Actinium Pharmaceuticals, Inc.

Administration of ^{131}I-apamistamab

ICD-10-PCS Coordination & Maintenance Committee Meeting
September 2023

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Acute Myeloid Leukemia (AML) Fast Facts

AML is an aggressive disease that can progress rapidly despite treatments

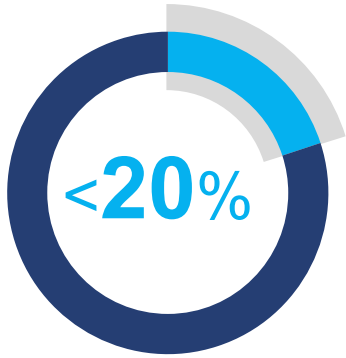
≈21,000
AML patients annually[1]

68 years
Median age at diagnosis[1]

10 drugs
approved for AML patients since 2017

Older patients have limited treatment options and poor outcomes

Develop R/R disease[2]



of AML patients access HCT[3]

HCT is the only potential curative treatment
for R/R AML,

but only younger or fit patients can access it

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1) SEER database; 2) Gyurkocza et al. Allogeneic hematopoietic cell transplantation in patients with AML not achieving remission: potentially curative therapy. Bone Marrow Transplantation (2017), 1-8; 3) Auletta JJ et al. Current use and outcome of hematopoietic stem cell transplantation: CIBMTR US summary slides, 2021.

