APTITUDE HEALTH

CASES

INSIGHTS INTO ACUTE MYELOID LEUKEMIA

August, 2019

Chicago, Illinois

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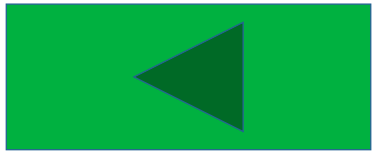

Click to return to previous slide

CONTENTS

CASES

STUDY OBJECTIVES

To gain advisors' perspectives on the following

- Management of newly diagnosed and relapsed/refractory acute myeloid leukemia (AML)

REPORT SNAPSHOT

- A moderated roundtable discussion focusing on treatment of AML was held on August 17, 2019, in Chicago, IL
- Disease state and data presentations were developed in conjunction with a medical expert from the University of Colorado
- The group of advisors comprised 8 community oncologists
- Insights on the following AML therapies were obtained: azacitidine, clofarabine, cytarabine and daunorubicin (ie, 7+3), decitabine, enasidenib, gemtuzumab ozogamicin, gilteritinib, glasdegib, liposomal daunorubicin and cytarabine, midostaurin, sorafenib, and venetoclax
- Data collection was accomplished through use of audience response system questioning and in-depth moderated discussion

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Participant Demographics

PARTICIPANT DEMOGRAPHICS

How many new patients with AML do you

How many unique patients with AML are

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Key Insights

TOPLINE TAKEAWAYS – AML

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FIRST-LINE THERAPY (1/3)

Topic	Insights and Data
Impact of	Some advisors treat all their newly diagnosed (both fit and unfit) AML patients in-house, while others refer

FIRST-LINE THERAPY (2/3)

Topic	Insights and Data
Transplant eligibility	Some advisors determine eligibility for transplant at the time of diagnosis, while others get a consult for transplant after

FIRST-LINE THERAPY (3/3)

Topic	Insights and Data
Perception of	All advisors except 1 have used midostaurin in at least 1 AML patient

QUOTES – FIRST-LINE THERAPY (1/2)

QUOTES – FIRST-LINE THERAPY (2/2)

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“I've seen it [venetoclax] tolerated very well and very

“We had some experience with midostaurin in all

MANAGEMENT OF RELAPSED/REFRACTORY DISEASE

Topic	Insights and Data

QUOTES – MANAGEMENT OF RELAPSED/REFRACTORY DISEASE

“AML is a disease that evolves from diagnosis to

STRATEGIC CONSIDERATIONS FOR VENETOCLAX

- Most of the advisors have used venetoclax to treat newly diagnosed AML patients, and given its approval, all

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Advisor Key Takeaways

KEY TAKEAWAYS

Dr 1

- New approach for fit and unfit patients

Dr 5

- Many good options for unfit patients

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ARS Data – AML: Management of Newly Diagnosed Disease

IN ADDITION TO CYTOGENETICS, WHICH OF THE FOLLOWING MOLECULAR MARKERS ARE YOU ROUTINELY TESTING FOR IN YOUR NEWLY DIAGNOSED AML PATIENTS? (SELECT ALL THAT APPLY)

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IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG LIPOSOMAL DAUNORUBICIN AND CYTARABINE (VYXEOS)? (N = 8)

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IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG GEMTUZUMAB OZOGAMICIN (MYLOTARG)? (N = 8)

