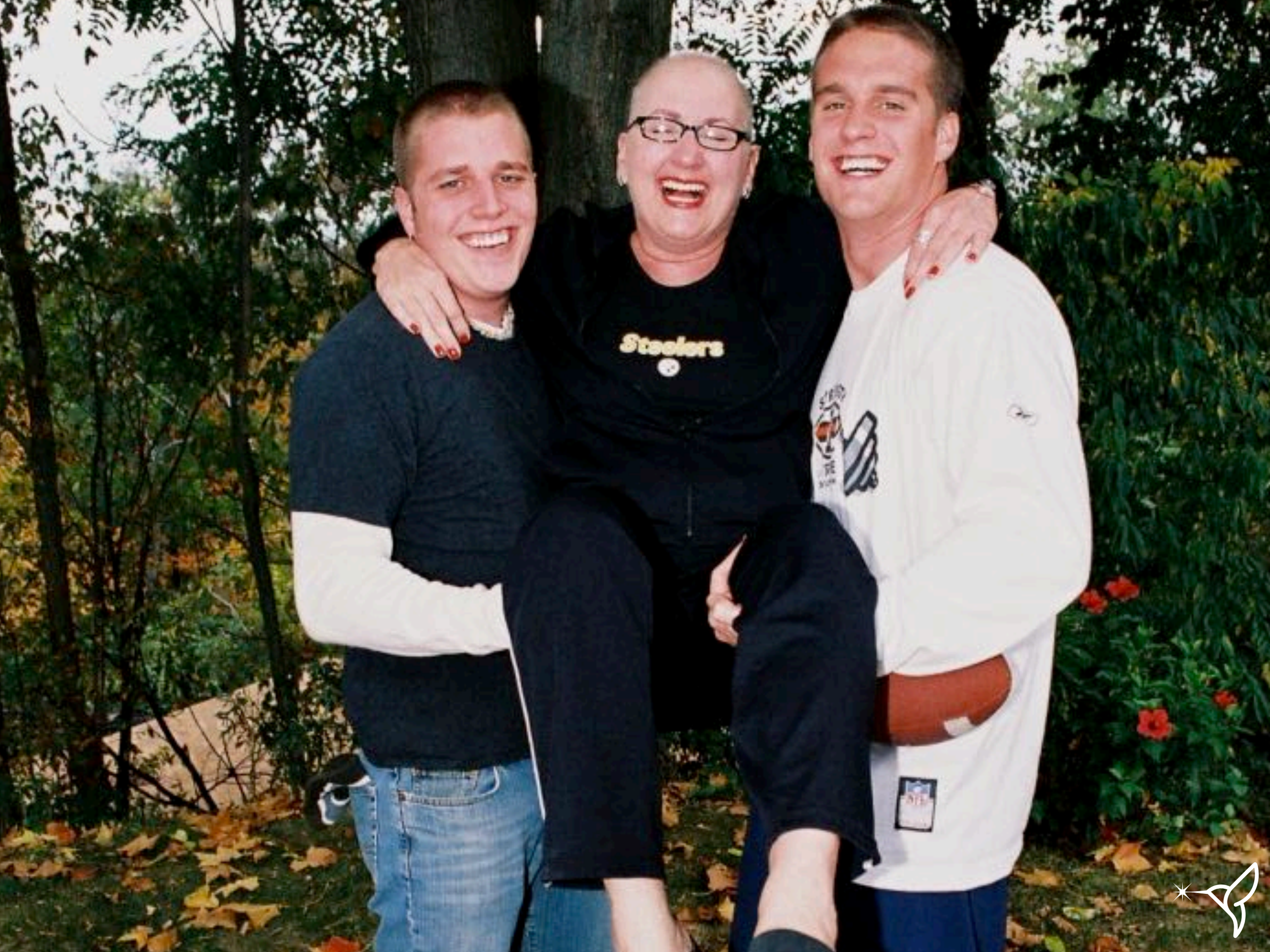
SparkCures

Myeloma support. Personalized.