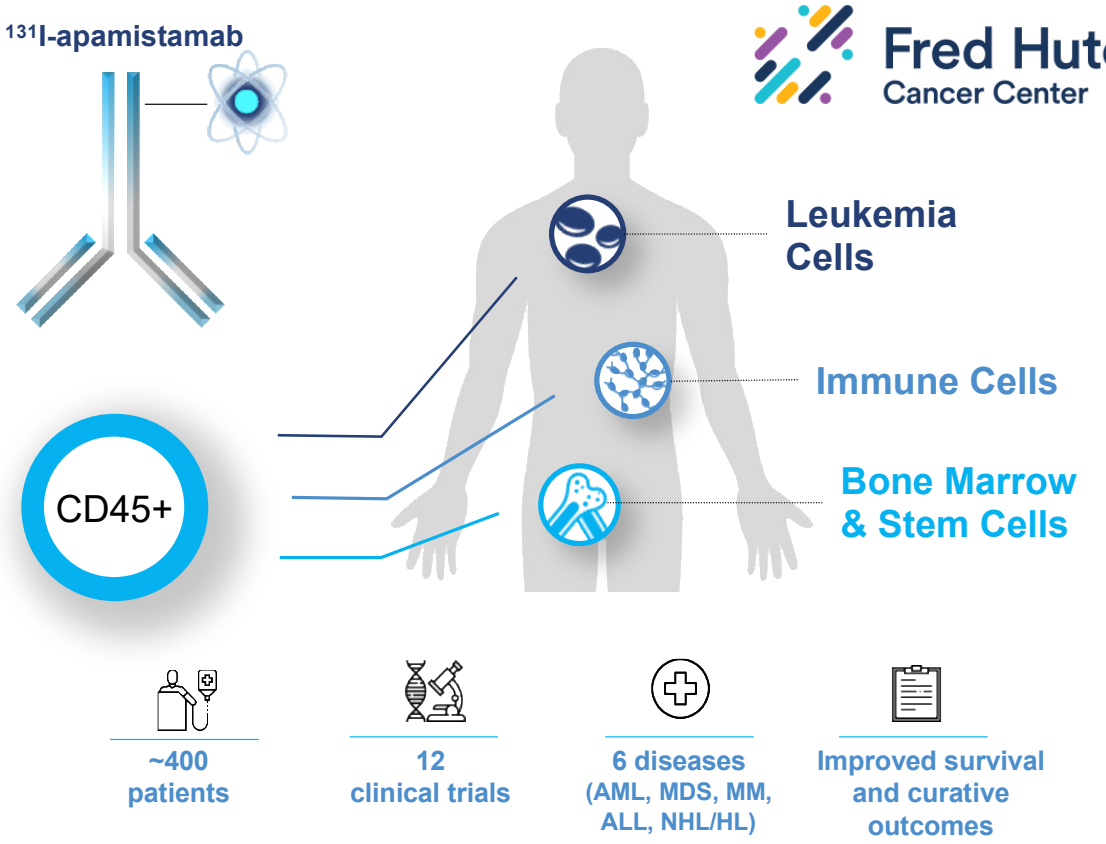
Challenges to Achieving Cures in AML

Patients must be able to overcome several challenges related to curative allogeneic hematopoietic cell transplant (alloHCT)

Challenge #1	**Need to attain a complete remission (CR)**	**Access**
Challenge #2	**Tolerate and survive effective alloHCT conditioning**	
Challenge #3	• **Achieve alloHCT engraftment** • **Achieve post-HCT CR**	**Outcomes**
Challenge #4	• **Surmount alloHCT related complications** – Graft failure – Side effects: sepsis, GVHD	

Overcoming these challenges can result in long-term survival and curative outcomes

^{131}I-apamistamab: A Next Generation Approach to Improve alloHCT Access, Outcomes



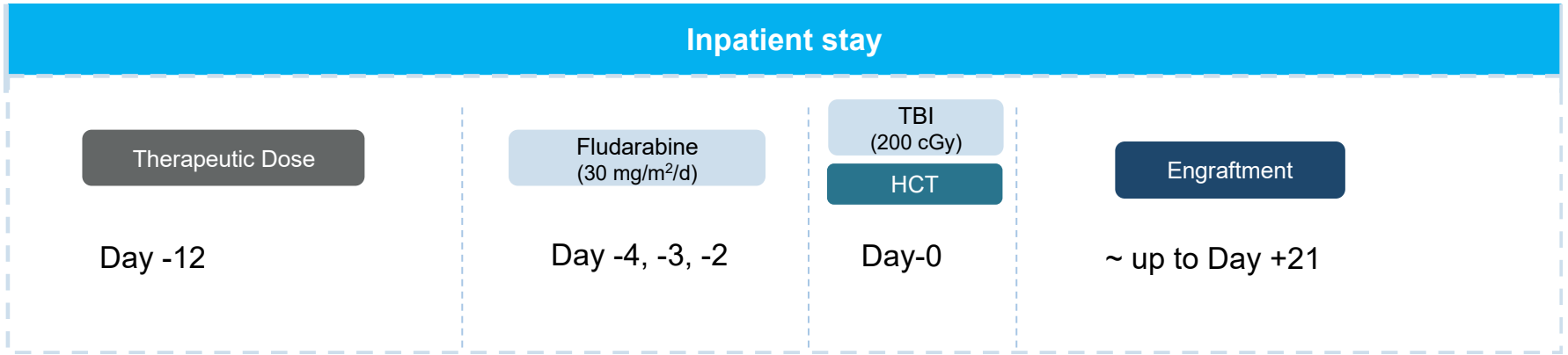
- ^{131}I-apamistamab targets CD45, which is highly expressed on AML, immune and stem cells
- Low CD45 expression outside the hematopoietic system spares organs and increases tolerability of ^{131}I-apamistamab
- Enables high amounts of radiation to be delivered to radiation sensitive AML and immune cells
- Induction and conditioning in one approach by simultaneously eliminating AML immune and bone marrow stem cells
- Allows patients with active disease to go directly to alloHCT rapidly via a single infusion

^{131}I-apamistamab targeted radiotherapy can produce myeloablative outcomes with the safety and tolerability of reduced intensity approaches

