ARC TALKS
WEBINAR SERIES

AL Amyloidosis Clinical Trials

April 14 | 12pm - 1pm ET

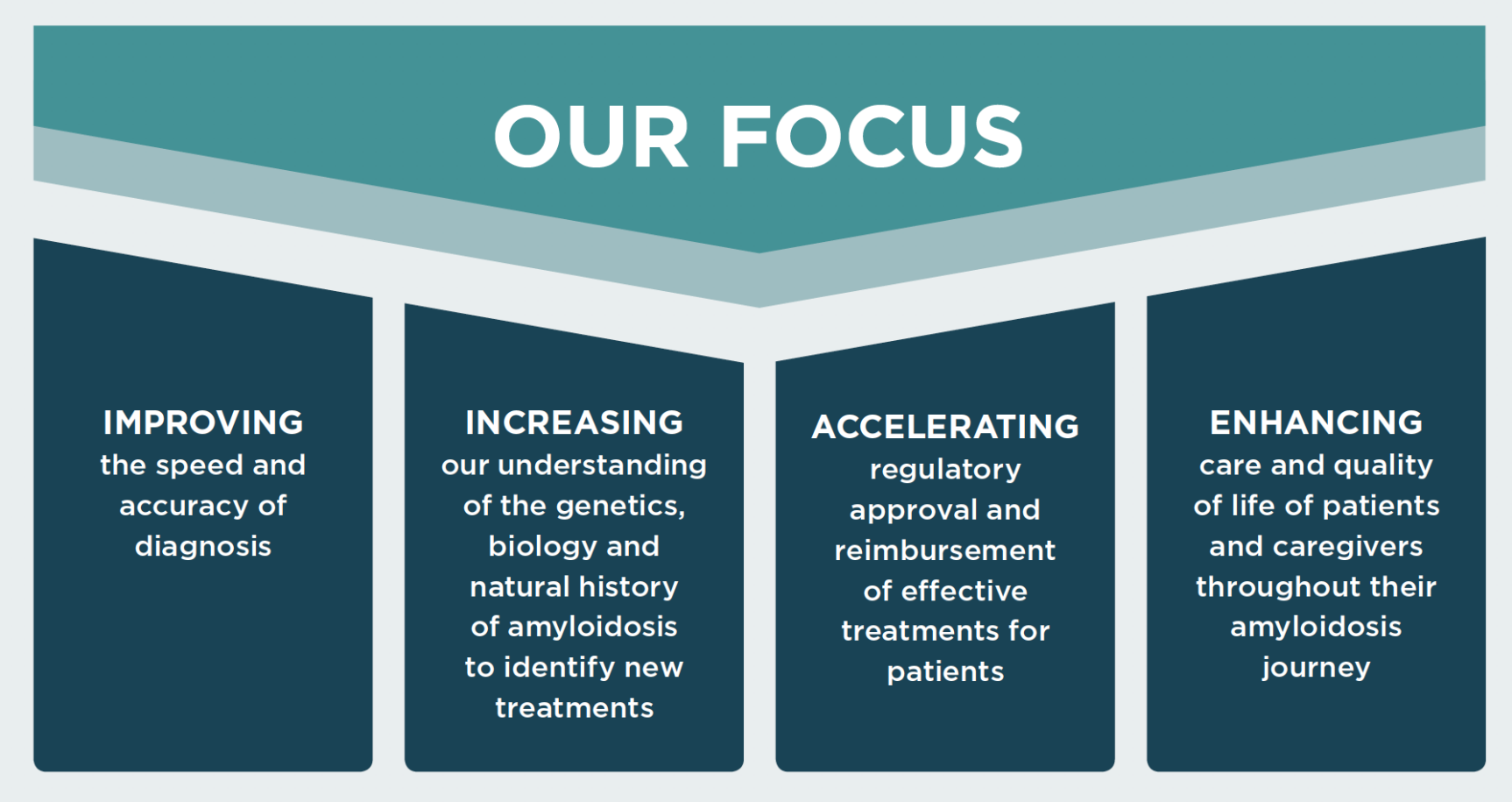
Kristen Hsu

Executive Director of Research
Amyloidosis Research Consortium

About ARC

Amyloidosis Research Consortium

ARC's mission is to improve and extend the lives of those with amyloidosis



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Alnylam® PHARMACEUTICALS

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Before We Begin

Amyloidosis Research Consortium

This webinar is recorded. We will post the webinar on our website so you can view it again later.

Submit your questions anytime via the Q&A box. We will try to answer them at the end.

If you are having trouble with the audio using your computer, you can dial in (check your email for info).

AL Amyloidosis Booklets

Amyloidosis Research Consortium

arci.org/booklets

ARC TALKS
WEBINAR SERIES

AL Amyloidosis Clinical Trials

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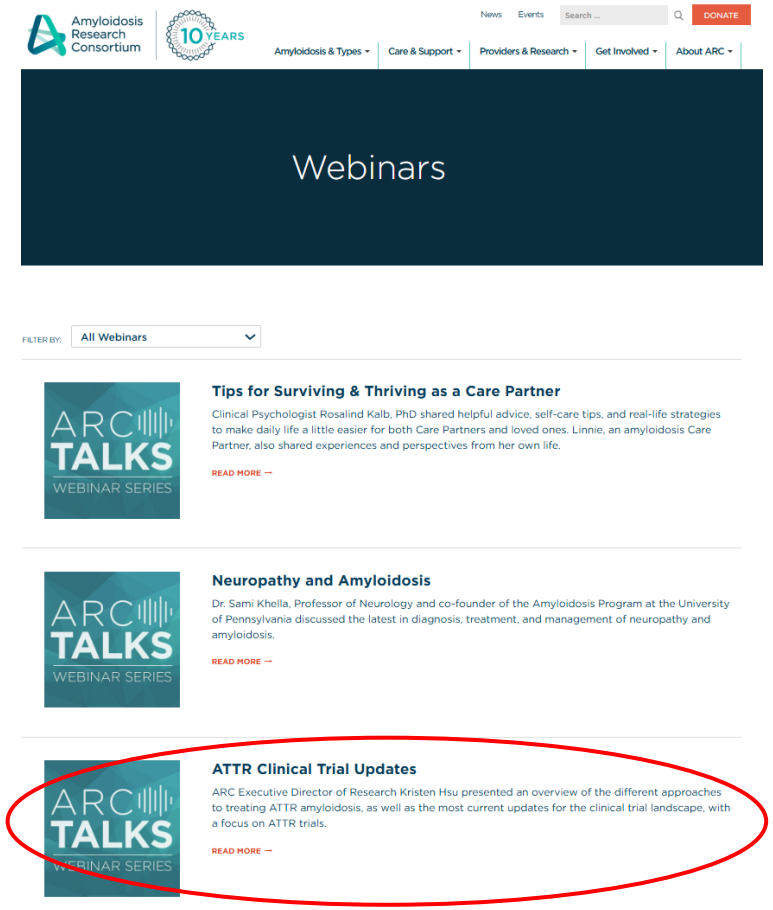
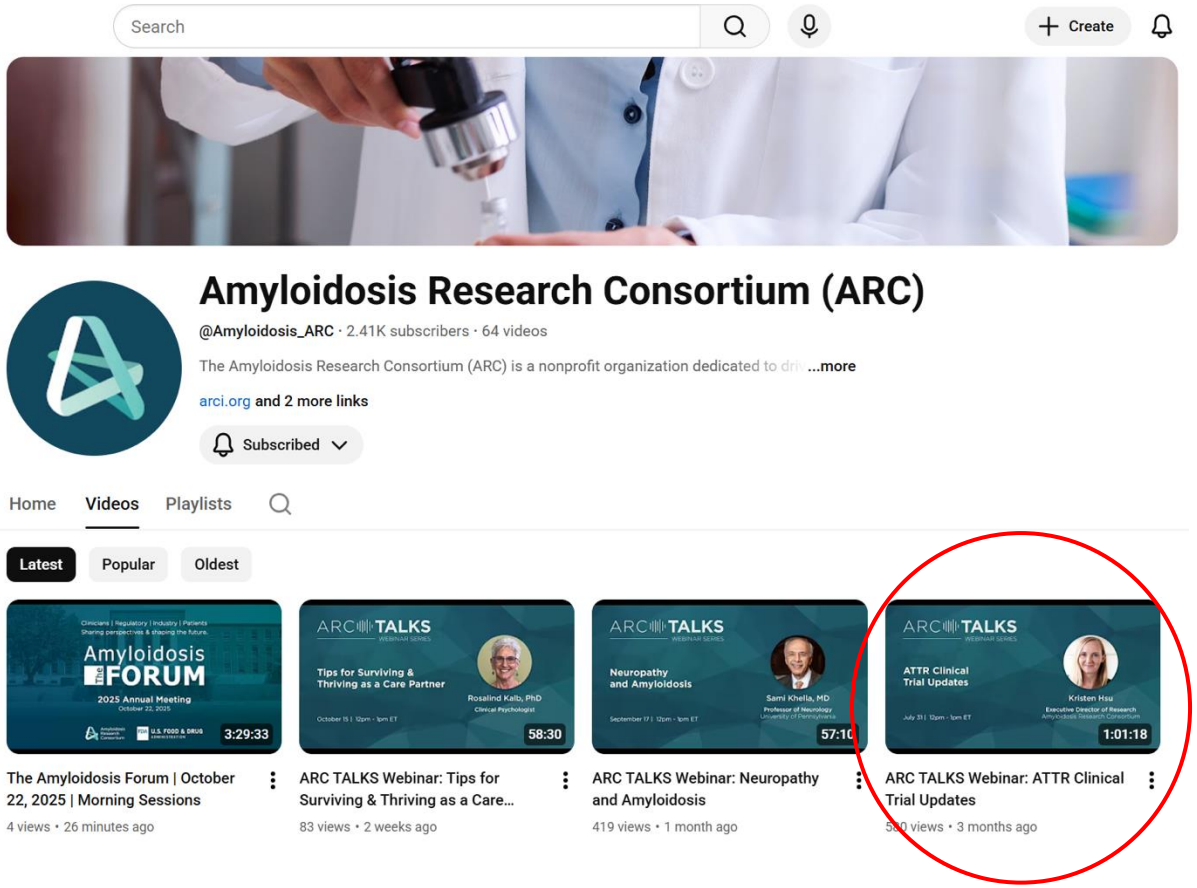
If you are here to learn about ATTR clinical trials…

