

# Iomab-B SIERRA Trial Update

August 15, 2018

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## **Executive Overview**

- Actinium is committed to improving bone marrow transplant (BMT) access and outcomes through targeted conditioning and is the only company with a multi-disease, multi-target portfolio for targeted conditioning
- We have made significant progress with the pivotal Phase 3 SIERRA trial that is now well over 25% enrolled
  - Held first successful DMC safety analysis and meeting
- Given the positive momentum across our pipeline for targeted conditioning we have added significant resources with deep domain expertise in BMT
  - Dr. Jeff Chell joined Board of Directors
    - Founder, CEO Emeritus of Be the Match and Center for Blood and Marrow Transplant Research (CIBMTR), the largest bone marrow registry in the world
  - Strengthened clinical development team with external hires with extensive transplant, clinical development and operations experience
- Our entire organization is committed and working collaboratively to successfully complete SIERRA trial enrollment and position the company for clinical and commercial success



# Iomab-B Highlights









## Pedigree

- Developed by Fred Hutchinson Cancer Research Center and National Cancer Institute
- Extensively studied by leading transplant physicians across a range of hematologic malignancies



#### De-risked

- Studied in over 500 patients to date
- Safety database from multiple Phase 1/2 clinical trials in multiple indications
- Several publications report long-term survival in multiple indications including AML and multiple myeloma



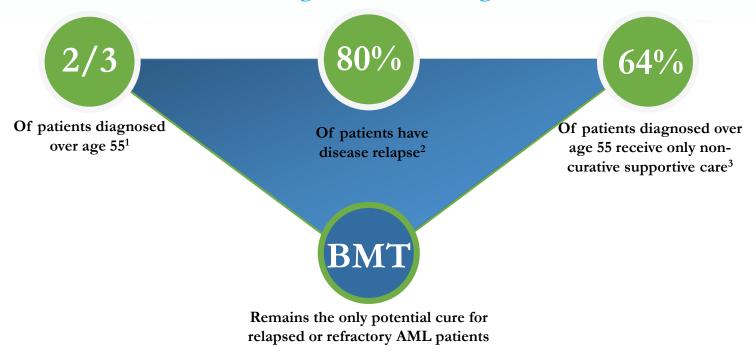
## Potentially Disruptive

- Only CD45 targeting agent in a pivotal Phase 3 trial
- Only targeted conditioning agent in a pivotal trial



# Iomab-B: Targeted Conditioning for BMT

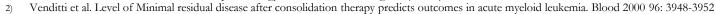
Potential for improving Bone Marrow Transplant access and outcomes via targeted conditioning



#### **Iomab-B Potentially Offers:**

- Clear path to BMT for patients with active, relapsed or refractory disease
- Targeted conditioning with superior safety profile compared to toxic chemotherapy
- Access to a potentially curative BMT in as little as 2-3 weeks





3) Menzin, et al. 2002; Lang, et al. 2005



## **SIERRA** Trial Overview



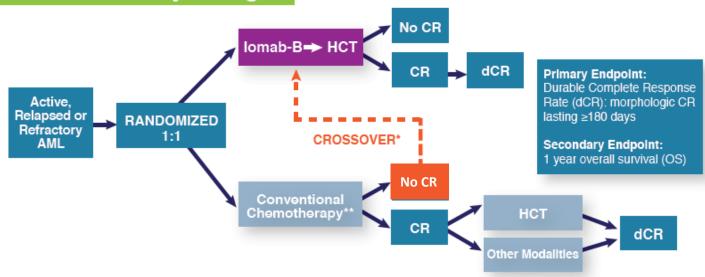








#### **SIERRA Study Design:**



\* Crossover – Patients that do not achieve CR can crossover to Iomab-B study arm

\*\*Control Arm = Physician's Choice:

Venetoclax with HMA, HMA's (Azacitidine & Decitabine), FLT3 inhibitors (Midostaurin & Sorafenib), Mylotarg, IDH2 inhibitors & Salvage chemo (Carboplatin, cytarabine, fludarabine, others)



# Key Protocol Amendments Based on Investigator Feedback

New clinical development team has increased interactions with sites, investigators and advisory board leading insights and actions

# January 2018: Expanded Salvage Chemo

Modified control arm to include Venetoclax in combination with an HMA, FLT3 inhibitors (Midostaurin), IDH2 inhibitor (Idhifa) and Mylotarg

# August 2018: Shortened Time to Crossover

Time for patient to crossover to Iomab-B treatment reduced from 28 days to 14 days for patients progressing on the control arm