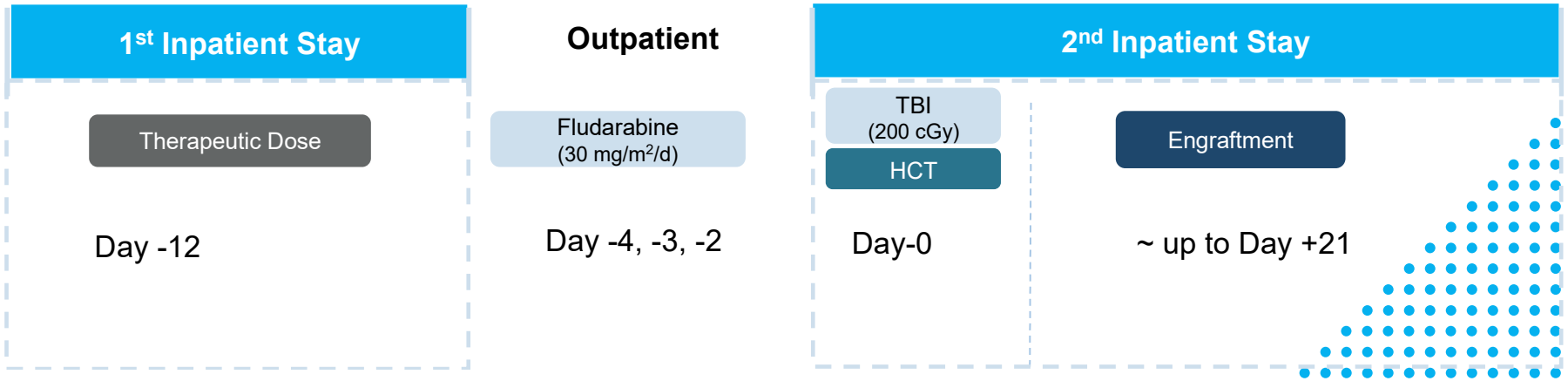
ALL – Acute Lymphoblastic Leukemia; HL – Hodgkin Lymphoma; MDS – Myelodysplastic Syndrome; MM – Multiple Myeloma; NHL – Non-Hodgkin Lymphoma

Personalized Single Dose Combined Induction/Conditioning

- This shows a single inpatient stay, where the patient receives the therapeutic dose (dosimetric dosing will typically occur on an outpatient basis). The patient then proceeds to a reduced intensity conditioning and to allogeneic hematopoietic cell transplant (alloHCT).



- This shows two inpatient stays; one where the patient receives the therapeutic dose (and is isolated until an acceptable level of radiation is achieved), and then receives fludarabine for days -4 to -2, and is admitted as an inpatient on day -0 for TBI and alloHCT.



