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MOLECULIN

December 2023 ASH Presentation

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Disclaimer

All statements contained herein other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. Our potential to sustain our relationship with MD Anderson revolves around the continued collaboration and capitalizing on intellectual property resulting from sponsored research. The feasibility and promptness of our clinical trials are influenced by regulatory stipulations from entities like the US Food & Drug Administration and their global counterparts. The implications of global events, such as the conflict in Ukraine, the COVID-19 pandemic, and prevalent supply chain challenges, play a role in our forward-looking statements. Additionally, our ongoing need for financing, fueling our clinical trial and product development initiatives, securing regulatory approvals in essential markets, and sourcing cost-effective drug solutions are core to our forward-looking statements. Furthermore, our commitments concerning intellectual property licenses, the potential efficacy of our drug candidates, market reception, potential product liabilities, and the emerging competitive landscape are also fundamental to our forward-looking statements. Our dependencies on third-party manufacturers, strategies for establishing business collaborations, the defense of our intellectual property rights, our plans for fostering company growth, and the imperative to retain key executive personnel also guide our projections. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the future events and trends discussed in this presentation may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. More detailed information about Moleculin is set forth in our filings with the Securities and Exchange Commission. Investors and security holders are urged to read these documents free of charge on the SEC's website at http://www.sec.gov. Data related to currently active trials of Moleculin, such as MB-106 & MB-107, are preliminary and subject to change until a final Clinical Study Report is published.





Core Management Belief...

Anthracyclines represent the most important first line treatments for AML and Advanced STS.

Annamycin allows, for the first time ever, a clear majority of patients to benefit from these treatments.



Pathway for AML Patients Showing Unmet Need for Annamycin



	Daunorubicin (+ Ara-C)	Venetoclax (+ Azacitidine)	Annamycin (+ Ara-C)
Regimen	7+3	Ven-Aza	AnnAraC
lb-population	Fit Patients (50%)	Unfit Elderly (50%)	Unfit/2 nd Line (71%)
Ourable CR%	30%	37%	38%
AML benefit ¹	14%	15%	27%
Critical naracteristics	Cardiotox	Tolerability	No Cardiotox More tolerable



Source: Management estimates and shown as if Annamycin becomes approved for AML; 1 - % of AML population sustaining durable positive outcome via BMT or remission

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Cardiotoxicity: Traditional Anthracyclines vs. Annamycin

Current Anthracyclines

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Annamycin



Source Current Cardiology Review, Anthracycline Cardiotoxicity: Prevalence, Pathogenesis and Treatment, Maria Volkova and Raymond Russel III. Referenced from Cancer. 2003 Jun 1;97(11):2869-79. "Congestive heart failure in patients treated with doxorubicin: a retrospective analysis of three trials". Swain SM, Whaley FS, Ewer MS., PMID: 12767102; Preliminary clinical studies from Moleculin.



Limitation for Current Standards of Care (SOC)

First Line Therapy in AML is Doxorubicin in a 7+3 Combination

AML: Ven+Aza CR of 30-40%



Standard-of-care therapies remain limited for unfit and elderly patients due to cardiotoxicity.

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- Ven+Aza is the SOC for 7+3 unfit patients
- CR rate in FDA approval trial was 37% with those having a median duration of 5.5 months
- Most common adverse reactions (≥20%) un the trial: Nausea, diarrhea, thrombocytopenia, constipation, neutropenia, febrile neutropenia, fatigue, vomiting, peripheral edema, pneumonia, dyspnea, hemorrhage, anemia, rash, abdominal pain, sepsis, back pain, myalgia, dizziness, cough, oropharyngeal pain, pyrexia, and hypotension

Source: https://ascopubs.org/doi/10.1200/jco.2015.62.4734 and management estimates; excludes Venclexta plus Decitibine data due to small "n" and management's belief of low utilization of this combination in practice

Preclinical Data Driving Annamycin AML Clinical Direction

AML¹

Preclinical Study at MD Anderson

Survival Benefits of Annamycin and ARA-C Combination in AML1-Turg2 Model



Demonstrated 68% Improvement in Overall Survival with Annamycin+Ara-C vs. Annamycin Alone in AML Mice Model