…check out our July webinar focusing on ATTR amyloidosis clinical trials on our website or YouTube channel.
Our next ATTR amyloidosis clinical trials webinar is planned for July 2026

https://arci.org/resources-category/webinars/

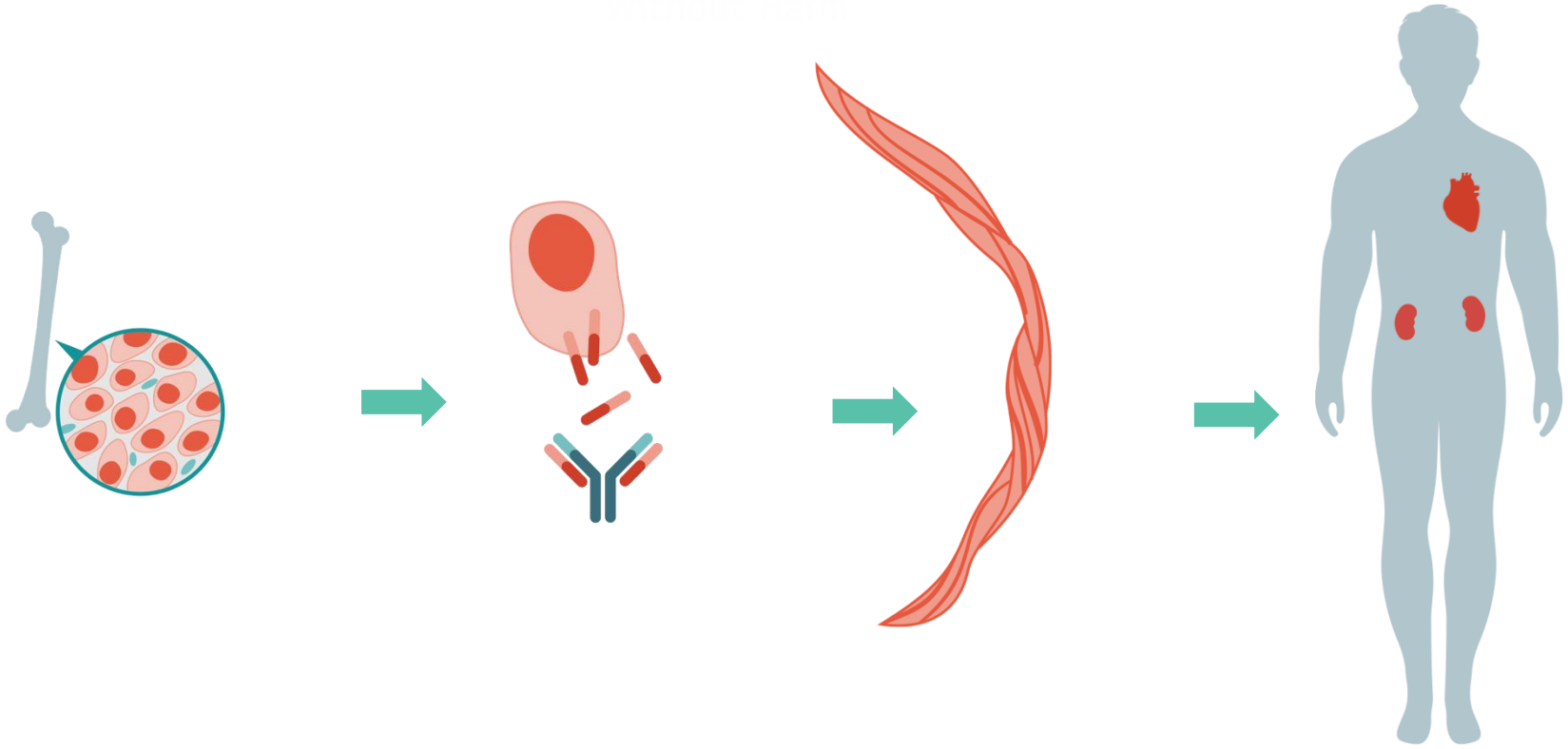


https://www.youtube.com/@Amyloidosis_ARC

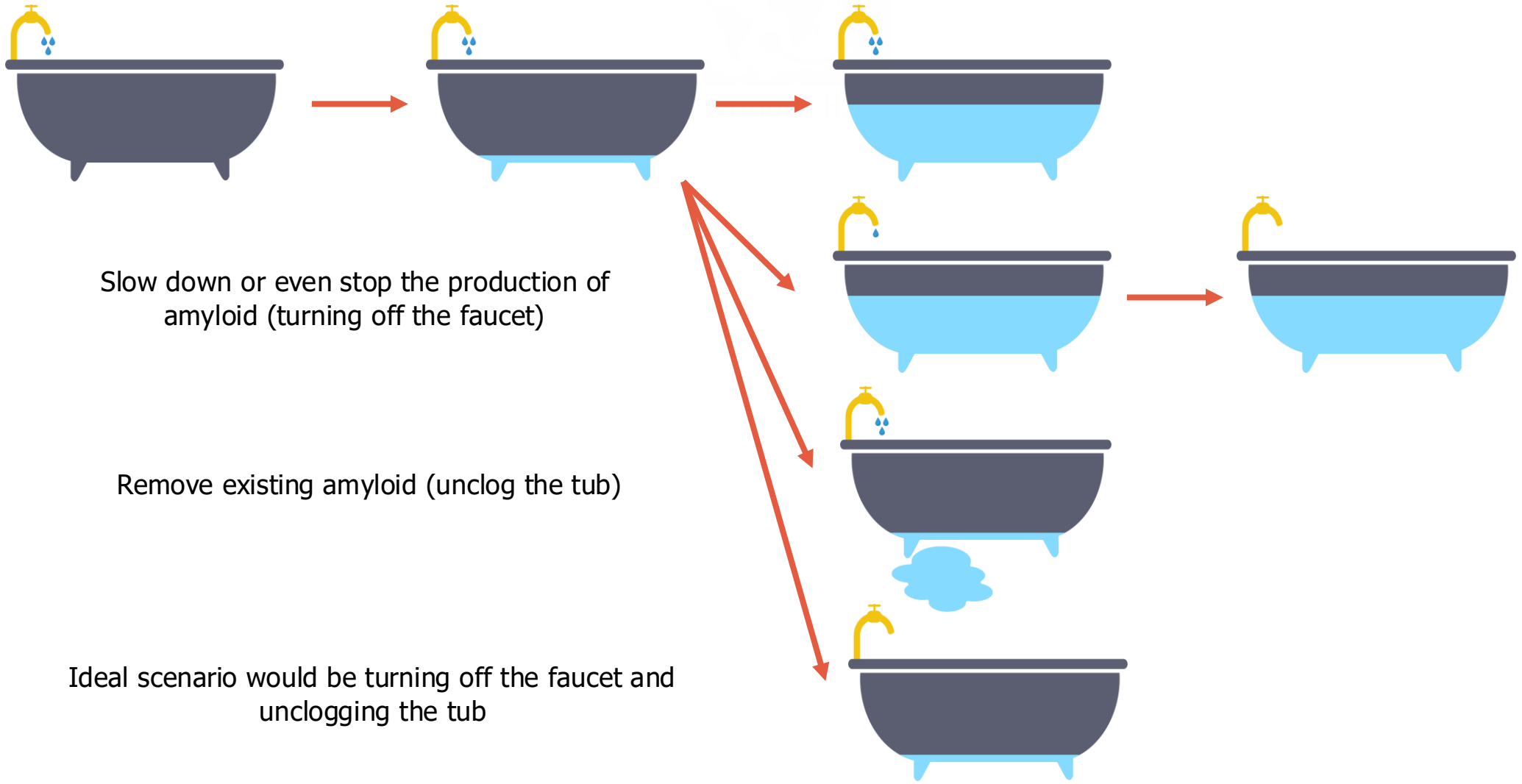


AL Amyloidosis Clinical trials

Investigative approaches to treating AL Amyloidosis....



…are like treating a clogged bathtub



Slow down or even stop the production of amyloid (turning off the faucet)

Remove existing amyloid (unclog the tub)

Ideal scenario would be turning off the faucet and unclogging the tub

Investigative Approaches to Treat AL Amyloidosis

Amyloidosis Research Consortium

Anti-plasma cell therapies

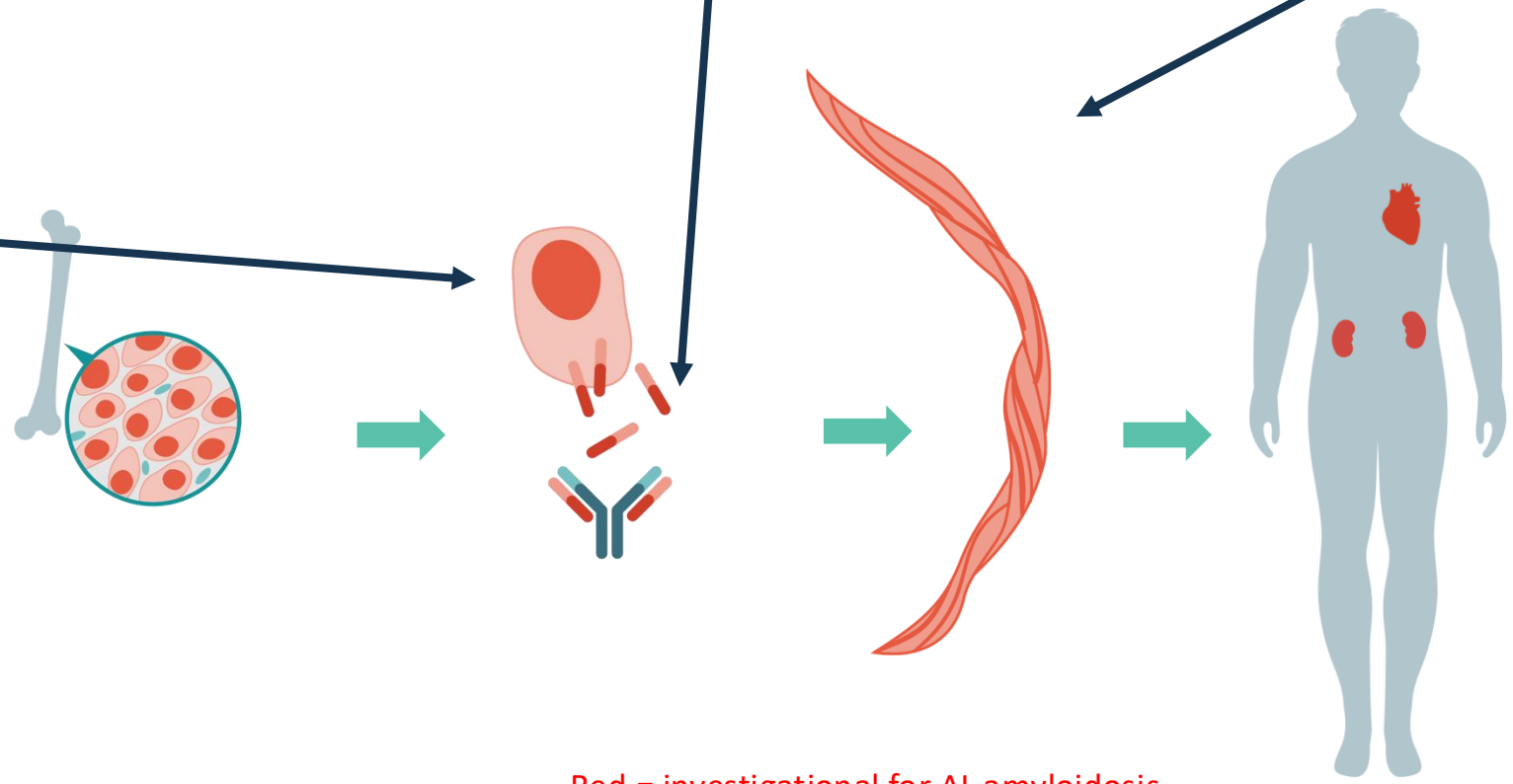
- Monoclonal antibodies
  - Daratumumab (DARZALEX)
  - Isatuximab (SARCLISA)
  - Elotuzumab (EMPLICITI)
  - Belantamab mafodotin (BLENREP)
- BCL-2 Inhibitors
  - Venetoclax (VENCLEXTA)
- Bispecific/Trispecific
  - Teclistamab (TECVAYLI)
  - Ramantamig (JNJ-79635322)
  - Linvoseltamab (LYNOZYFIC)
  - Etentamig (ABBV-383)
  - Elrantamab (ELREXFIO)
- Cellular Therapies
  - AZD0120
  - NXC-201
  - AUTO8

Light chain Stabilizers

- PROT-001 (lambda)

Anti-Fibril Agents