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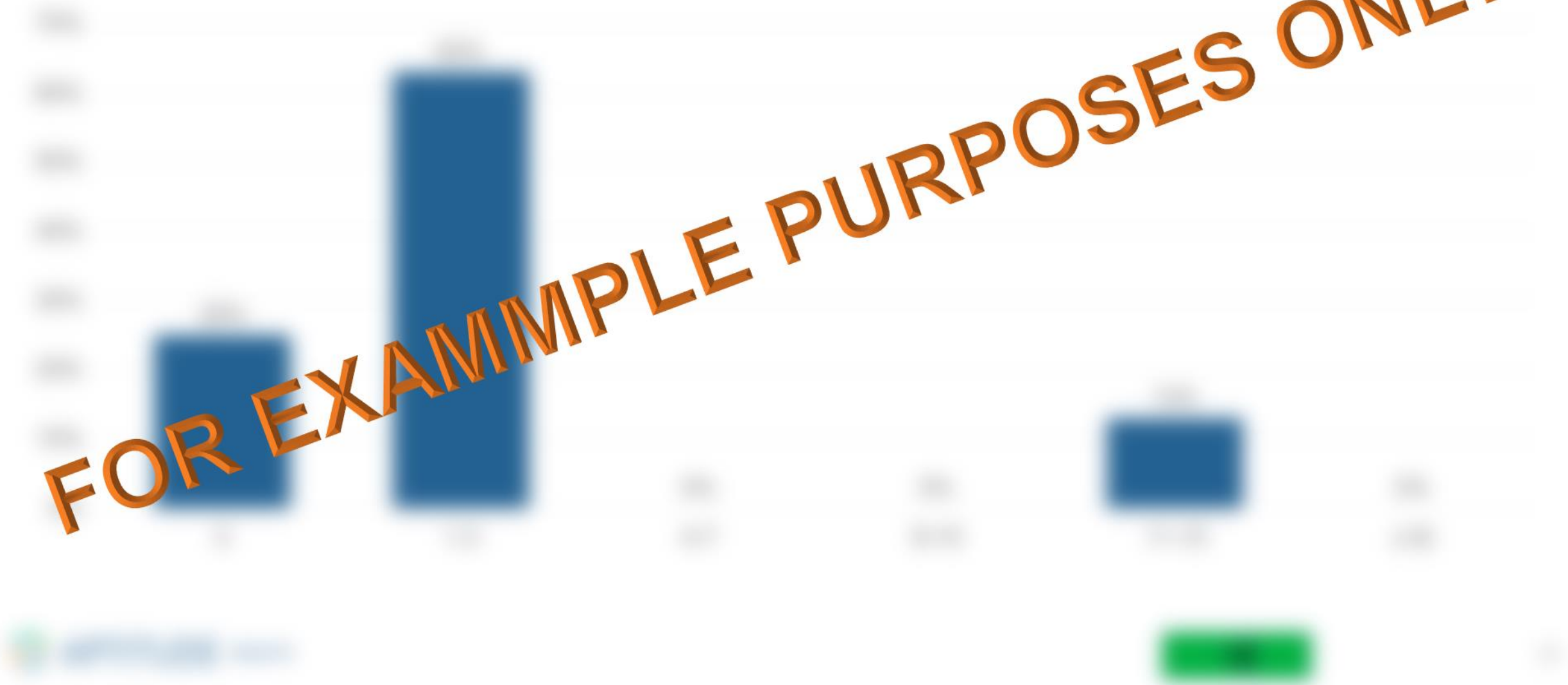

IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG MIDOSTAURIN (RYDAPT)? (N = 8)

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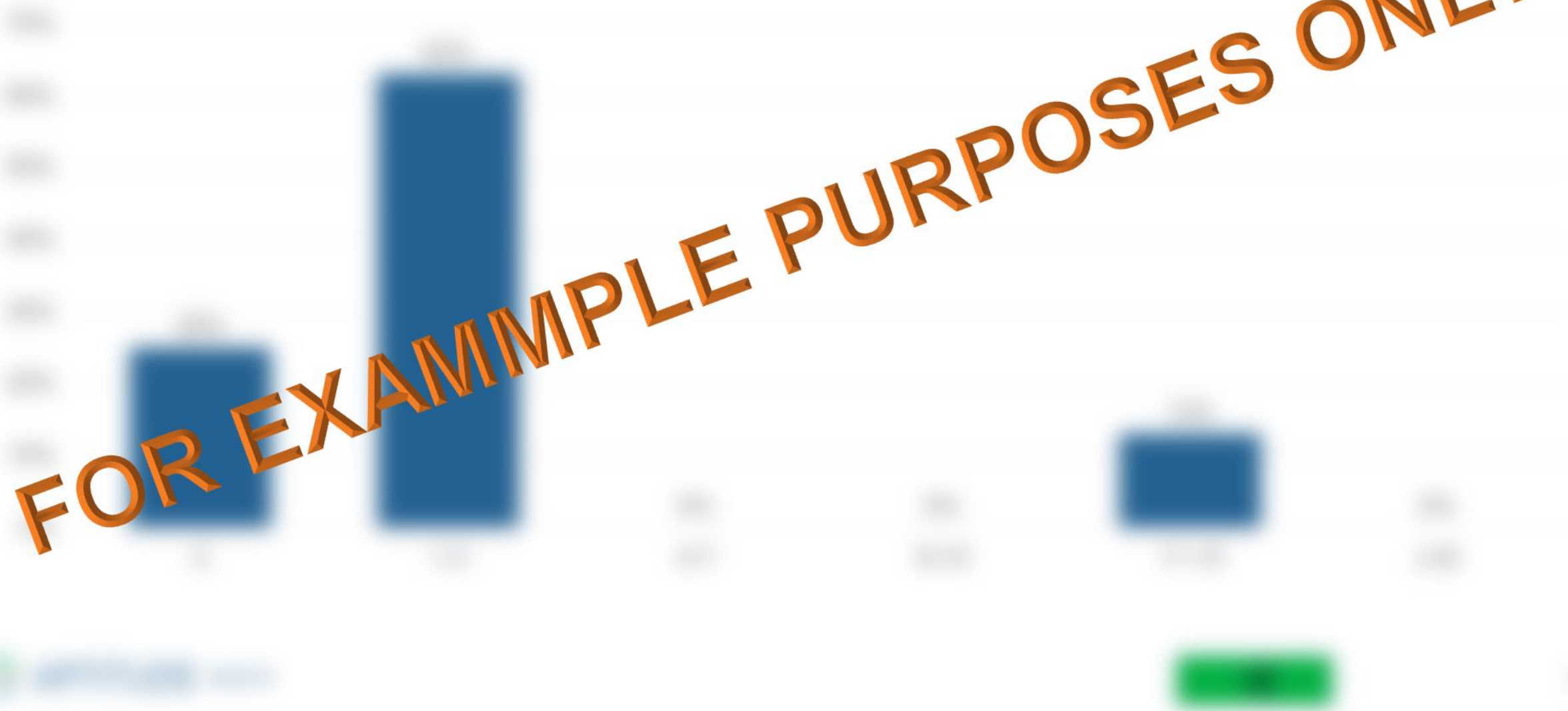

IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG GILTERITINIB (XOSPATA)? (N = 8)

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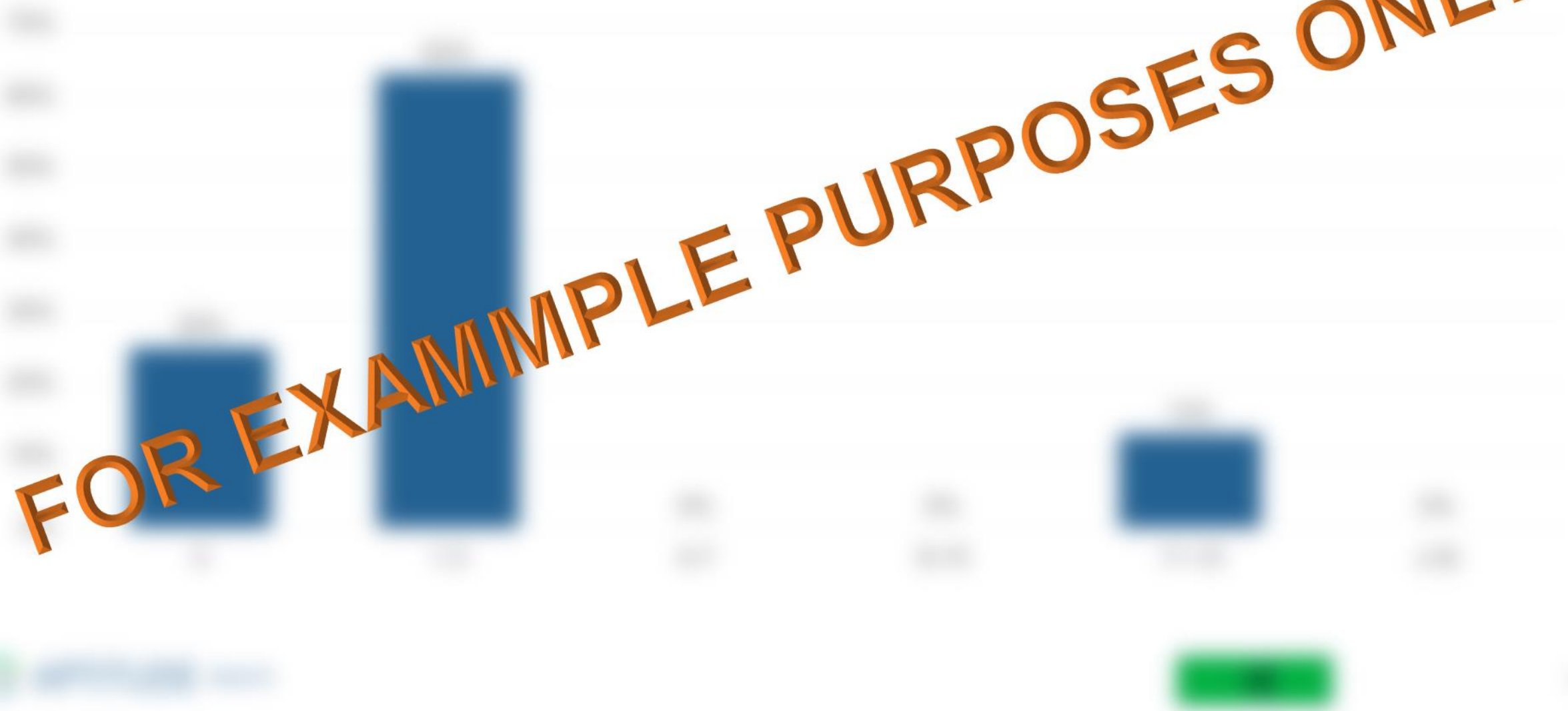

IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG ENASIDENIB (IDHIFA)? (N = 8)