Steelers


1-800-547-5995

My **Clinical Trials**

Personalized Responses to Dietary Composition Trial 3	Observational	5 months
CPS-3 Study	Observational	8 years
Growing Up Today Study	Observational	26 years
A Natural History Study to Evaluate Functional and Anatomical Progression in Retinitis Pigmentosa	Observational	4 months

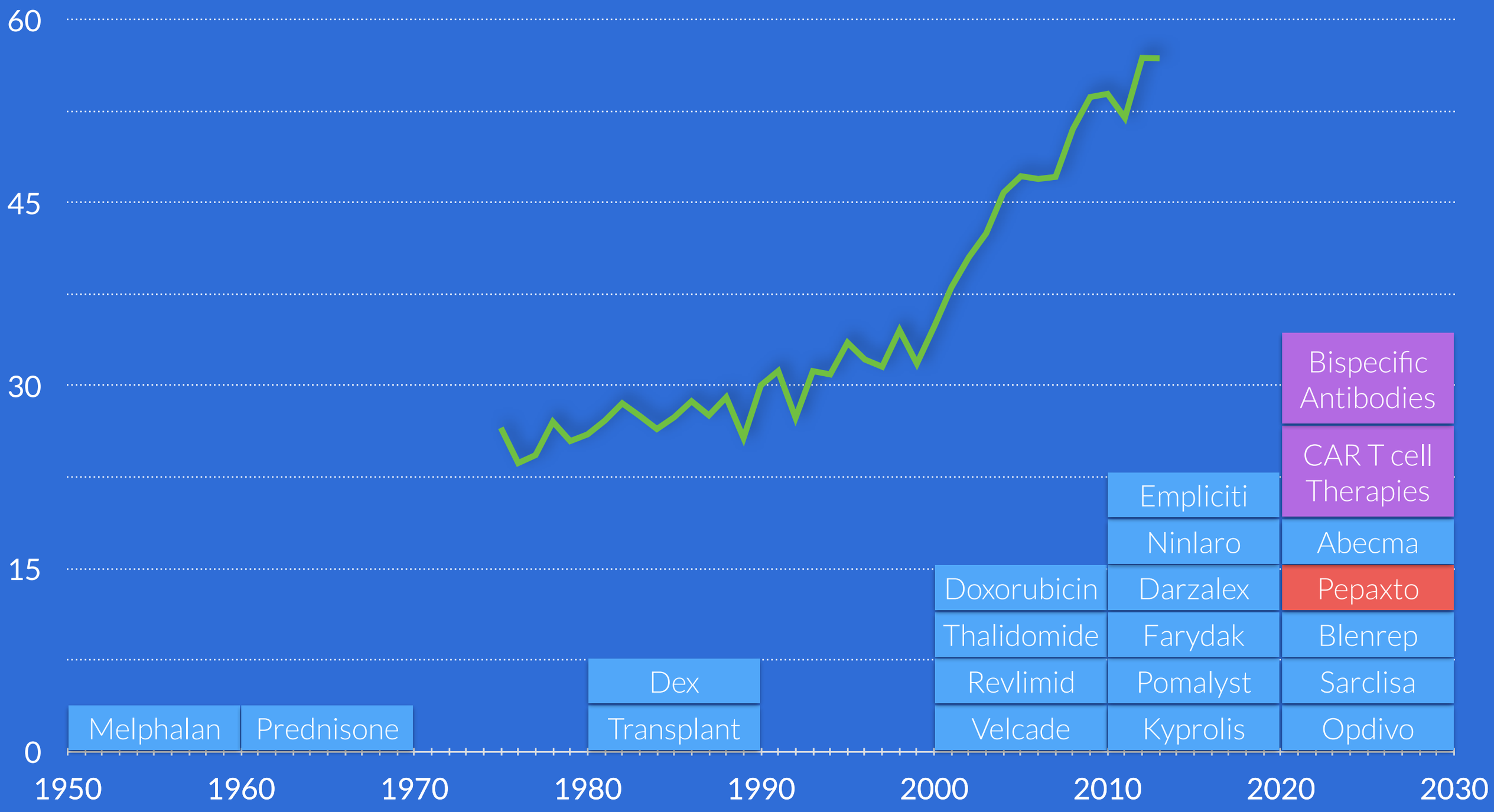
"A mighty flame followeth a tiny spark..."

Who's the **boss**?