- Anselamimab (CAEL-101)
- NI009 (lambda)
- AT-02



Red = investigational for AL amyloidosis

Recruiting Trials for Novel AL Therapies in 2026

Amyloidosis Research Consortium

				Pre-clinical	Phase I	Phase II	Phase III	Commercial
Monoclonal Antibodies	Janssen	Daratumumab (Darzalex)	Approved					
	Sanofi	Isatuximab	Phase 2 IST status unk					
	BMS	Elotuzumab	Phase 2 IST status unk					
	GSK	**Belantamab mafodotin**	**Phase 2 recruiting**					
Bispecific/ Trispecific Antibodies	Janssen	**Teclistamab**	**Phase 2 recruiting**					
		Ramantamig (JNJ-79635322)	**Phase 1 recruiting**					
	Regeneron	**Linvoseltamab**	**Phase 1/2 recruiting**					
	AbbVie	**Etentamig (ABBV-383)**	**Phase 1b recruiting**					
	Pfizer	Elrantamab	Phase 1/2 IST recruiting					
Cellular Therapies	Nexcella	NXC-201	Phase 2 results Q3 2026					
	Alexion/AZ	**AZD0120**	**Phase 1b/2 recruiting**					
	Autolus	AUTO8	Phase 1 recruiting					
BCL2 Inhibitors	AbbVie	Venetoclax	Phase 1/2 ISTs recruiting					
LC Stabilizer	Protego	PROT-001 (lambda AL)	Phase 2/3 planned 2026					
Anti-Fibril Agents	Alexion/AZ	Anselamimab (CAEL-101)	P3 completed; benefit in kappa AL patients					
		NI009 (lambda AL)	Preclinical					
	Attralus	AT-02	Phase 2 (renal) ongoing					

ALANIS (Belantamab Mafodotin; antibody-drug conjugate)

