



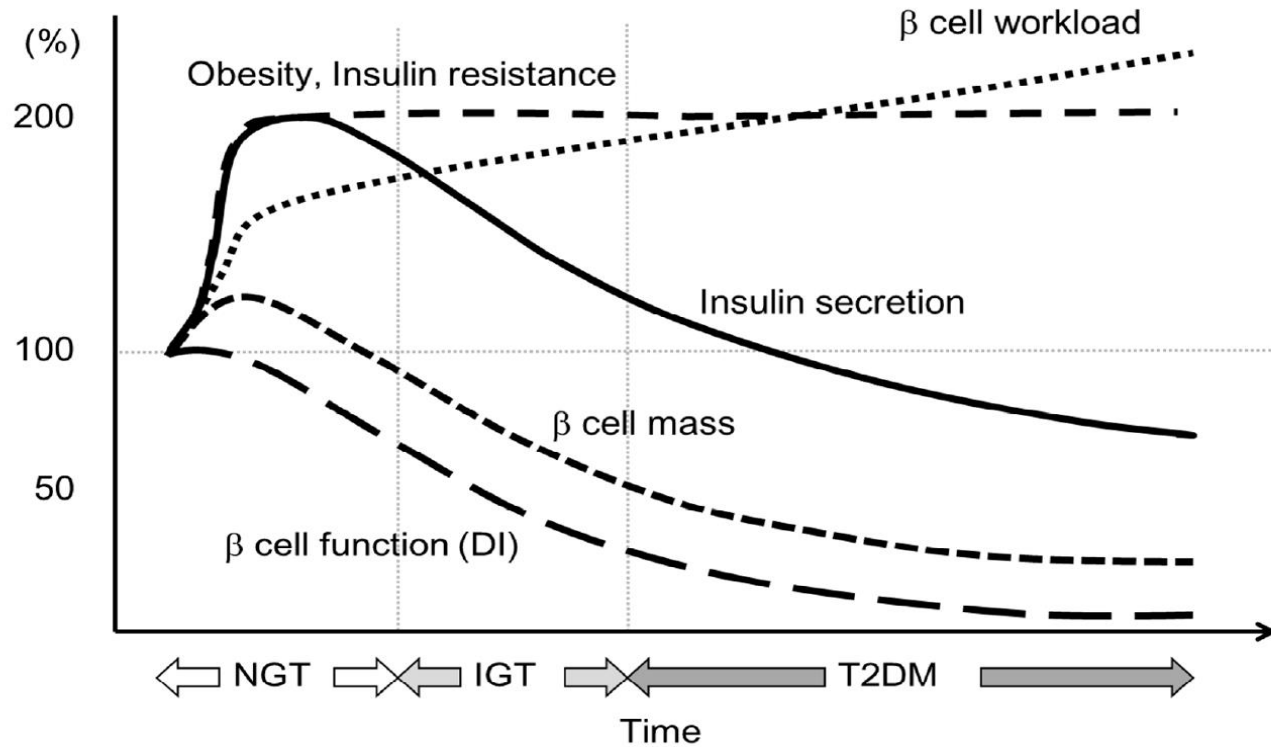
- | Conference Call December 15, 2022  
FDA Clearance of Investigational New Drug (IND)  
Application for Covalent Menin Inhibitor BMF-219 in  
Type 2 Diabetes

## Disclaimer

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# Diabetes Progression of Type 1 and Type 2 Driven by Beta Cell Loss



**Prior Paradigm**

Type 1 diabetes	Type 2 diabetes
β cell destruction β cell mass ↓↓ Insulin secretion ↓↓	Obesity Insulin resistance Hyperinsulinemia

**Current Paradigm**

Type 1 diabetes	Type 2 diabetes
β cell destruction β cell mass ↓↓ Insulin secretion ↓↓	β cell loss β cell mass ↓ Insulin secretion ↓

**Causes**

Autoimmune	Insulin resistance β cell overwork
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Insulin Resistance leads to an increase in Beta Cell Workload which ultimately leads to Beta Cell Failure and Death and the Progression of Type 2 Diabetes.

Type 1 and Type 2 Diabetes results in Beta Cell Loss and Reduction in Beta Cell Mass

\*Int. J. Mol. Sci. 2016, 17, 744; doi:10.3390/ijms17050744

## COVALENT-111 (ENROLLING)

# A Phase 1/2 Randomized, Double-Blind, Placebo-Controlled Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of BMF-219, an Oral Covalent Menin Inhibitor, in Healthy Adult Subjects and in Adult Subjects with Type 2 Diabetes Mellitus

### Phase 1 (SAD)

#### SAD C1 to SAD C4 (HVs)

Total N=40

Dose [100, 200, 400, and 600 mg]

### Phase 2 (MAD)

#### MAD C1 (HVs)

Total N = 16

#### MAD C2 to MAD C8 (T2D)

Total N=108

Dose [100, 200, 300, 400, 600 mg]

In the Phase 2, COVALENT-111 will enroll subjects with a HbA1C of 7-10% despite being on standard of care, up to three agents of therapy.

### Study Treatment: BMF-219

- A covalent small molecule menin inhibitor, administered orally daily in 28 day cycles

### Primary Objective:

- Evaluate safety and tolerability of BMF219

### Secondary Objectives:

- Evaluate PK of BMF-219
- Evaluate the effect on BMF-219 on glycemic parameters (HbA1C, PG) and few additional parameters using OGTT, 7-day CGM
- Evaluate the changes in beta cell function
- Evaluate impact on lipid parameters, body weight etc.

### Exploratory Objectives:

- To assess the durability of response to glycemic parameters

Multiple Clinical Read Outs over the coming Quarters

## Near Term Milestones – Biomea Fusion (NASDAQ: BMEA)

			Key Milestones	Expected Timeline
BMF-219 Menin Programs	COVALENT-101 (Liquid Tumors)	AML/ALL (Leukemia)	Phase I: Clinical Data in AML Initiation of Phase I additional Cohort in DLBCL Enrolling in Phase I additional Cohort in MM Enrolling in Phase I additional Cohort in CLL	1H 2023
		DLBCL (Lymphoma)		In Progress
		MM (Lymphoma)		In Progress
CLL (Lymphoma)		In Progress		
	COVALENT-102 (KRAS Solid Tumors)	NSCL (Lung)	Initiation of Phase I KRAS Study in CRC, PDAC, NSCLC	In Progress
		PDAC (Pancreas)		
		CRC (Colon)		
	COVALENT-111 (Diabetes)	Type 2 Diabetes	Healthy Volunteers of PI/II COVALENT-111 Trial Phase II: Clinical Data in Type 2 Diabetes	Completed 1H 2023
BMF-500 FLT3 Programs	COVALENT-103 (Liquid Tumors)	AML/ALL (Leukemia)	Preclinical Data Presentation IND Filing	ASH 2022 1H 2023
Additional Oncology Programs	Target # 3	Oncology	Progress Update	1H 2023

# THANK YOU



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