Understand Your Options

- Myeloma Specialists
- Clinical Trials

FDA Approvals

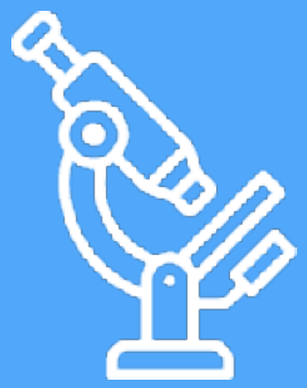


SOURCE: seer.cancer.gov

Clinical trials ask a question.

Types of Clinical Trials

TREATMENT / INTERVENTIONAL



OBSERVATIONAL

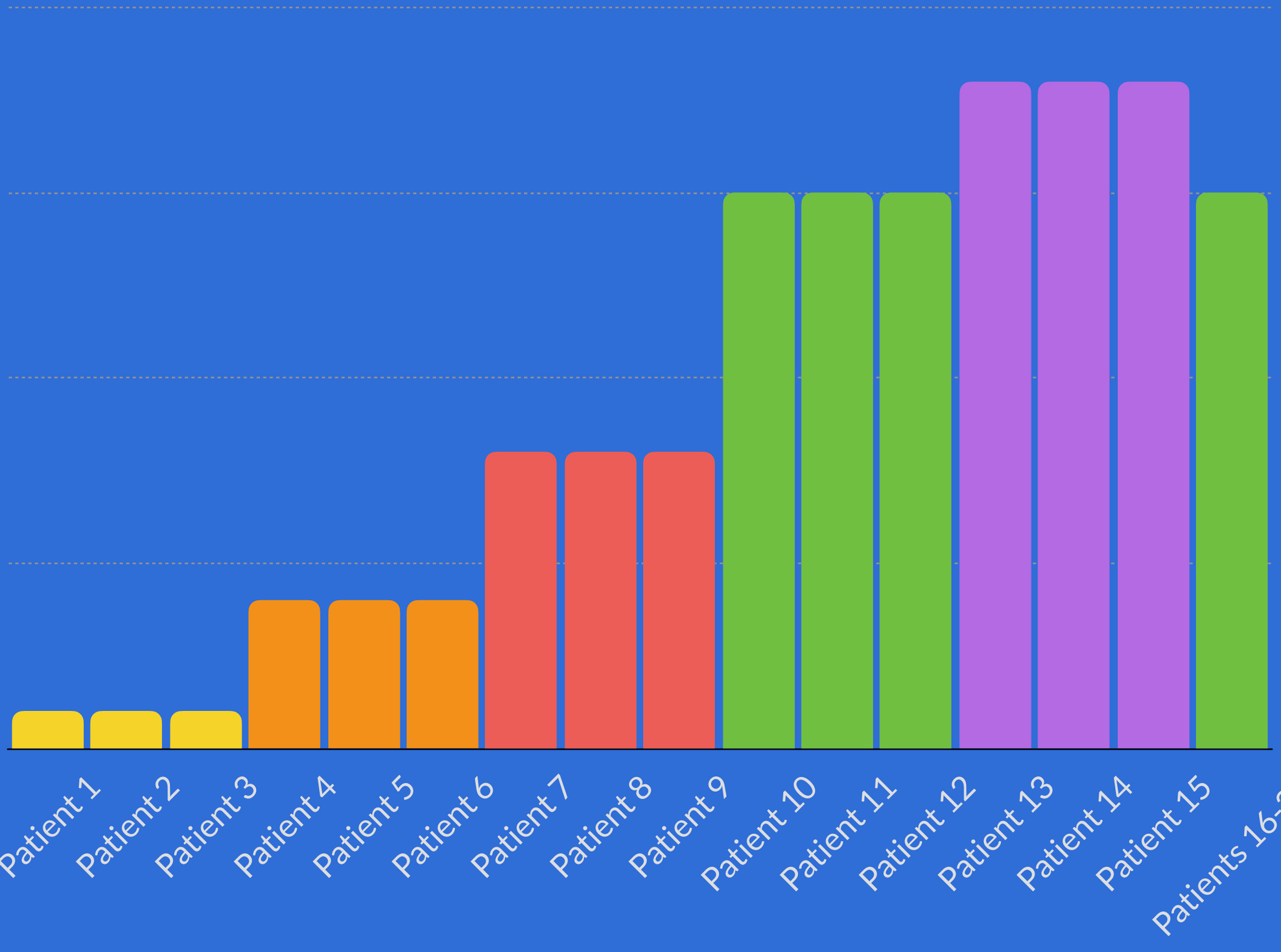
Clinical Trial **Phases**

- First-in-**human**
- First-in-**myeloma**
- Dose **escalation** or dose **expansion**

PHASE 1

Is this treatment safe? Dosage?