Newly diagnosed AL amyloidosis

Amyloidosis Research Consortium

Study Phase	Phase 2
Purpose of the study	Evaluate the efficacy and safety of belantamab mafodotin in combination with cyclophosphamide, bortezomib, and dexamethasone (CyBorD) in newly diagnosed AL
Primary endpoint	Overall complete hematologic response rate
Key eligibility criteria	• Newly diagnosed, no prior treatments • Not considered candidate for high-dose chemotherapy with autologous stem cell transplantation (ASCT) as part of first line of therapy • Mayo Stage I, II, or IIIa
Number of patients	60
Study Drug	Belantamab mafodotin (1 of 2 possible doses, given as an IV infusion) and CyBorD
Chance of receiving study drug?	All patients will receive study drug
How long?	Up to 2 years

Recruiting ALANIS Countries (as of 09Apr2026)

Amyloidosis Research Consortium

IMPACT-AL (Teclistamab; BCMA-CD3 bispecific antibody)

Newly diagnosed AL amyloidosis

Amyloidosis Research Consortium

Study Phase	Phase 2
Purpose of the study	Assess the effectiveness and safety of teclistamab-daratumumab combination; evaluate whether this combination is able to effectively decrease the level light chains, avoiding organ damage, improving organ function, and prolonging life
Primary endpoint	Hematologic Complete Response (Heme-CR)
Key eligibility criteria	• No prior plasma cell directed therapy • Measurable hematologic disease defined as dFLC≥ 50mg/L or serum M-protein ≥ 5g/L • 1 of more organs involved
Number of patients	25
Study Drug	Teclistamab and Daratumumab (given as subcutaneous (under the skin) injections) - Teclistimab: Step up dosing for 1st week, weekly dosing until Month 1, then monthly dosing through Month 6 - Daratumumab: Weekly for 1st 2 months, then biweekly (every 2 weeks) through Month 6
Chance of receiving study drug?	All patients will receive study drug
How long?	6 months

Recruiting IMPACT-AL Centers (as of 09Apr2026)

Amyloidosis Research Consortium

Recruiting Centers:

- **Massachusetts-** Boston*
- **New York-** New York
- **Wisconsin**- Milwaukee*

- *not yet recruiting

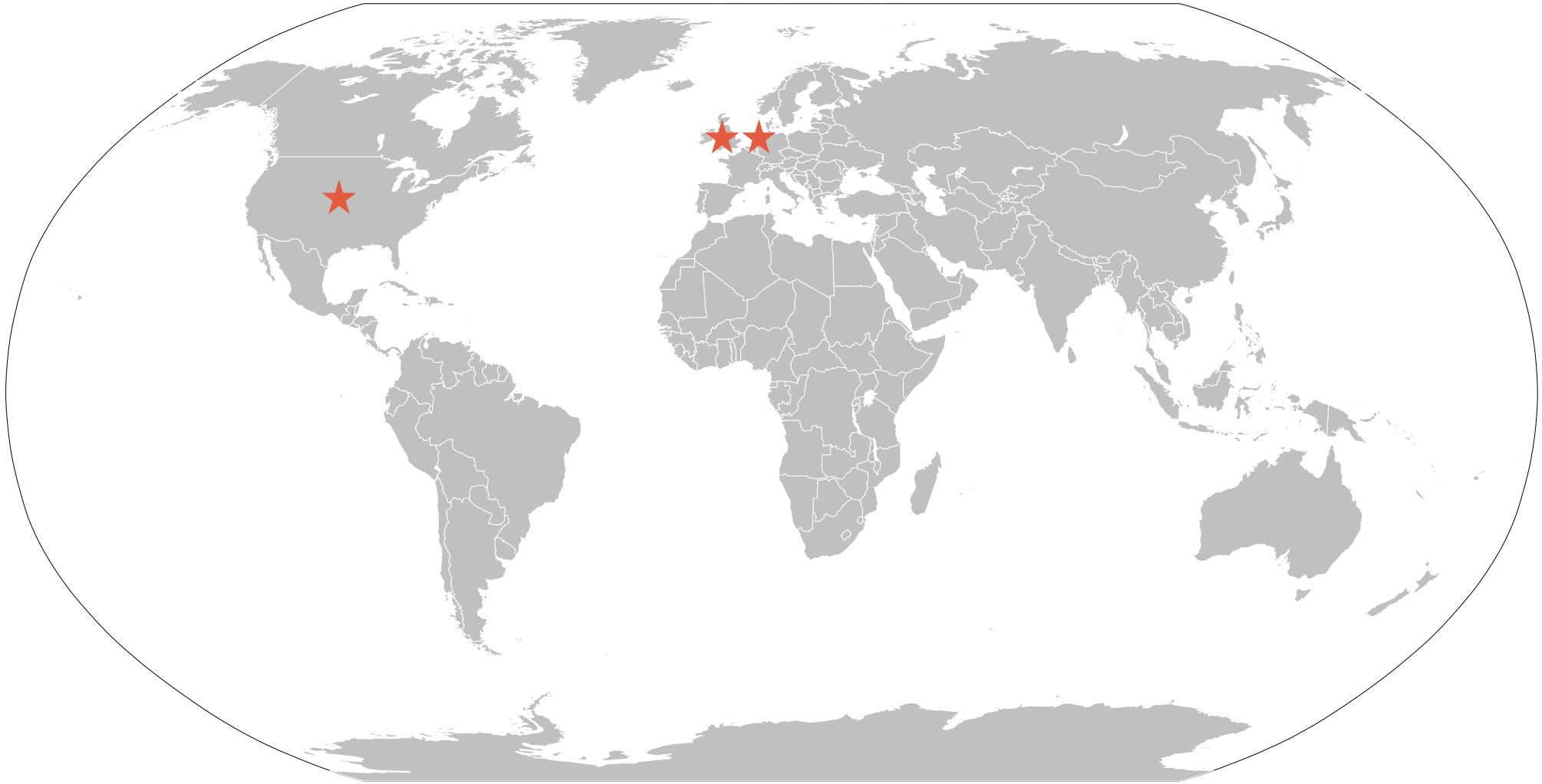
RAMANTAMIG study (JNJ-79635322; BCMA-GPRC5D-CD3 trispecific antibody)

