, INVOLVED IN THE REVIEW OF LANDMARK DIABETES AND METABOLIC THERAPIES INCLUDING METFORMIN, THE FIRST RAPID-ACTING INSULIN ANALOGS, EARLY STATINS, AND PPAR AGONISTS

The new data presented today with icovamenib in patients with type 1 diabetes suggest a potential new therapeutic avenue in a disease where fundamental unmet need has long persisted. To date, approved therapies have not directly addressed the progressive loss of functional beta cells that underlies diabetes.

Biomea has made critical progress in identifying and characterizing this molecule, which has demonstrated the ability to reduce menin protein levels and activate pathways associated with beta cell function. Today's icovamenib type 1 data further validates and deepens our understanding of icovamenib's mechanism of action. Congratulations to the Biomea team on reaching this important therapeutic milestone.

Rohit Kulkarni, MD, PhD
PROFESSOR OF MEDICINE, HARVARD MEDICAL SCHOOL | SENIOR INVESTIGATOR & SECTION CO-HEAD (ISLET CELL & REGENERATIVE BIOLOGY), JOSLIN DIABETES CENTER

What stands out to me in the icovamenib diabetes data is not only the emerging signal of biological activity, but also the safety profile observed to date with using icovamenib in diabetes studies. That combination is important, because safety ultimately determines whether rational combination strategies can be explored as the program moves forward.

Looking ahead, future studies will be critical in determining whether the improvements observed in beta cell function of these Type 1 diabetes patients can be maintained over time, particularly in the presence of ongoing immune activity. It will also be important to understand whether combination approaches–including immunomodulatory therapies– are needed and can further enhance or stabilize the observed effects. These are key questions that will inform the long term clinical potential of this approach.

David Baidal, MD
ASSISTANT PROFESSOR DIABETES RESEARCH INSTITUTE, UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE

KOL perspectives across clinical significance, biology, and future development in T1D

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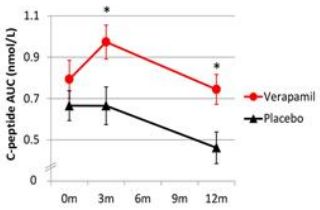
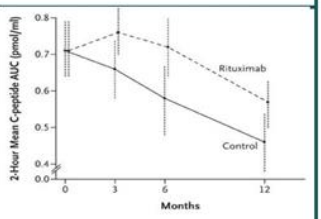
> The icovamenib data in Type 1 diabetes naturally makes us pause and reflect on what it could ultimately mean for people living with Type 1 diabetes. While these early findings require confirmation, they suggest a different way of thinking about treatment, one that extends beyond glucose management and begins to engage underlying disease biology. For younger individuals in particular, the possibility of preserving or improving endogenous beta cell function over time could have meaningful implications for lifelong disease burden.
>
> Results like these invite consideration of how the treatment landscape in Type 1 diabetes may evolve if such approaches prove durable and safe.

Alice Cheng, M.D.
ENDOCRINOLOGIST, ASSOCIATE PROFESSOR OF MEDICINE UNIVERSITY OF TORONTO

> The icovamenib data in type 1 diabetes are encouraging, this is particularly interesting as icovamenib targets a pathway that has not been meaningfully explored in this disease. Despite advances in insulin delivery and glucose monitoring, disease-modifying options remain limited for patients. These findings support the need for focused, proof-of-concept studies in well-characterized patient populations to better understand this signal, its durability, and the underlying biology.
>
> An important next step will be examining the interplay between beta cell effects and the autoimmunity inherent in type 1 diabetes, and whether combination approaches with immunomodulatory therapies could further enhance or stabilize these beta cell effects.