Clinical Trial **Phases**



Clinical Trial **Phases**

PHASE 3

Does the treatment work better than the current standard of care?

PHASE 2

Does this treatment work?

PHASE 1

Is this treatment safe? Dosage?

Access to Treatments

- Standard of Care
- Clinical Trials
- Off-Label
- Compassionate Use

Common **Myths**

My doctor didn't mention a trial. That means there's not one that's right for me.

MAYO CLINIC

mSMART

- The general approach is presented below (mSMART – off-study). However, ***clinical trials must be considered and are preferred*** at every level (mSMART – on-study).
- Management decisions are also varied depending on renal function and presence or absence of coexisting amyloidosis.

Dispenzieri et al. Mayo Clin Proc 2007;82:323-341; Kumar et al. Mayo Clin Proc 2009 84:1095-1110; Mikhael et al. Mayo Clin Proc 2013:88:360-376. v13 v14 //last reviewed May 2018

Common **Myths**

I don’t want to receive a placebo!

0

Common **Myths**

I’m not sick enough. I’m not out of options.

Common **Myths**

MGUS	15 **trials**
Smoldering Myeloma	26 **trials**
Untreated Myeloma	57 **trials**
Relapsed / Refractory Myeloma	200+ **trials**

A frog on a lily pad

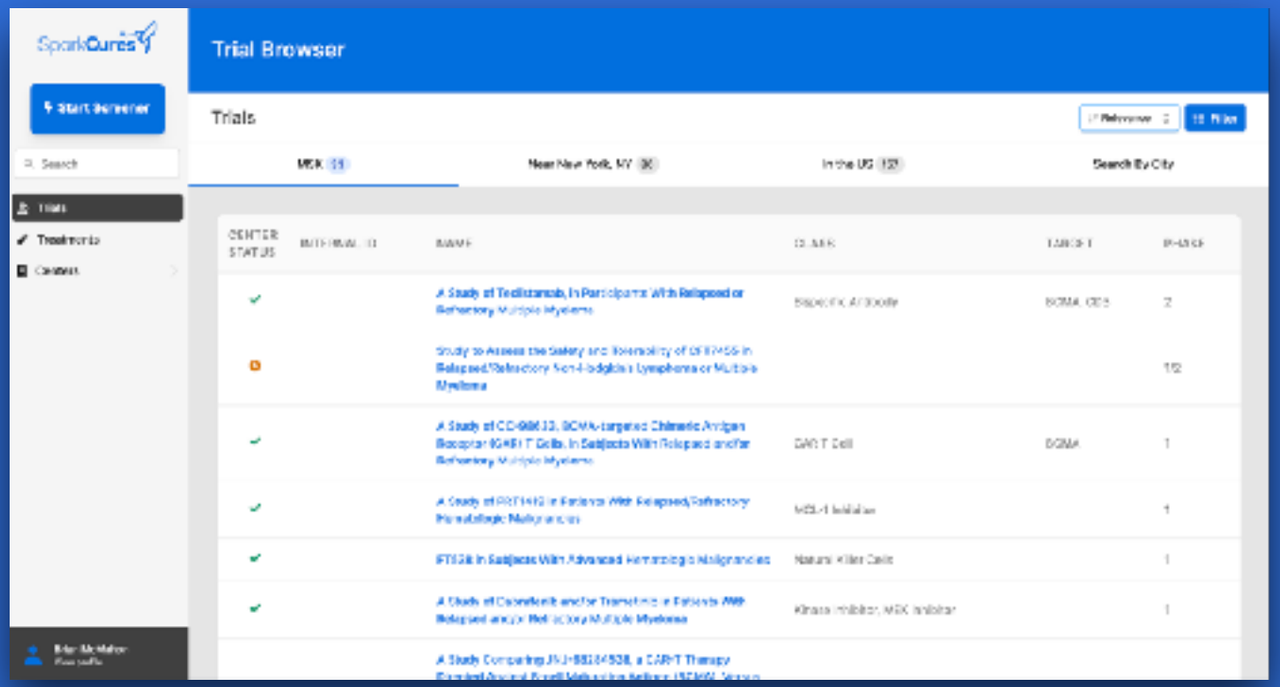
Immunotherapy **Targets**

SLAMF7		CD74
CD138		
CD38	FCRH5	CD48
GPRC5D	GPRC5D	CD46
BCMA	BCMA	BCMA
CAR T	**Bispecific Antibodies**	**Antibody Drug Conjugate**

a.k.a. Alphabet Soup

Crystal Ball **Questions**

Patient Portal



Doctor Portal

Create Your **Free Profile**

SparkCures.com

(888) 828-2206

Personalized Results

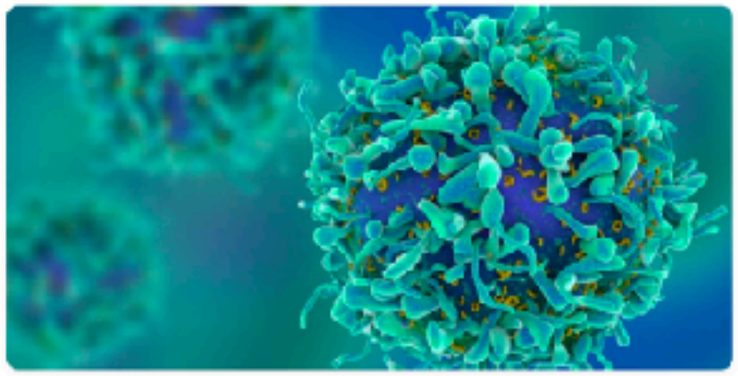
SparkCures

Trials Centers Tags Treatments My Profile

Clinical Trials

There are 194 active clinical trials attached to your account. Explore and learn more about clinical trials that may be right for you.

View My Trials



Myeloma Centers

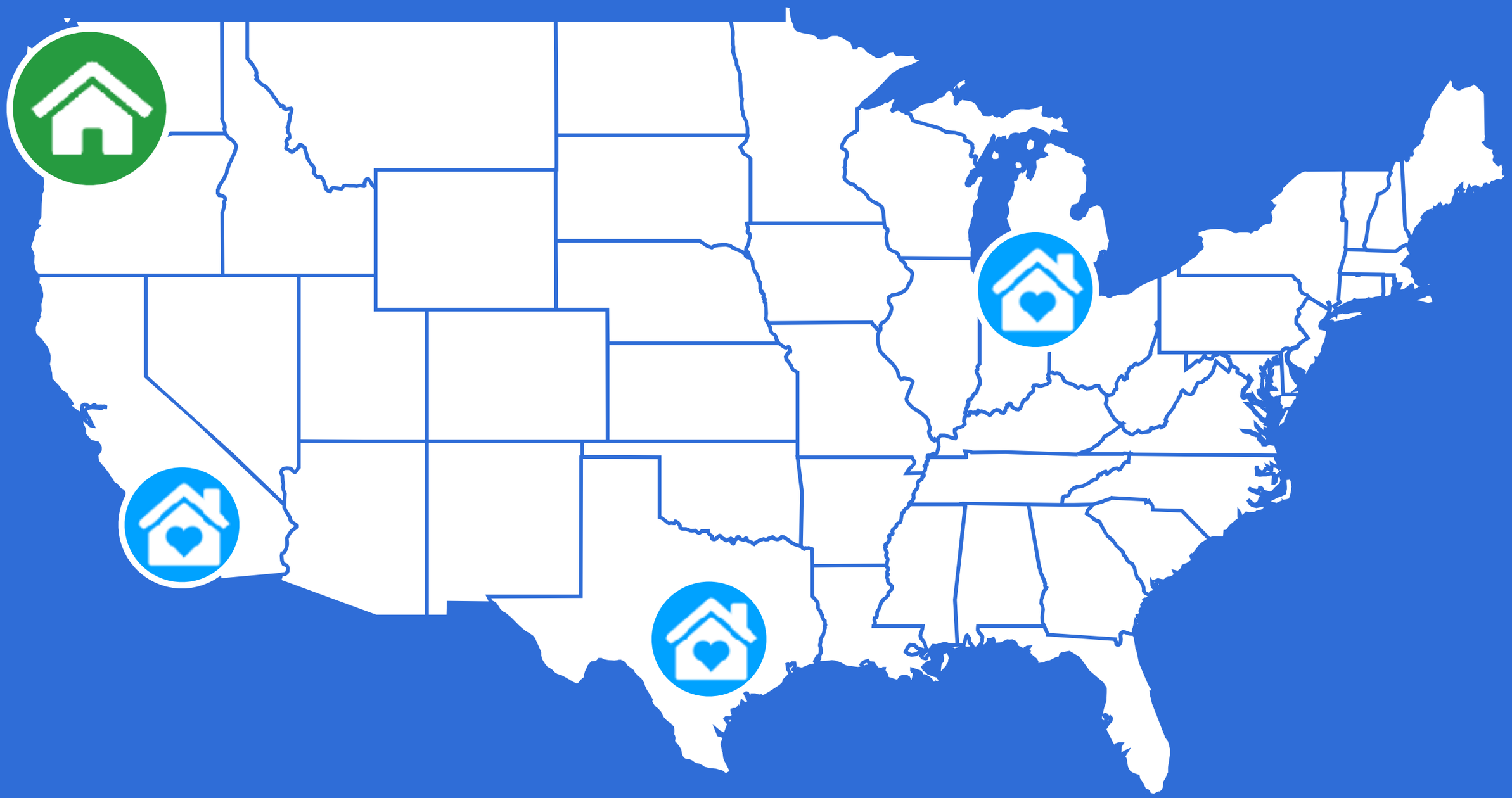
As a patient, having a myeloma specialist on your team is the most important choice that you can make. Explore myelome centers and specialists from around the United States.