Previously treated AL amyloidosis

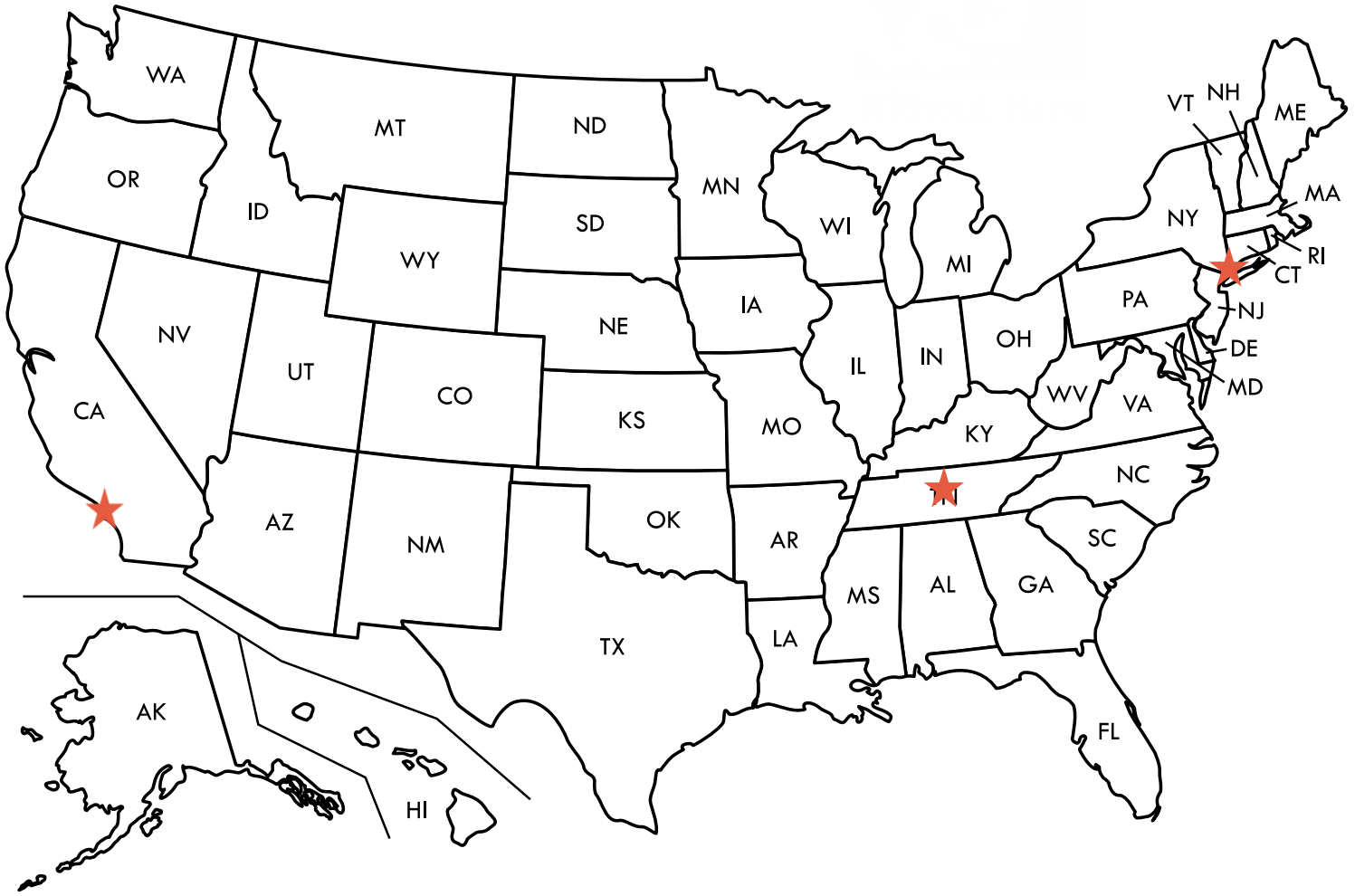
Study Phase	Phase 1
Purpose of the study	Part 1 (dose escalation): identify the recommended phase 2 dose and schedule(s) to be safe for Ramantamig Part 2 (dose expansion): characterize the safety and tolerability of Ramantamig at the selected doses and in disease subgroups
Primary endpoint	Dose limiting toxicities, adverse events, and abnormal lab values
Key eligibility criteria (AL amyloidosis)	• at least 3 cycles of 1 prior line of therapy or a total of at least 2 cycles of 2 or more prior lines of therapy for AL amyloidosis • Measurable hematologic disease defined as dFLC≥ 50mg/L or serum M-protein ≥ 5g/L • 1 of more organs involved • Left ventricular ejection fraction (LVEF) >=45%
Number of patients	10 AL amyloidosis patients (170 multiple myeloma)
Study Drug	Ramantamig, given as given as subcutaneous (under the skin) injections
Chance of receiving study drug?	All patients will receive study drug
How long?	Up to 2 Years 5 months

Recruiting Ramantamig Centers (AL) (as of 09Apr2026)

Amyloidosis Research Consortium



Recruiting Ramantamig Centers (AL) (as of 09Apr2026)



Recruiting Centers:

- **California-** Duarte
- **New York-** New York
- **Tennessee-** Nashville

LINKER-AL2 (linvoseltamab; BCMA-CD3 bispecific antibody)

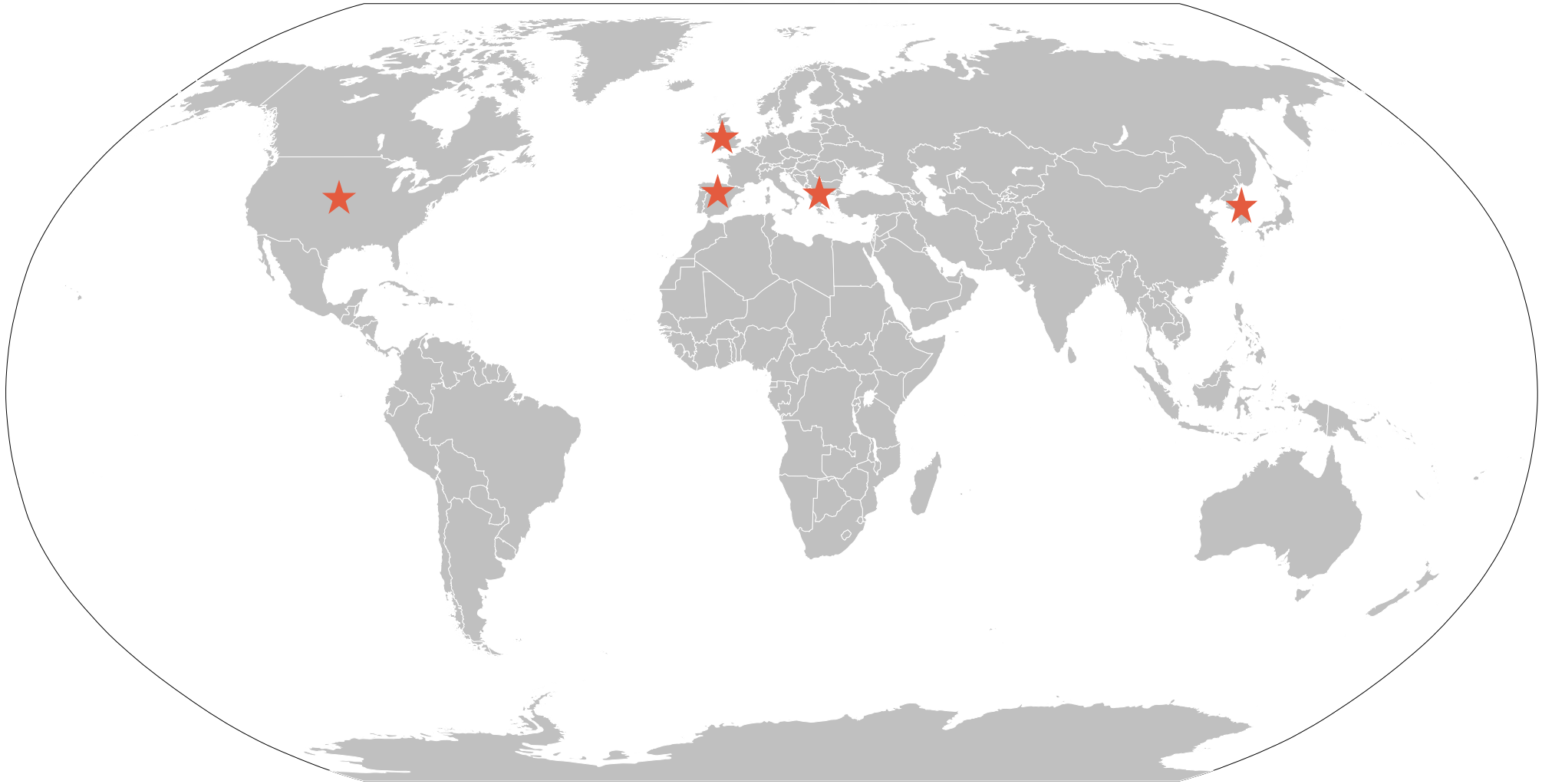
Relapsed/refractory AL amyloidosis

Amyloidosis Research Consortium

Study Phase	Phase 1/2
Purpose of the study	- Phase 1: Evaluate the safety of linvoseltamab and determine recommended Phase 2 dose - Phase 2: Evaluate the safety and efficacy of linvoseltamab
Primary endpoint	- Phase 1: Evaluate the safety of linvoseltamab and determine recommended Phase 2 dose - Phase 2: Evaluate the safety and efficacy of linvoseltamab
Key eligibility criteria	- Measurable disease (serum difference between involved and uninvolved free light chains (dFLC) concentration) - Patients with at least 1 prior line of therapy and still requires further treatment - NT-proBNP ≤8500 ng/L
Number of patients	220
Study Drug	linvoseltamab
Chance of receiving study drug?	All patients will receive study drug
How long?	~3 years
	https://clinicaltrials.regeneron.com/clinical-trials/a0MPr0000008ANBMA2/nct06292780
	https://clinicaltrials.gov/study/NCT05137054

Recruiting LINKER-AL2 Countries (as of 09Apr2026)

Amyloidosis Research Consortium



Recruiting LINKER-AL2 Centers (as of 09Apr2026)

Recruiting Centers:

- **California-** Duarte
- **Colorado**- Denver
- **Michigan**- Detroit
- **New York-** Buffalo
- **Ohio-** Columbus
- **Texas**- Houston
- **Tennessee**- Nashville

ETENTAMIG (ABBV-383) study (BCMA-CD3 bispecific antibody)