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Advancing Annamycin in AML

Phase 1: MB-104 MONOTHERAPY 100-120 mg/m ²	Phase 1/2: MB-105 MONOTHERAPY 120-240 mg/m2	Phase 1/2: MB-106 COMBINATION THERAPY Annamycin + Cytarabine				
 N = 6 17% CRi (at suboptimal dosing) Dosing limited by FDA Lifetime Anthracycline Dose (LTMAD) Trial location – US 	 N = 20 Median lines of therapy = 4 Median age of 240 mg/m² (RPD2) cohort = 65 years 60% CR/CRi in 240mg/m² Cohort (N=5) Trial location - Poland 	 Recruitment to date = 16 (planned n = 27) or 59% complete 4 CR's = 36% ITT (n=11) or 44% dosed with Annamycin and evaluable (n=9) Median lines of prior therapies = 1 Median age = 69 Durability: 3 to 8 mos & increasing; 1 BMT; No MB-106 CR's have relapsed to date Trial location – Poland & Italy 				
Key Findings						
 Well-tolerated in the study population Limited to low doses Morphologic leukemia free state was achieved in one subject in the 120 mg/m² cohort 	 Positive correlation between response rate and dose 	 "5+3" therapy Durability: up to 8 months and increasing Early evidence of efficacy in patients with previous therapy failures 				
Regulatory Significance						
 Demonstrated safe dosing within FDA-mandated limitations for anthracycline exposure 	 Demonstrated safe dosing beyond FDA (and EMA) limitations for cumulative anthracycline exposure and early efficacy as single agent 	 Addition of Cytarabine supported by compelling preclinical data showing improvement over Annamycin monotherapy 				

Source: Clinical study reports for MB-104 & MB-105. In MB-105 CRi = BMA <5%. MB-106 data is preliminary and subject to change.



Significant Patient Experiences in MB-106 Annamycin + Ara-C

	PROVEN DURABLE		TOO RECENT FOR DURABILITY	
Age (Yrs) Relapsed or Refractory	78 - Relapsed	64 - Refractory	70 – Relapsed	72- Relapsed
Prior Therapy (Mos)	2 Arm Study (7 mos) Ven/Aza (17 mos)	Ven/Aza (3 mos)	Kladrybine/Cytarabine (2 mos) Cytarabine (11 mos)	Kladrybine/LD AraC (7 mos)
Best Response in MB-106	Durable CR	Durable CR	CR	CR
Annamycin Dose (Course)	190 mg/m ² (2 courses w/ 1 add'l scheduled)	230 mg/m ² (1 course)	230 mg/m ² (2 courses)	230 mg/m ² (1 course w/ 2 nd course planned Jan '24)
Durability	~8 mos (and climbing)	Successful BMT (3 mos after single course)	TBD ~2 mos (and climbing)	TBD ~1 mo (and climbing)
Total anthracycline exposure	1140 mg/m ²	690 mg/m ²	1380 mg/m ²	690 mg/m ²



Annamycin: Results from 3 Clinical Trials



- Three trials 30 subjects to date with data; ~69% relapsed; Low dose start to prove noncardiotoxicity
- Efficacy reached at higher doses (& in combination) – even when faced with heavily pretreated subjects
- MB-104: P1; 100-120 mg/m²; US trial only
- MB-105: P1,120-240 mg/m²; EU (Poland)
- MB-106: 5+3 with Cytarabine; P1b; Two cohorts 190& 230 mg/m²; EU (Poland & Italy), P2 started at 230 mg/m²
- Success with VenAza relapsed and refractory patients. Success with cladribine/LDAC relapsed patients.
- Excluded 2 most recent subjects in MB-106 as data has not been entered into database
- No cardiotoxicity documented to date

CR/CRi: <5% blasts with or without recovery of blood counts

PR: >50% reduction of blasts

*met protocol criteria for CRi, recorded as PR by investigator

Some data is preliminary – Subject to change



Advantages of Annamycin Over Traditional Anthracyclines







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