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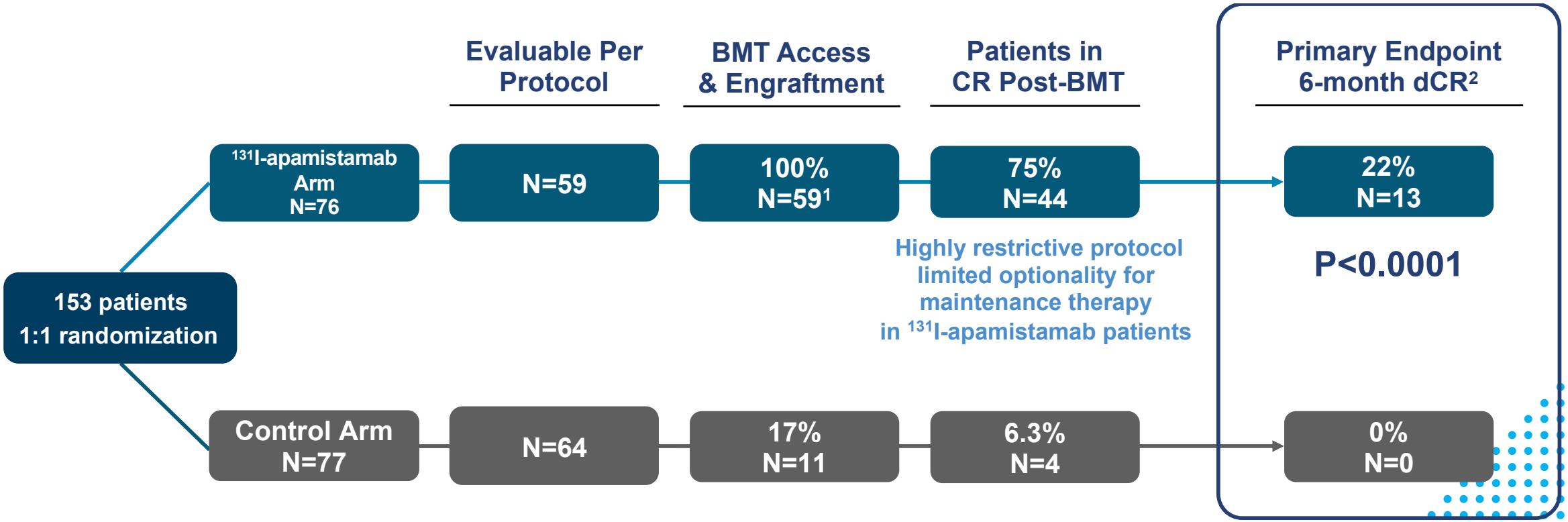
Note: in both instances, the patient will receive GvHD prophylaxis per institutional guidelines.
RIC: reduced intensity conditioning; FLU: fludarabine; TBI: total body irradiation; HCT: hematopoietic cell transplant

Dosage and Documentation

- The administration of the therapeutic dose for ^{131}I-apamistamab will be documented in the medical record in the same manner as infusion of other targeted therapy and in the treating bone marrow transplanter (hematologist/oncologist) physician's note
- The full name for ^{131}I-apamistamab is ^{131}Iodine apamistamab (also known as Iomab-B)
  - It is also described as Radiolabeled ^{131}Iodine Anti-CD45 (BC8) Antibody in scientific literature

SIERRA Results: ^{131}I-apamistamab Overcomes Key HCT Challenges

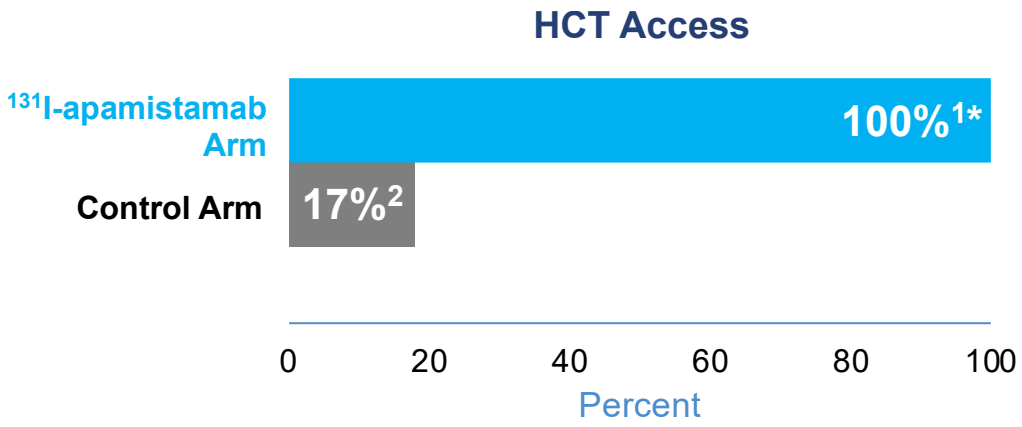
Primary endpoint met with high statistical significance: High rates of post-HCT remissions resulted in significantly higher durable complete remissions with ^{131}I-apamistamab