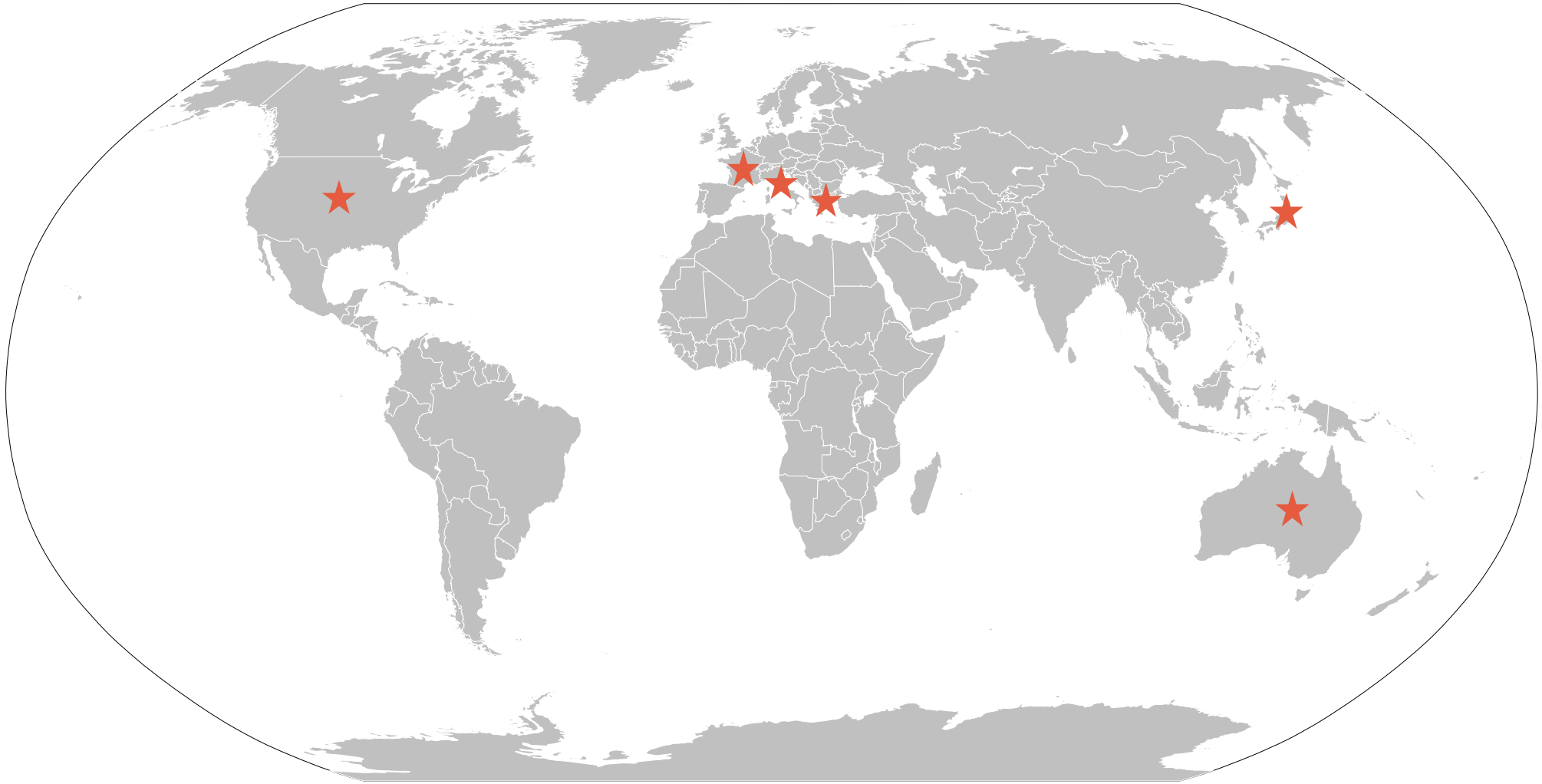
Relapsed/refractory AL amyloidosis

Amyloidosis Research Consortium

Study Phase	Phase 1b
Purpose of the study	Safety evaluation and preliminary activity
Primary endpoint	Dose limiting toxicities and recommended dose of etentamig monotherapy in AL amyloidosis (Secondary: preliminary activity of Etentamig monotherapy in AL amyloidosis)
Key eligibility criteria	• Patients with at least 1 prior therapy that includes prior proteosome inhibitor and anti-CD38 • At least one organ historically involved • Measurable disease (difference between involved and uninvolved free light chains (dFLC) >= 50 mg/L) • Must not have other non-AL amyloid disease, plasma cell leukemia, multiple myeloma, Waldenstrom's macroglobulinemia
Number of patients	Approximately 76 patients
Study Drug	Infusions of etentamig every 4 weeks
Chance of receiving study drug?	All patients will receive study drug
How long?	Up to 2 years

Recruiting Etentamig Countries (as of 09Apr2026)

Amyloidosis Research Consortium



Recruiting Etentamig Centers (as of 09Apr2026)

Recruiting Centers:

- **Florida-** Miami
- **Massachusetts-** Boston
- **Minnesota-** Rochester
- **New York-** New York (3 centers)
- **North Carolina-** Charlotte, Winston-Salem
- **Oregon**- Portland
- **Washington-** Seattle
- **Wisconsin**-Milwaukee

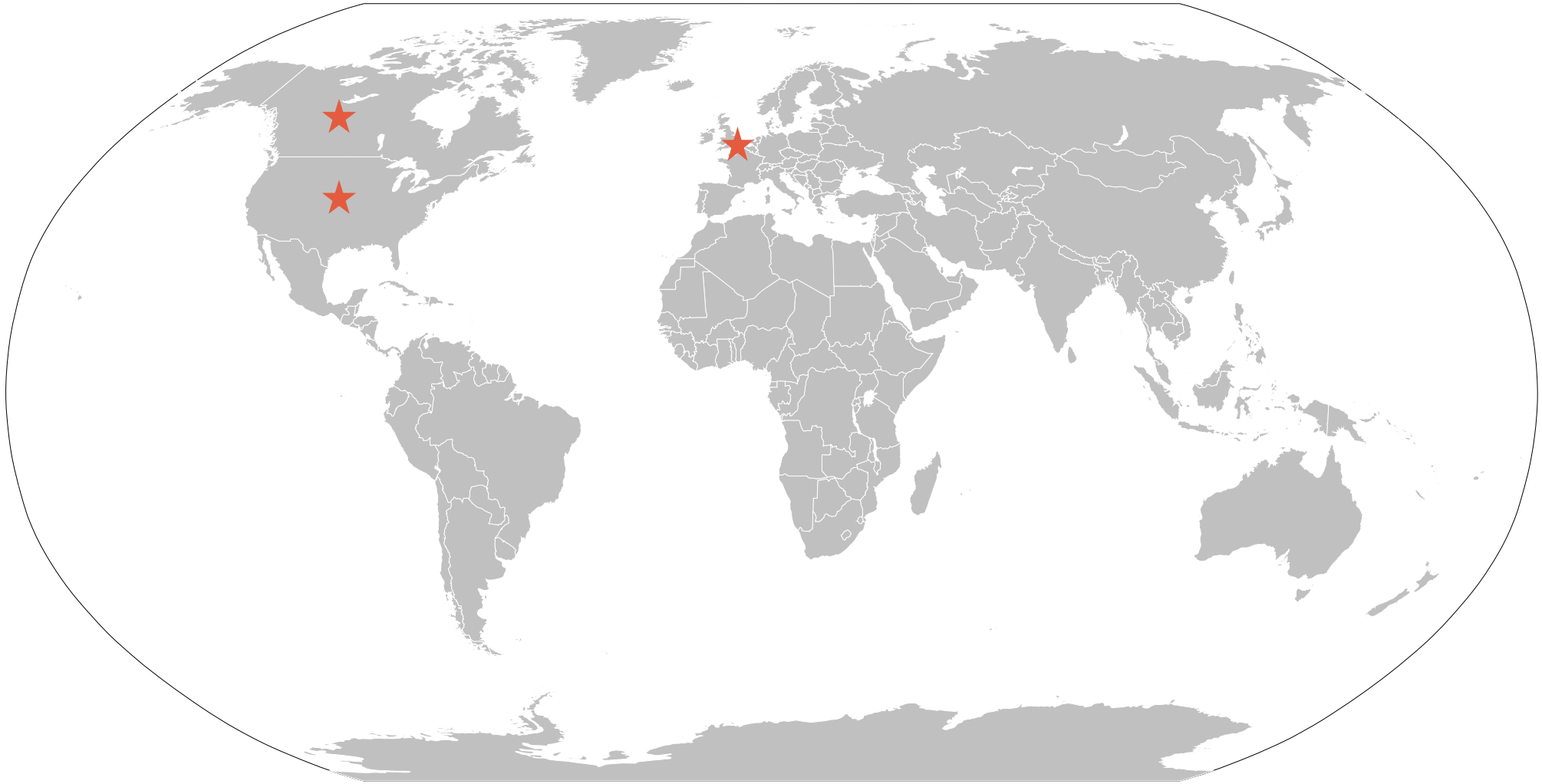
ALACRITY (AZD0120; CD19/BCMA chimeric antigen receptor T (CAR-T) cell therapy)