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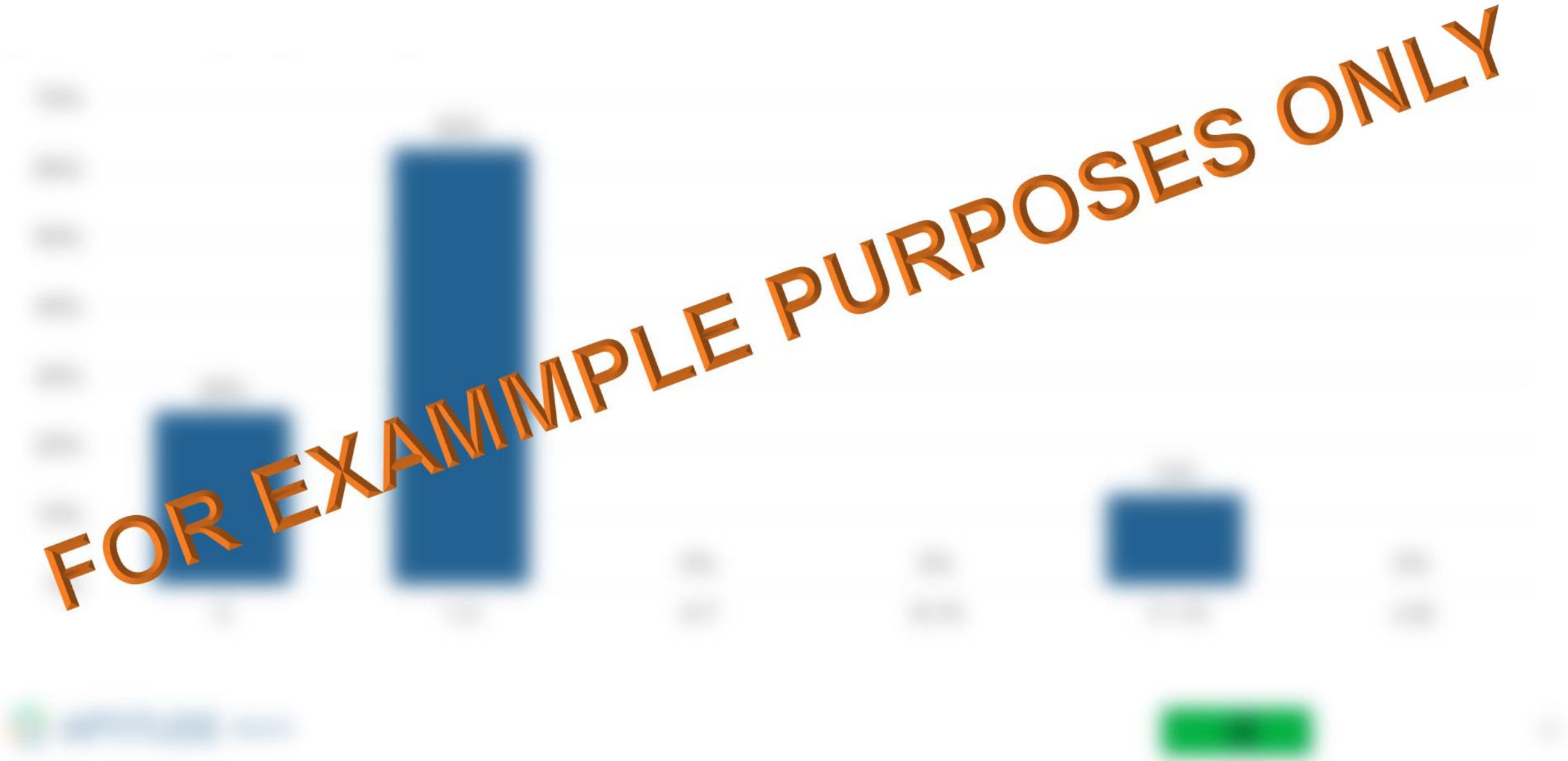

IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG IVOSIDENIB (TIBSOVO)? (N = 8)

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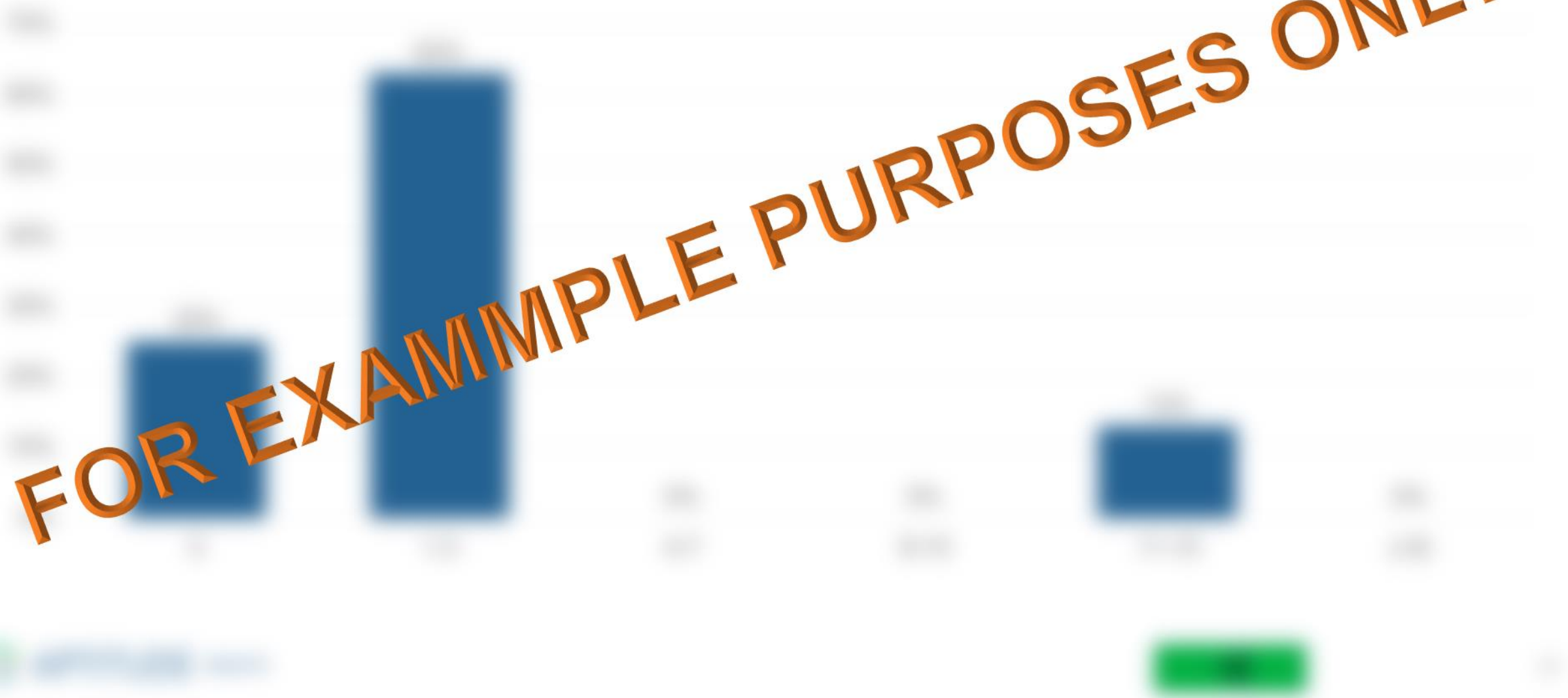

IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG GLASDEGIB (DAURISMO)? (N = 7)

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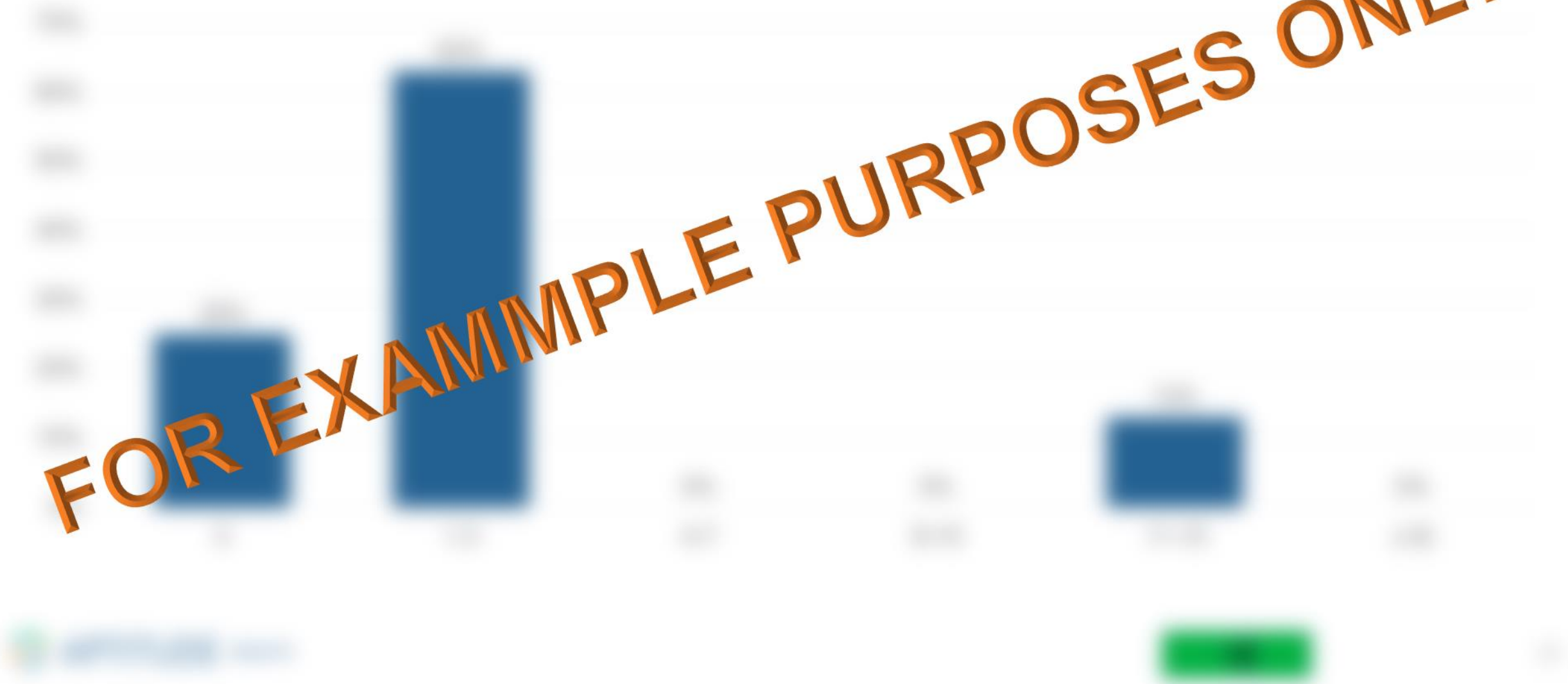