1) 100% access in patients receiving a therapeutic dose of ^{131}I-apamistamab; 2) Per protocol analysis: 22% maintained durable CR lasting 180 days or more in the ^{131}I-apamistamab arm and none had a durable remission in the control arm
Late Breaking Abstract, TCT 2023, Efficacy and Safety Results of the Sierra Trial: A Multicenter, Pivotal Phase 3 Study of Iomab-B Prior to Allogeneic HCT Versus Conventional Care in Older Patients with Active, R/R AML

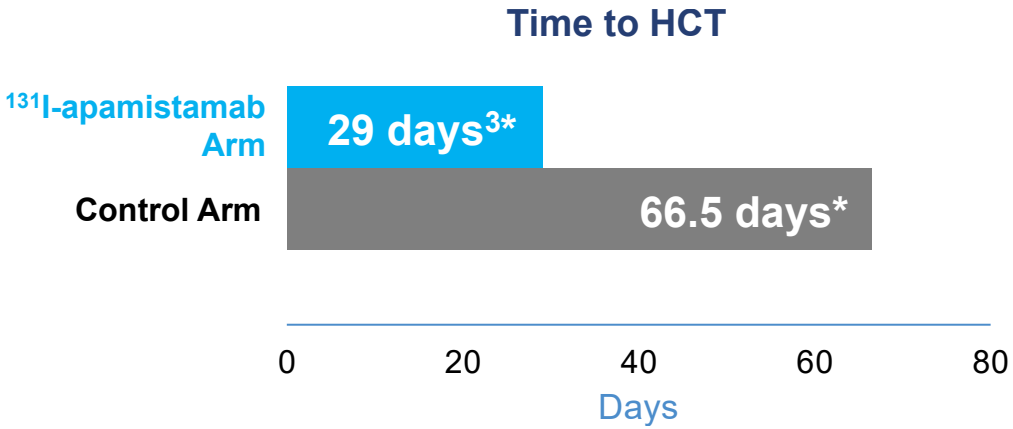
Challenge 1 & 2 Addressed: Unprecedented Access to HCT in Half the Time

Unprecedented Access to HCT



- **Targeted nature of ^{131}I-apamistamab** results in effective myeloablation with improved tolerability
- **Less than 20%** of patients on the control arm had access to transplant vs. 100% on ^{131}I-apamistamab

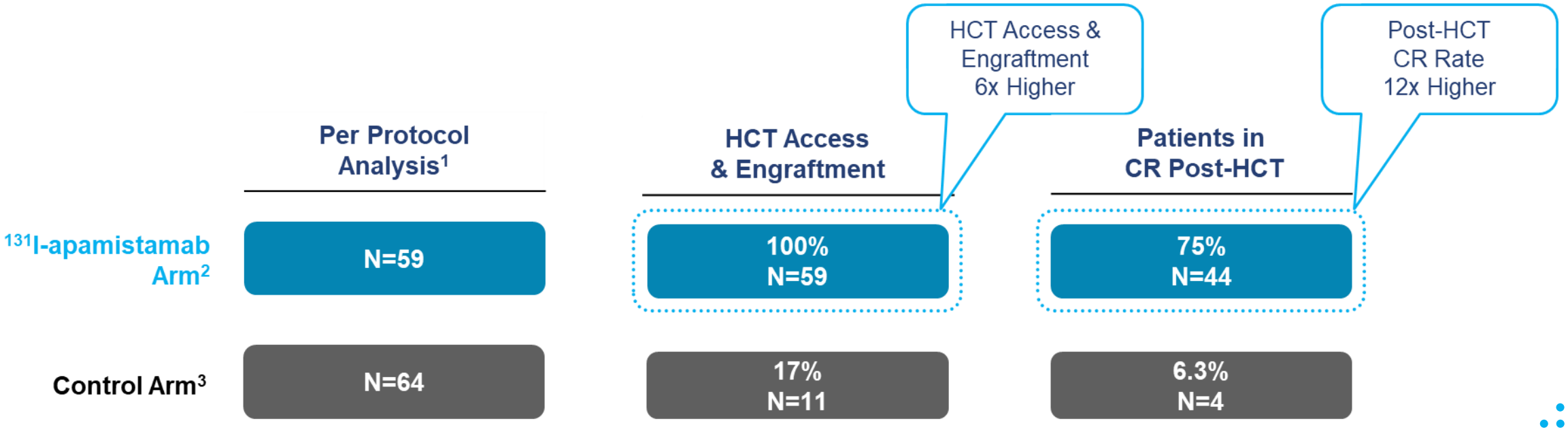
Access to HCT in Less Than Half the Time