Relapsed/refractory AL amyloidosis

Amyloidosis Research Consortium

Study Phase	Phase 1b/2
Purpose of the study	Evaluate the Safety and Tolerability of AZD0120
Primary endpoint	Phase 1b: Number of participants with incidence and severity or treatment emergent adverse events Phase 2: Proportion of participants experiencing a complete response
Key eligibility criteria	• At least 1 line of anti-plasma cell-directed therapy with need for additional therapy. • At least 1 organ currently or previously affected • Measurable hematological disease (difference between involved and uninvolved free light chains (dFLC)> 20mg/L or serum M-protein > 5g/L) • ECOG performance status: 0-1 (relatively active and healthy) • No prior CAR-T, no prior BCMA-targeting therapy, no prior treatment within last 6 months with bispecific or trispecifics
Number of patients	91
Study Drug	AZD0120; Single infusion following leukopharesis and lymphodepletion
Chance of receiving study drug?	All patients will receive AZD0120
How long?	Minimum of 6 months

Recruiting ALACRITY Countries (as of 09Apr2026)



Recruiting ALACRITY Centers (as of 09Apr2026)

Amyloidosis Research Consortium

Recruiting Centers:

- **Arizona-** Phoenix
- **California**- San Francisco*
- **Florida-** Tampa
- **Massachusetts-** Boston
- **Michigan-** Detroit
- **Minnesota-** Rochester
- **Missouri-** St. Louis
- **New York-** New York (x3)
- **Ohio-** Cleveland
- **Tennessee**- Nashville

*not yet recruiting

Planned Trials for Novel AL Therapies in 2026

Amyloidosis Research Consortium

				Pre-clinical	Phase I	Phase II	Phase III	Commercial
Monoclonal Antibodies	Janssen	Daratumumab (Darzalex)	Approved					
	Sanofi	Isatuximab	Phase 2 IST status unk					
	BMS	Elotuzumab	Phase 2 IST status unk					
	GSK	Belantamab mafodotin	Phase 2 planned					
Bispecific/ Trispecific Antibodies	Janssen	Teclistamab	Phase 2 recruiting					
		Ramantamig (JNJ-79635322)	Phase 1 recruiting					
	Regeneron	Linvoseltamab	Phase 1/2 recruiting					
	AbbVie	Etentamig (ABBV-383)	Phase 1b recruiting					
	Pfizer	Elrantamab	Phase 1/2 IST recruiting					
Cellular Therapies	Nexcella	NXC-201	Phase 1b/2 recruiting					
	Alexion/AZ	AZD0120	Phase 1b/2 recruiting					
	Autolus	AUTO8	Phase 1 recruiting					
BCL2 Inhibitors	AbbVie	Venetoclax	Phase 1/2 ISTs recruiting					
LC Stabilizer	Protego	**PROT-001 (lambdaAL)**	**Phase 2/3 planned 2026**					
Anti-Fibril Agents	Alexion/AZ	Anselamimab (CAEL-101)	P3 completed; benefit in kappa AL patients					
		NI009 (lambda AL)	Preclinical					
	Attralus	AT-02	Phase 2 (renal) ongoing					

PROT-001 (lambda light chain stabilizer)
AL amyloidosis

Amyloidosis Research Consortium

Study Phase	Phase 1 (complete)
Purpose of the study	Test PROT-001 for the first time in humans (healthy volunteers) to make sure it is sure it is safe and well tolerated
Primary endpoint	Safety and pharmacokinetic (how the drug moves through the body) measures
Number of patients	102
Study Drug	PROT-001, given as an oral pill
How long?	Up to 14 days
Next Study	Pivotal trial expected to start in 2nd half of 2026

News and Upcoming Milestones for Novel AL Therapies in 2026

Amyloidosis Research

				Pre-clinical	Phase I	Phase II	Phase III	Commercial
Monoclonal Antibodies	Janssen	Daratumumab (Darzalex)	Approved					
	Sanofi	Isatuximab	Phase 2 IST status unk					
	BMS	Elotuzumab	Phase 2 IST status unk					
	GSK	Belantamab mafodotin	Phase 2 planned					
Bispecific/ Trispecific Antibodies	Janssen	Teclistamab	Phase 2 recruiting					
		Ramantamig (JNJ-79635322)	Phase 1 recruiting					
	Regeneron	Linvoseltamab	Phase 1/2 recruiting					
	AbbVie	Etentamig (ABBV-383)	Phase 1b recruiting					
	Pfizer	Elrantamab	Phase 1/2 IST recruiting					
Cellular Therapies	Nexcella	NXC-201	Phase 1b/2 recruiting					
	Alexion/AZ	AZD0120	Phase 1b/2 recruiting					
	Autolus	AUTO8	Phase 1 recruiting					
BCL2 Inhibitors	AbbVie	Venetoclax	Phase 1/2 ISTs recruiting					
LC Stabilizer	Protego	PROT-001 (lambda AL)	Phase 2/3 planned 2026					
Anti-Fibril Agents	Alexion/AZ	Anselamimab (CAEL-101)	P3 complete; benefit in kappa AL patients					
		NI009 (lambda AL)	Preclinical					
	Attralus	AT-02	Phase 2 (renal) data 2nd half 2026					

NEXICART-2 (NXC-201; BCMA-targeted investigational chimeric antigen receptor T (CAR-T) cell therapy)

Relapsed or refractory AL amyloidosis

Amyloidosis Research Consortium

Study Phase	Phase 1b/ Phase 2 Expansion
Purpose of the study	Measure the safety and efficacy NXC-201
Primary endpoint	- Number of patients with adverse events - Confirm the maximum tolerated dose and recommended dose
Key eligibility criteria	- ≥1 line of therapy with a CD38 monoclonal antibody and a proteosome inhibitor and not be in VGPR or CR at the time of inclusion. - No prior CAR-T therapy or BCMA targeted therapy - Measurable disease (difference between involved and uninvolved free light chains (dFLC) >20 mg/L with an abnormal kappa:lambda ratio) - ECOG performance status: 0-2 (up and about more than half the day but not fully able to carry out normal activities) - Symptomatic organ involvement
Number of patients	40
Study Drug	NXC-201; Single infusion following leukopharesis and lymphodepletion
Chance of receiving study drug?	All patients will receive NXC-201
How long?	2 years

CARES (anselamimab (CAEL-101); anti-fibril antibody)

Newly Diagnosed AL amyloidosis

Amyloidosis Research Consortium

Study Phase	Phase 3
Purpose of the study	Determine whether anselamimab improves overall survival, reduces cardiovascular related hospitalizations and it is safe and well tolerated in patients with stage IIIa or stage IIIb AL amyloidosis.
Primary endpoint	Measurement of (1st) whether the treatment with anselamimab helps people live longer, and (2nd) whether it reduces trips to the hospital for heart problems

Key eligibility criteria	• Advanced AL amyloidosis
	  • Stage IIIa (elevated NT-proBNP and troponin), NT-proBNP > 650 ng/L and <8,5000 ng/L at Screening
	  • Stage IIIb (NT-proBNP > 8,500 ng/L) at Screening
	• Heart involvement
	• Planned treatment for plasma cell dyscrasia is CyBorD-based regimen as standard of care

Number of patients	281 stage IIIa; 125 stage IIIb
Study Drug	Anselamimab combined with SoC plasma cell dyscrasia;intravenous (into a vein) infusions
Chance of receiving study drug?	2/3 (66.7%) received anselamimab and standard of care 1/3 (33.3%) received placebo and standard of care
How long?	At least 18 months