- ♦ Despite many new regimens in the control arm for several months, significant unmet need still exists
- ♦ Based on results to date, crossover rate remains high and above original forecast
- ♦ Cross-over can now occur earlier for patients progressing on salvage therapy



## **SIERRA** Trial Updates

#### **DMC** Analysis



Unanimous recommendation to continue SIERRA trial as is

No safety concerns raised regarding Iomab-B by the DMC

#### **Trial Observations**

- Crossover rate continues to be higher than original forecasts
- Demand from investigators in U.S., Canada and EU supports continued site expansion
- SIERRA well received by BMT community and by referring hematologists paving way for further site expansion



## **SIERRA** Trial Positioned for Success

#### Recently strengthened and optimized SIERRA trial team deeply committed to success

#### Right TEAM



- Strategic hires with core competency in BMT, clinical operations and field support in place since Q2 2018
- Extensive engagement with key stakeholders at each site leading to improved SIERRA clinical trial execution

#### Strong execution focus designed to capitalize on solid progress to date

#### Right Messages



- Simplified and optimized SIERRA protocol based on investigator feedback expected to positively impact enrollment
  - Reduced legacy data collection requirements
  - Continue to expand salvage chemotherapy options to accommodate recent drug approvals and other home brew regimens
  - Communicate to principal investigators key trial learnings and clinical observations including positive DMC results and rationale for expanding treatment choices in the control arm
- Programs leveraging our recent greater understanding of referral patterns within sphere of influence of key sites expected to positively impact SIERRA trial



## Multiple New Tools to Support Enrollment

Driving key messages to key target audience of high volume BMT referring hematologists

#### Webcasts

#### **Direct Mailings**

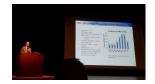
#### Ad Boards













#### **Enhanced SIERRA Trial Awareness**

Right Messages



Able to communicate significantly more information to current and prospective investigators than ever before

Right Team



Able to capitalize on strong momentum internally and externally

Right Tools



Able to target and deliver powerful messages to a significant number of key stakeholders



### **SEIRRA** Well Positioned for Success

Clinical trial sites now ideally situated to capture referrals from high volume hematologists with positive messages from SIERRA experience and facilitated outreach efforts



US Population Distribution >55 years old

~<1 million

1 -2 million

2-3 million

> 4.0 million



#### **Active SIERRA Sites**





























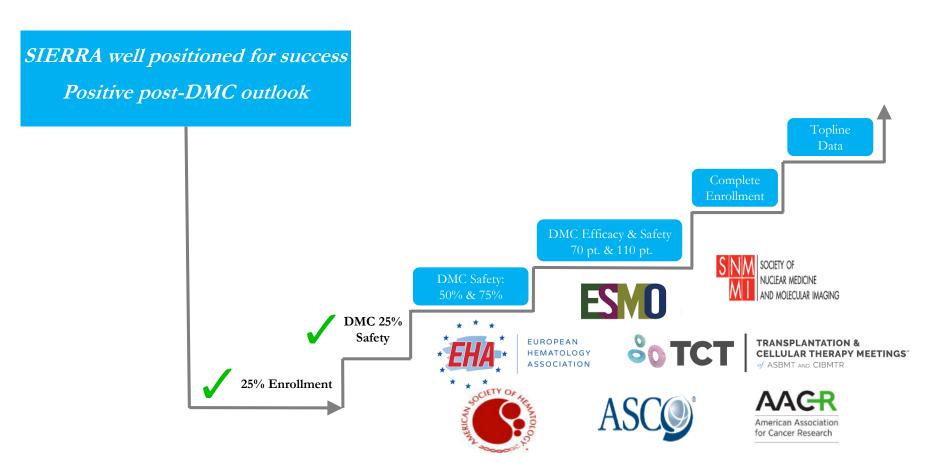






# Significant Tailwinds Support Positive SIERRA Outlook

Several milestones and events expected to reinforce the strong value proposition of SIERRA including additional interim readouts and data publications at major medical conferences





# Iomab-B: Linchpin for a Targeted Conditioning Franchise

- Positive DMC outcome bodes well for trial outlook
- SIERRA trial can establish Iomab-B as the only approved targeted conditioning agent with the ability to address a significant unmet medical need in AML by improving BMT access and outcomes
- Significant potential for development of Iomab-B beyond current indication in multiple hematologic malignancies
- Actinium has the only clinical stage portfolio with a multi-disease, multi-target approach to targeted conditioning for BMT
- Intend to build the leading, independent, fully-integrated targeted conditioning franchise and committed to improving BMT access and outcomes





Thank You