- **With ^{131}I-apamistamab there is no need to achieve a CR;** patients with active disease can go to directly to BMT in days and engraft successfully
- **1 – 2+ cycles of chemotherapy** required to attain CR if CR can even be produced

*From randomization. 1) ^{131}I-apamistamab Arm (N=76); 10 patients did not receive a therapeutic dose of ^{131}I-apamistamab; per protocol analysis; 2) Control Arm (N=77); 1 patient did not receive treatment on the control arm; per protocol analysis; 3) Time from ^{131}I-apamistamab therapeutic infusion 12 – 14 day Late Breaking Abstract, TCT 2023, Efficacy and Safety Results of the Sierra Trial: A Multicenter, Pivotal Phase 3 Study of Iomab-B Prior to Allogeneic HCT Versus Conventional Care in Older Patients with Active, R/R AML

Challenge 3 Addressed: Unprecedented HCT Access & Engraftment and High Post-HCT CR



1) Per protocol analysis: 59 of 76 patients in ^{131}I-apamistamab arm and 64 of 77 patients in control arm; 2) 6 patients on ^{131}I-apamistamab arm not evaluable for primary endpoint; 3) 3 patients on control arm not evaluable for primary endpoint
Late Breaking Abstract, TCT 2023, Efficacy and Safety Results of the Sierra Trial: A Multicenter, Pivotal Phase 3 Study of Iomab-B Prior to Allogeneic HCT Versus Conventional Care in Older Patients with Active, R/R AML

Challenge 4 Addressed: Excellent Safety of Targeted Radiotherapy

^{131}I-apamistamab related adverse events are meaningfully lower, implying less complexity (and cost) pre- and post-transplant.

Adverse Event* (%)	^{131}I-apamistamab Arm N=66	Control Arm N=14
Sepsis[1]	6.1%	28.6%
Febrile Neutropenia	43.9%	50.0%
Mucositis[2]	15.2%	21.4%
Acute GVHD (Gr II-IV)[3]	26.1%	35.7%

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* Relevant adverse events in transplanted ^{131}I-apamistamab patients. 1) "Sepsis" includes Preferred Terms of Sepsis, Septic Shock, Neutropenic Sepsis & Septic Embolus; 2) "Mucositis" includes Preferred Terms of Stomatitis & Mucosal Inflammation; 3) All ^{131}I-apamistamab pts received Cyclosporin and Mycophenolate Mofetil for GVHD prophylaxis. Late Breaking Abstract, TCT 2023, Efficacy and Safety Results of the Sierra Trial: A Multicenter, Pivotal Phase 3 Study of Iomab-B Prior to Allogeneic HCT Versus Conventional Care in Older Patients with Active, R/R AML

Challenge 4 Addressed: Excellent Safety of Targeted Radiotherapy (cont.)