IN HOW MANY UNIQUE AML PATIENTS HAVE YOU USED THE DRUG VENETOCLAX TABLETS (VENCLEXTA)? (N = 8)

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WHAT INDUCTION REGIMEN DO YOU ROUTINELY RECOMMEND FOR A 50-YEAR-OLD PS 0 PATIENT WITH INTERMEDIATE-RISK AML (CD33+ AND WITHOUT *FLT3* MUTATION)? (N = 8)

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WHAT INDUCTION REGIMEN DO YOU ROUTINELY RECOMMEND FOR A 77-YEAR-OLD PS 1 PATIENT WITH INTERMEDIATE-RISK AML (CD33+ AND WITHOUT *FLT3* MUTATION)? (N = 8)

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WHAT INDUCTION REGIMEN DO YOU ROUTINELY RECOMMEND FOR A 70-YEAR-OLD PS 1 PATIENT WITH THERAPY-RELATED AML FOLLOWING TREATMENT FOR MANTLE CELL LYMPHOMA (INCLUDING AUTOLOGOUS STEM CELL TRANSPLANT)? GENOMIC PROFILING IS UNKNOWN. (N = 8)

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I AM CURRENTLY TREATING ALL *FLT3* MUTATION-POSITIVE AML PATIENTS WITH STANDARD INDUCTION CHEMOTHERAPY PLUS MIDOSTAURIN, WHENEVER FEASIBLE, REGARDLESS OF OTHER RISK FACTORS. (N = 8)

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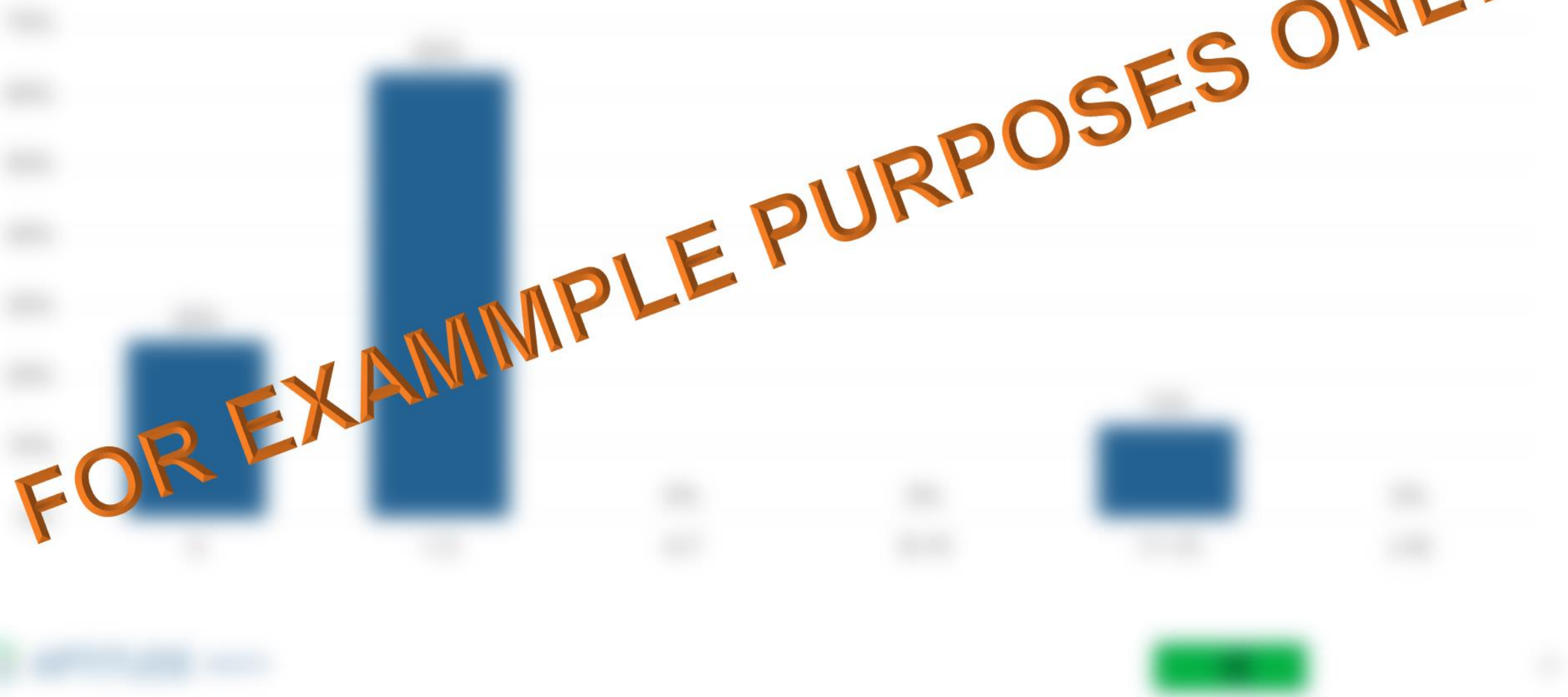