AT-02 (anti-fibril depleter)
AL amyloidosis with kidney disease

Amyloidosis Research Consortium

Study Phase	Phase 2
Purpose of the study	Evaluate the Long-term Safety and Tolerability of AT-02
Primary endpoint	Incidence, frequency, and severity or treatment emergent adverse events Safety and tolerability of AT-02 through lab results

Key eligibility criteria	• Must have already received plasma cell directed therapy achieved a very good partial response (VGPR) or complete response (CR); may be on daratumumab maintenance therapy
	• At least 6 months from that hematologic response.
	• Must meet one or both of these:
	  • Kidney function test (eGFR) between 20 and 75 mL/min/1.73m².
	  • Ongoing protein in the urine that has not improved (urine protein/creatinine ratio not reduced by at least 25% in the past year or since treatment response)

Number of patients	15
Study Drug	AT-02, given as an IV infusion once every 2 weeks, for up to 24 weeks (6 months)
Chance of receiving study drug?	All patients will receive study drug
How long?	At least 6 months

Other Recruiting and Planned Clinical Trials

Amyloidosis Research Consortium

	Investigational Product	Study Name/Description	Clinicaltrials.gov link
Investigator Sponsored and Single Center Trials	Venetoclax	Phase 1 Trial of Venetoclax, MLN9708 (Ixazomib Citrate) and Dexamethasone for the Treatment of Relapsed or Refractory AL Amyloidosis (24 patients, 15 locations); Dose expansion phase will open soon	https://clinicaltrials.gov/study/NCT04847453
		Open-label Phase I/II Trial of Venetoclax-Dexamethasone in Relapsed and/or Refractory t(11;14) AL Amyloidosis (53 patients, MA MN, NY, WI)	https://clinicaltrials.gov/study/NCT05451771
	Daratumumab	Phase 3 Trial Comparing Dara-VCD Chemotherapy Plus Stem Cell Transplant to Dara-VCD Chemotherapy Alone for People Who Have Newly Diagnosed AL Amyloidosis (338 patients, 35 centers in the US)	https://clinicaltrials.gov/study/NCT06022939
		EMILIA: Phase 2 Trial of Daratumumab Maintenance Therapy for Improving Survival in Patients With AL Amyloidosis (96 patients, MN, AZ)	https://clinicaltrials.gov/study/NCT05898646
	Belantamab Mafodotin	Phase 1/2a Study of Belantamab Mafodotin in Relapsed or Refractory AL Amyloidosis (37 patients, TX, CA, MA, MN)	https://clinicaltrials.gov/study/NCT05145816
	Elranatamab	A Phase I/II, Open Label, Study of Elranatamab in Patients With Relapsed or Refractory AL Amyloidosis (49 patients, MA)	https://clinicaltrials.gov/study/NCT06569147
	AUTO8	ALARIC: A CAR T trial for AL Amyloidosis (University College London)	https://www.isrctn.com/ISRCTN49320109
Imaging Trials	124I Evuzamitide	REVEAL: Research With I-124 Evuzamitide to Elucidate Cardiac Amyloidosis (recruitment complete; results expected in 2026)	https://clinicaltrials.gov/study/NCT06788535
		Characterizing Iodine-124 Evuzamitide (AT-01) in Systemic Amyloidosis (150 patients, OR)	https://clinicaltrials.gov/study/NCT05758493
	[18F]Florbetaben	CArdiag: Efficacy of [18F]Florbetaben PET for Diagnosis of Cardiac AL Amyloidosis	https://clinicaltrials.gov/study/NCT05184088
	F-18 florbetapir PET, C-11 acetate PET, and MRI	Molecular Imaging of Primary Amyloid Cardiomyopathy (MICA) (171 patients, MA)	https://clinicaltrials.gov/study/NCT02641145

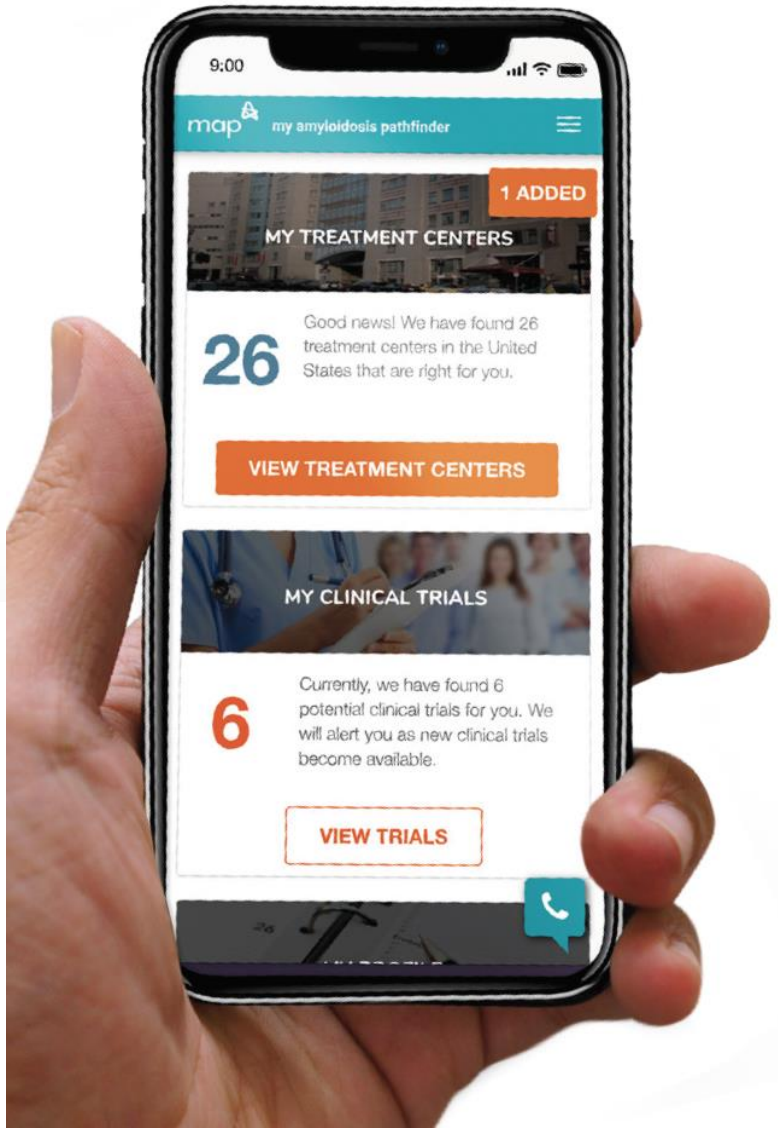
Treatments by light chain type and disease status

Amyloidosis Research Consortium

			Light chain type: Lambda vs kappa	Disease Status: Newly Diagnosed	Disease Status: Relapsed/Refractory
Monoclonal Antibodies	Janssen	Daratumumab (Darzalex)		Approved	
	Sanofi	Isatuximab		Clinical trial active not recruiting	Clinical trial status unknown
	BMS	Elotuzumab			Clinical trial status unknown
	GSK	Belantamab mafodotin		Clinical trial recruiting	
Bispecific/ Trispecific Antibodies	Janssen	Teclistamab		Clinical trial recruiting	
		Ramantamig (JNJ-79635322)			Clinical trial recruiting
	Regeneron	Linvoseltamab			Clinical trial recruiting
	AbbVie	Etentamig (ABBV-383)			Clinical trial recruiting
	Pfizer	Elrantamab			Clinical trial recruiting
Cellular Therapies	Nexcella	NXC-201			Clinical trial results Q3 2026
	Alexion/AZ	AZD0120			Clinical trial recruiting
	Autolus	AUTO8			Clinical trial recruiting
BCL2 Inhibitors	AbbVie	Venetoclax			Clinical trials recruiting
LC Stabilizer	Protego	PROT-001	Lambda	Clinical trial planned; disease status TBD	
Anti-Fibril Agents	Alexion/AZ	Anselamimab (CAEL-101)	Kappa	P3 benefit seen; pathway TBD	
		NI009	Lambda	Clinical trial planned; disease status unknown	
	Attralus	AT-02 (renal AL)			Clinical trial results 2H 2026

How to find clinical trials

- You can find and stay informed of clinical trials a few different ways:
  - Clinicaltrials.gov
  - Talk to your healthcare provider
  - Follow patient organizations like ARC, ASG, country specific groups, etc.
  - Sign up for My Amyloidosis Pathfinder (MAP)



Discover Personalized Treatment Centers & Clinical Trials for Your Amyloidosis

myamyloidosispathfinder.org

map

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