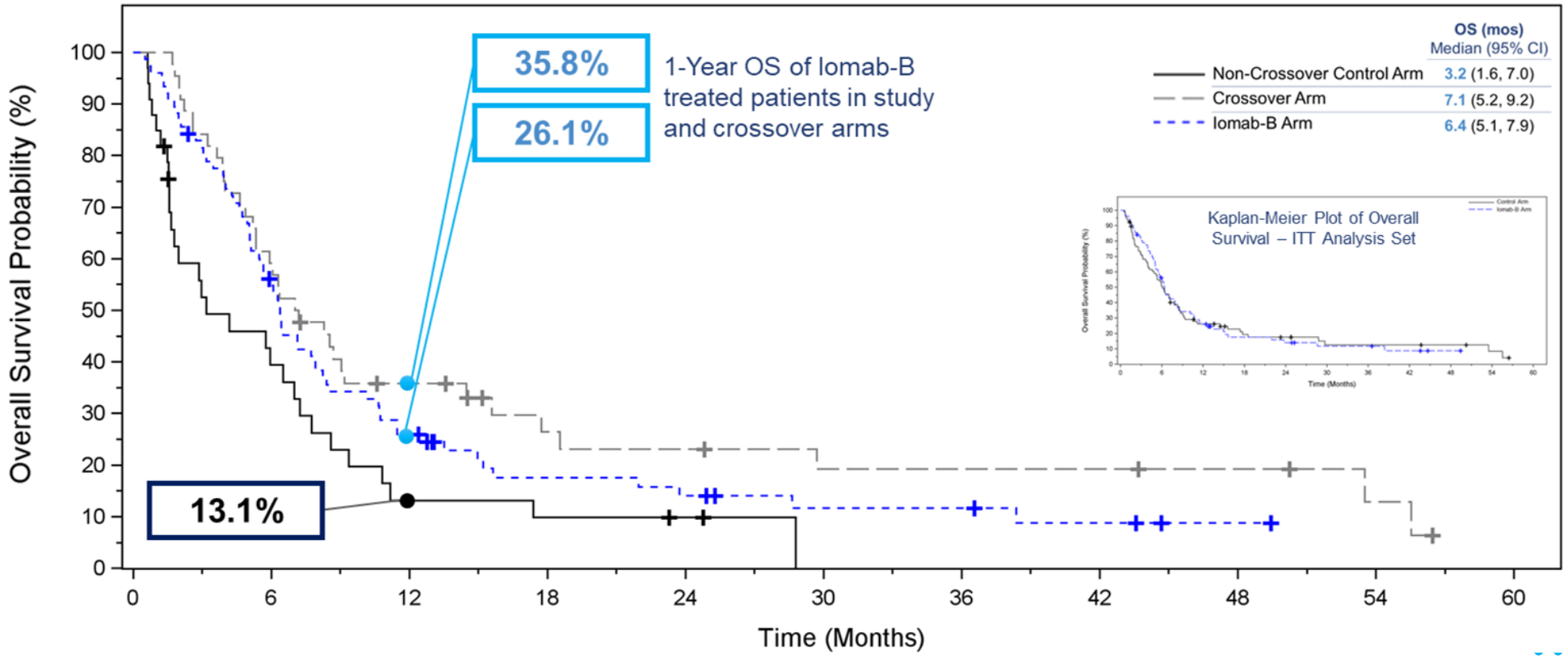
This table shows supplemental information on the >= grade 3 common drug-related Adverse Events (AEs) in >=5% in either group.

	Crossed Over to Iomab-B (N=44), N (%)	Iomab-B Arm (N=72), N (%)	Total (N=116), N (%)
Blood & Lymphatic System Disorders	14 (31.8)	21 (29.2)	35 (30.2)
Investigations	8 (18.2)	18 (25.0)	26 (22.4)
Infections & Infestations	8 (18.2)	14 (19.4)	22 (19.0)
Metabolism & Nutrition Disorders	8 (18.2)	6 (8.3)	14 (12.1)
Gastrointestinal Disorders	6 (13.6)	7 (9.7)	13 (11.2)
Respiratory, Thoracic & Mediastinal Disorders	3 (6.8)	9 (12.5)	12 (10.3)
General Disorders & Administration Site Conditions	4 (9.1)	7 (9.7)	11 (9.5)

Data from TFLs (tables, figures and listings) included with SIERRA CSR (Clinical Study Report).