Jason Gaglia, MD, MMSc
ASSISTANT PROFESSOR OF MEDICINE, HARVARD MEDICAL SCHOOL | STAFF PHYSICIAN, JOSLIN DIABETES CENTER – ONE OF THE WORLD'S LEADING DIABETES CENTERS

Type 1 diabetes (stage 3) therapies in development - beta cell protection

DRUG	MOA	ROUTE & DOSING	N	AGE (YRS)	TIME SINCE TID DX	PHASE	C-PEPTIDE AUC (~WEEK 52)	SAFETY	C-PEPTIDE AUC VS PLACEBO
Verapamil	Beta cell protection *Nature. 2018 Aug;24(8):1108-1112*	Oral daily	88	7–17	≤31 days	2	**~30–35% less decline** vs placebo *(inferred; near-stable vs decline)*	Well-tolerated	
Rituximab	Anti-CD20 monoclonal antibody; B-cell depletion *NEJM. 2009 361:2143-2152*	IV, 4 weekly infusions	87	8–40	≤100 days	2	**~20–25% preservation** vs placebo	Mainly infusion-related AEs; broader class risks include infection and late neutropenia	

Type 1 diabetes (stage 3) therapies in development - immunomodulation / suppression

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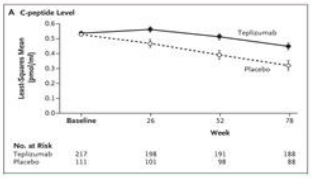
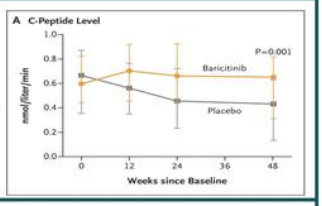
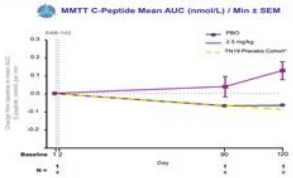
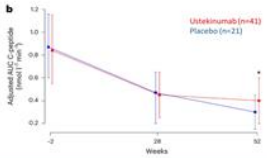
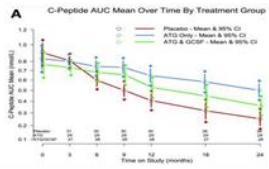
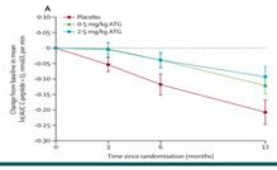
DRUG	MOA	ROUTE & DOSING	N	AGE (YRS)	TIME SINCE T1D DX	PHASE	C-PEPTIDE AUC (~WEEK 52)	SAFETY	C-PEPTIDE AUC VS PLACEBO
Teplizumab (Tzield)	Anti-CD3	IV (12d × 2 cycles)	328	8-17	≤6 weeks	3	**~59% less decline** vs placebo *(Week 78 proxy)*	CRS, lymphopenia-rash	
Baricitinib	JAK1/2 inhibitor	Oral dail	91	Adult	≤100 days	2	**~40-50% less decline** vs placebo *(inferred from 0.65 vs 0.43)*	Chronic immuno-suppression risk	
SAB-142	Human anti-thymocyte Ig	IV (2-day + 6 mo)	4	5-40	3.3 years	2b	**~13% C-peptide increase** vs baseline at ~120 days	Favorable safety	

ESPE Yearbook of Paediatric Endocrinology (2024) 21 10.2

N Engl J Med 2023;389:2140-2150

SAB Bio website corporate presentation (March 10, 2026) https://www.sab.bio/

Type 1 diabetes (stage 3) therapies in development - immunomodulation / suppression

DRUG	MOA	ROUTE & DOSING	N	AGE (YRS)	TIME SINCE T1D DX	PHASE	C-PEPTIDE AUC (~WEEK 52)	SAFETY	C-PEPTIDE AUC VS PLACEBO
Ustekinumab	IL-12/23	SC (1x every 12 weeks)	72	12-18	≤100 days	2	**~30-40% less decline** vs placebo	Well-tolerated	
	Nature Medicine 2024 vol 30, 2657-2666								
ATG (TrialNet)	T-cell depletion	IV (1x over 2 days)	89	12-45	≤100 days	2	**~50-60% less decline** vs placebo	CRS, serum sickness	
	Diabetes Care 2018 Jul 16;41(9):1917-1925								
MELD-ATG	Optimized ATG	IV (1x over 2 day)	114-117	5-25	≤100 days	2	**~25-35% less decline** vs placebo	CRS, serum sickness	
	Lancet 2025 Sep 27;406(10510):1375-1388								

*Ladarixin and Diamyd, both Immune modulating, not mentioned here as they demonstrated no meaningful difference compared to placebo