VENETOCLAX HAS RECENTLY BEEN APPROVED FOR NEWLY DIAGNOSED ADULT AML PATIENTS WHO ARE 75 YEARS OR OLDER. DO YOU PLAN TO INCREASE YOUR USE OF THIS THERAPY OPTION IN NEWLY DIAGNOSED AML PATIENTS? (N = 8)

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ARS Data – AML: Management of Relapsed/Refractory Disease

DO YOU ROUTINELY REPEAT BIOMARKER TESTING IN YOUR AML PATIENTS AT THE TIME OF RELAPSE? (N = 8)

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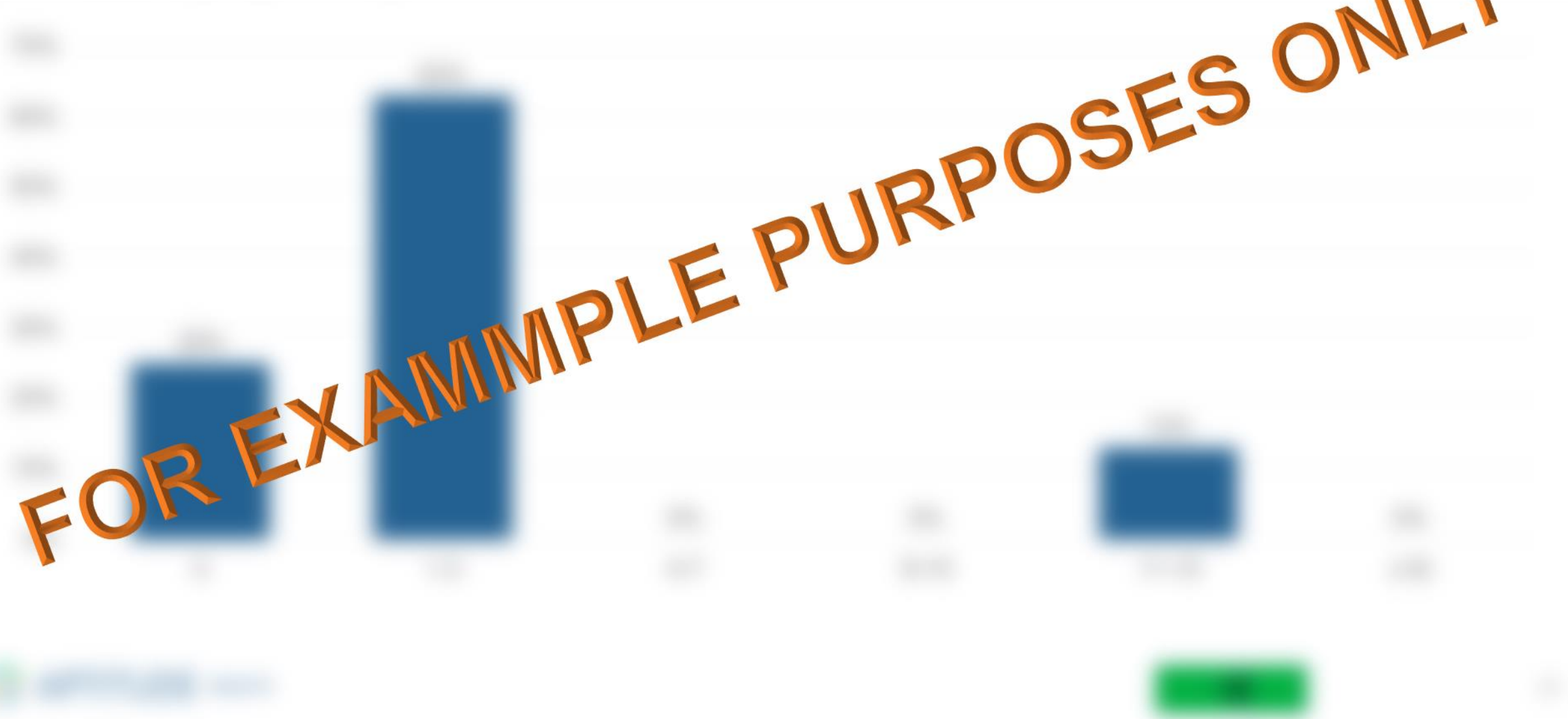
I GENERALLY REQUIRE A CR1 OF AT LEAST __ MONTHS BEFORE RECOMMENDING REINDUCTION IN MY RELAPSED AML PATIENTS (N = 8)



A 52-YEAR-OLD FEMALE WHO HAS INVERSION 16 COMPLETES STANDARD INDUCTION WITH 7+3, AND 4 CYCLES OF CONSOLIDATION; 1.5 YEARS FOLLOWING COMPLETION OF CONSOLIDATION, SHE RELAPSES WITH AML AND INVERSION 16. WHAT DO YOU TREAT HER WITH? (N = 8)