View My Centers

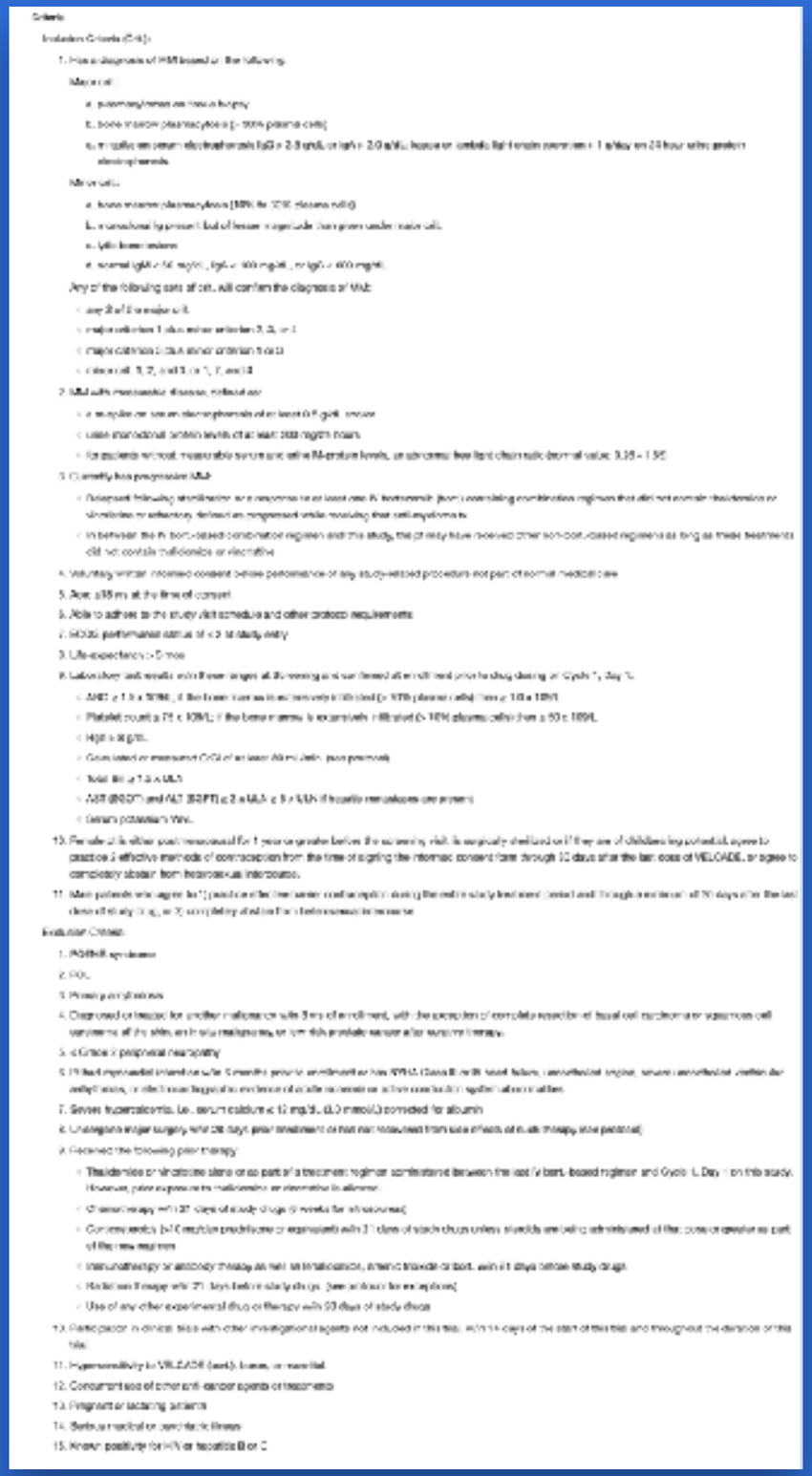
Explore More Myeloma Options

Help

Travel Preferences



Inclusion/Exclusion Criteria



Criteria

Inclusion Criteria (Cycle 1):

1. Have a diagnosis of MM based on the following:

   Major criteria:

   a. plasmacytoma on tissue biopsy

   b. bone marrow plasmacytosis (≥ 30% plasma cells)

   c. monoclonal serum immunoglobulin IgG ≥ 3.5 g/dL or IgA ≥ 2.0 g/dL, tissue or urinary light chain excretion ≥ 1 g/day on 24 hour urine protein electrophoresis

   Minor criteria:

   a. bone marrow plasmacytosis (30% to 10% plasma cells)

   b. monoclonal gammopathy but of lesser magnitude than given under major criteria

   c. lytic bone lesions

   d. normal IgM < 50 mg/dL, IgA < 100 mg/dL, or IgG < 600 mg/dL

   Any of the following can all can confirm the diagnosis of MM:

   - any 2 of 3 minor criteria
   - major criterion 1 plus minor criterion 2, 3, or 4
   - major criterion 2, plus minor criterion 3 or 4
   - criteria all 1, 2, and 3, or 1, 2, and 4

2. MM with measurable disease, defined as:

   - a monoclonal serum plasma protein at least 0.5 g/dL on urine
   - Urine monoclonal protein levels that exceed 200 mg/24 hours
   - For patients without measurable serum and urine M-protein levels, an abnormal free light chain ratio (normal value: 0.26 – 1.65)

3. Currently has progressive MM:

   - Disease following identification of a response to at least one IV bortezomib (bort) containing combination regimen that did not include daratumumab or elotuzumab or refractory, defined as progressive while receiving that said regimen(s).