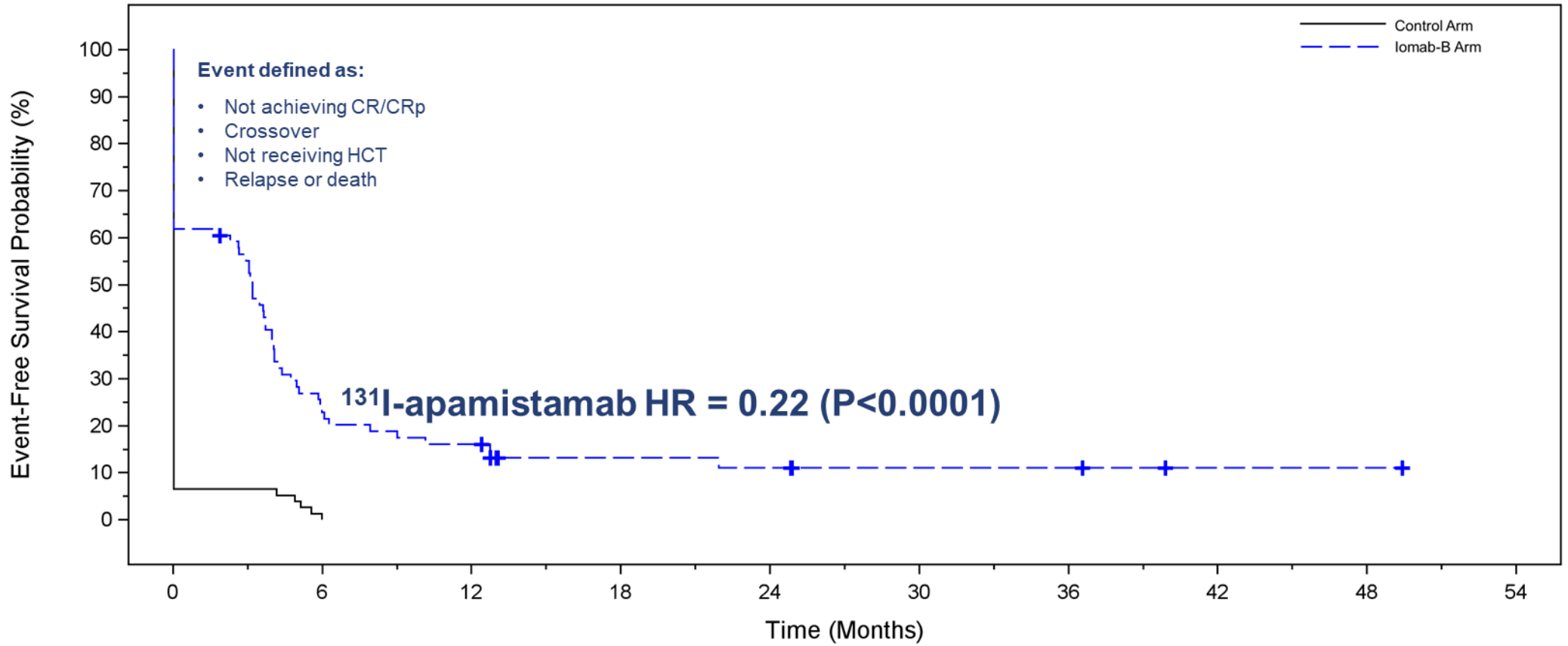
^{131}I-apamistamab Demonstrates Clear Survival Benefit

^{131}I-apamistamab doubled 1-year survival rates and median overall survival



Crossover confounds OS statistics; Ad hoc analysis

^{131}I-apamistamab Reduced the Probability of an Event by 78%



EFS HR of 0.22 (P<0.0001) compared to control arm clearly supports the use of ^{131}I-apamistamab in this high-risk population

^{131}I-apamistamab Represents a New Paradigm

Clear separation in access and outcomes favor ^{131}I-apamistamab utilization