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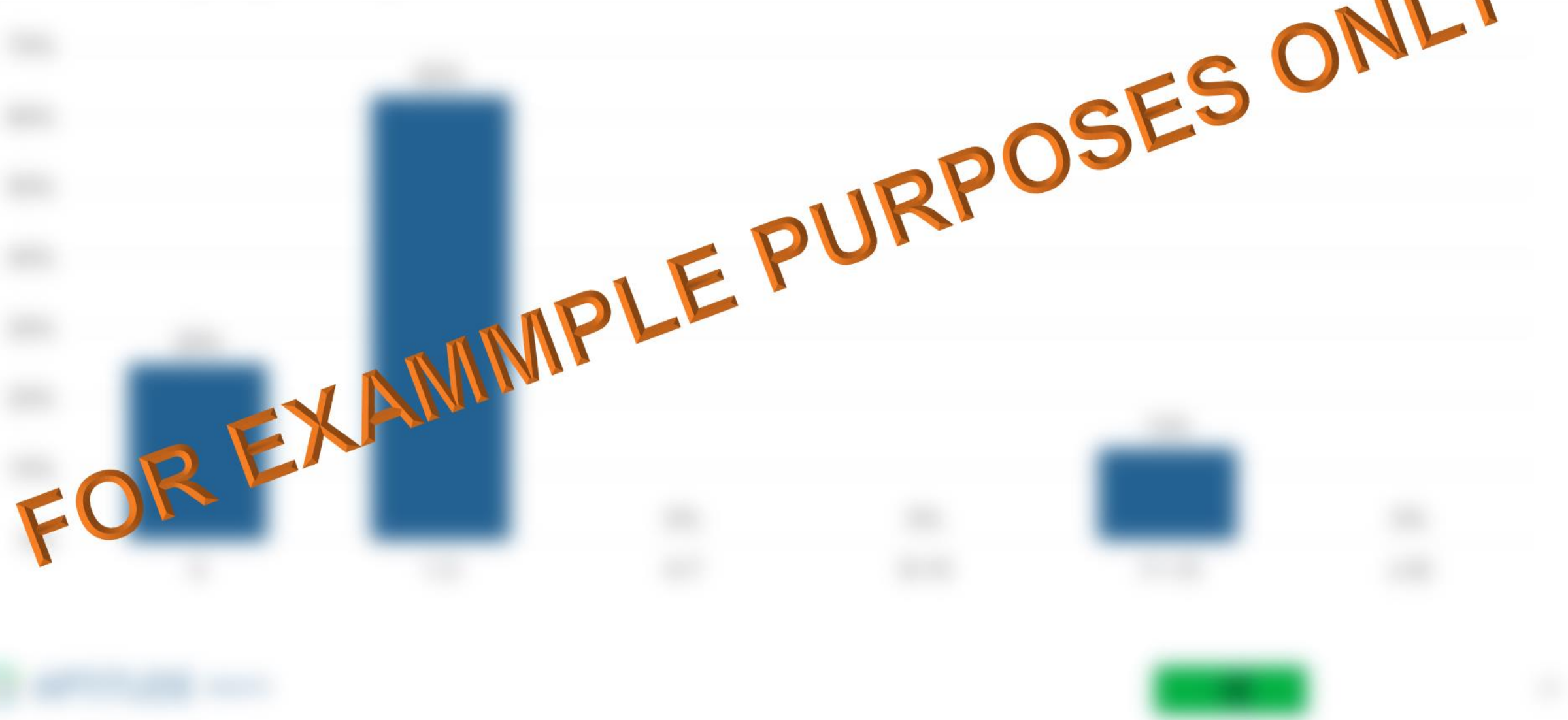
A PATIENT WHO WAS INITIALLY TREATED WITH INDUCTION LIPOSOMAL DAUNORUBICIN-CYTARABINE HAS A DAY 14 MARROW THAT SHOWS REDUCTION IN DISEASE, BUT STILL 20% CELLULAR WITH 35% BLASTS. WHAT WOULD YOU CONSIDER NEXT? (N = 8)



A 77-YEAR-OLD MALE COMES IN WITH AML, NORMAL CYTOGENETICS, NO *FLT3 ITD/NPM1/CEBP-ALPHA* MUTATION. HE RECEIVES 7+3 AND HAS A POSITIVE DAY 14 MARROW. HE DEVELOPS A SIGNIFICANT FUNGAL INFECTION DURING INDUCTION, AND IS NOT FIT FOR REINDUCTION. NGS SHOWS *IDH2* AND *DNMT3* MUTATION. WHAT DO YOU CONSIDER NEXT? (N = 7)

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A 75-YEAR-OLD MAN WITH HIGH-RISK MDS HAS A HISTORY OF PROSTATE CANCER TREATED WITH RADIATION THERAPY 3 YEARS AGO. DURING FOLLOW-UP, HE WAS FOUND TO HAVE PANCYTOPENIA. BM EVALUATION REVEALED 11% BLASTS. CG REVEALED +8 AND –7. PATIENT RECEIVED HMA THERAPY AND ACHIEVED A RESPONSE FOR 9 MONTHS. EVALUATION REVEALED 25% BLASTS WITH PROGRESSIVE DISEASE. WHAT WOULD YOU CONSIDER NEXT? (N = 8)

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