   - In between the IV bort-based combination regimen and this study, the patient may have received other non-bort-based regimens as long as these treatments did not contain ruxolitinib or elotuzumab
4. Voluntarily written informed consent before performance of any study-related procedure not part of normal medical care
5. Age ≥18 yrs at the time of consent
6. Able to adhere to the study visit schedule and other protocol requirements
7. ECOG performance status ≤ 2 at study entry
8. Life-expectancy > 3 mos
9. Laboratory test results within these ranges at the screening visit (tests must be performed within 14 days prior to drug dosing on Cycle 1, Day 1):
   - ANC ≥ 1.5 x 10^9/L (if the bone marrow is adequately infiltrated [≥ 10% plasma cells] then ≥ 1.0 x 10^9/L)
   - Platelet count ≥ 75 x 10^9/L (if the bone marrow is adequately infiltrated [≥ 10% plasma cells] then ≥ 50 x 10^9/L
   - Hgb ≥ 8 g/dL
   - Corrected or measured CrCl of at least 40 mL/min per protocol
   - Total Bili ≤ 1.5 x ULN
   - AST (SGOT) and ALT (SGPT) ≤ 2 x ULN ≤ 3 x ULN if hepatic metastases are present
   - Serum potassium WNL
10. Female if is either post-menopausal for 1 year or greater before the screening visit, is surgically sterilized or if they are of childbearing potential, agree to practice 2 effective methods of contraception from the time of signing the informed consent form through 12 days after the last dose of VELCADE, or agree to completely abstain from heterosexual intercourse.
11. Male patients who agree to [1] practice effective contraception during the entire study treatment period and through a minimum of 90 days after the last dose of study drug, or [2] undergo a vasectomy and have documentation of azoospermia

Exclusion Criteria:

1. POEMS syndrome
2. PCL
3. Primary amyloidosis
4. Diagnosed or treated for another malignancy within 3 yrs of enrollment, with the exception of complete resection of basal cell carcinoma or squamous cell carcinoma of the skin, or in situ melanoma, or low risk prostate cancer after curative therapy
5. ≥ Grade 2 peripheral neuropathy
6. Has experienced myocardial infarction within 6 months prior to enrollment or has NYHA Class III or IV heart failure, uncontrolled angina, severe uncontrolled cardiac dysrhythmias, or other clinically significant cardiovascular disease that would preclude safe administration of study medication
7. Severe hypercalcemia, i.e., serum calcium ≥ 12 mg/dL (3.0 mmol/L) corrected for albumin
8. Undergone major surgery within 28 days prior treatment or not recovered from side effects of such therapy, as a general
9. Received the following prior therapy:
   - Thalidomide or its analogs alone or as part of a treatment regimen administered between the last IV bort.-based regimen and Cycle 1, Day 1 on this study. However, prior exposure to multicenter or alternative is allowed.
   - Cytotoxic therapy within 28 days of study drugs (6 weeks for nitrosoureas)
   - Corticosteroids (>1 mg/kg prednisone or equivalent) within 21 days of study drug unless steroids are being administered at the dose or regimen as part of the new regimen
   - Immunotherapy or antibody therapy as well as immunosuppressive, antineoplastic or bort. within 21 days before study drugs
   - Radiation therapy within 28 days before study drugs (one exception for emergencies)
   - Use of any other experimental drug or therapy within 28 days of study dosing
10. Participation in clinical trials with other investigational agents not included in this trial within 14 days of the start of this trial and throughout the duration of this trial
11. Hypersensitivity to VELCADE (bort), boron, or mannitol
12. Concomitant use of other anti-cancer agents or treatments
13. Pregnant or lactating patients
14. Serious medical or psychiatric illness
15. Known positive for HIV or hepatitis B or C

Am I **Eligible?**

Pass

Based on your profile, you may pass the following trial criteria.

- Patients diagnosed with multiple myeloma
- 18 years of age or older
- Patients who have undergone stem cell transplant must be at least 100 days from transplant
- Absolute neutrophil count (ANC) ≥ 1.5 x 10^9/L

Not Yet Eligible

Based on your profile, you may not yet be eligible for the following criteria.

- Patient with at least 2 prior regimens

Doctor Review

The following criteria will require additional review from your myeloma specialist.

- Bone marrow biopsy demonstrating at least 5% plasma cell involvement
- Patients with progressive disease

Trial **Buckets**

Current Trials

Future Trials

Favorite Trials

Not Interested Trials

Past Trials

Daily Updates


PATIENTS
FIRST

Our **Promise**

- Our services are free for patients and doctors – always have been and always will be.
- Your data belongs to you.

What We **Won't Do**

- We will never share or sell your personal information – **EVER**.
- We do not allow our relationships with our partners to influence treatment or trial decisions.

How We **Work With Industry**

- We help pharmaceutical companies understand why patients ARE NOT eligible.
- We help pharmaceutical companies understand where patients are UNDERSERVED.

If you aren't seeing a myeloma specialist...

We can help you find one.

If you have never considered
a clinical trial...

Let us help you understand
what your options may be
now or in the future.

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You Have **Q's**
We Have **A's**.

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