



# AMGEN'S CLINICAL TRIALS

Advancing oncology at the speed of life™




**AMGEN**®

Oncology


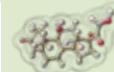
## MULTIPLE MYELOMA

	<b>Pavurutamab (AMG 701)</b> HLE BiTE® platform (HLE BiTE® molecule targeting BCMA)		
NCT: 03287908	Amgen ID*: 20170122	Status	
First-in-Human Study of Pavurutamab in Multiple Myeloma	<b>(R)</b>		Phase 1/2
	<b>Carfilzomib<sup>†</sup></b> Small molecule (proteasome inhibitor)		
NCT: 03091127	Amgen ID*: 20150262	Status	
Real-world Use of Carfilzomib Among Patients With Relapsed MM in Europe	<b>(C)</b>		Phase Observational
NCT: 03859427	Amgen ID*: 20180015	Status	
Study of Once-Weekly vs Twice-Weekly Carfilzomib in Combination With Lenalidomide and Dexamethasone in Patients With Relapsed or Refractory Multiple Myeloma (A.R.R.O.W.2)	<b>(R)</b>		Phase 3
NCT: 03158688	Amgen ID*: 20160275	Status	
Study Comparing Carfilzomib, Dexamethasone, and Daratumumab to Carfilzomib and Dexamethasone in Relapsed and/or Refractory Multiple Myeloma (CANDOR)	<b>(A)</b>		Phase 3
NCT: 04191616	Amgen ID*: 20180117	Status	
Study of Carfilzomib Plus Pomalidomide and Dexamethasone in Patients With First or Second Relapse of Multiple Myeloma (SELECT)	<b>(R)</b>		Phase 2


## LEUKEMIA ACUTE MYELOID LEUKEMIA

	<b>AMG 330</b> BiTE® platform (BiTE® molecule targeting CD33)		
NCT: 02520427	Amgen ID*: 20120252	Status	
First-in-Human Study of AMG 330 in Adult Patients With Relapsed or Refractory AML	<b>(R)</b>		Phase 1
	<b>AMG 427</b> HLE BiTE® platform (HLE BiTE® molecule targeting FLT3 antigen)		
NCT: 03541369	Amgen ID*: 20170528	Status	
First-in-Human Study of AMG 427 in Patients With Relapsed/Refractory AML	<b>(A)</b>		Phase 1
	<b>AMG 176</b> Small molecule (intravenous MCL-1 inhibitor)		
NCT: 02675452	Amgen ID*: 20150161	Status	
First-in-Human Study of AMG 176 in Relapsed or Refractory AML	<b>(R)</b>		Phase 1


## LEUKEMIA ACUTE LYMPHOBLASTIC LEUKEMIA

	<b>Blinatumomab</b> BiTE® platform (BiTE® molecule targeting CD19)		
NCT: 03117621	Amgen ID*: 20150136	Status	
Observational Study of Blinatumomab	<b>(R)</b>		Phase Observational
NCT: 04524455	Amgen ID*: 20190177	Status	
Study of Blinatumomab in Combination With AMG 404 in Adults With Relapsed or Refractory B-precursor ALL	<b>(R)</b>		Phase 1b
NCT: 04521231	Amgen ID*: 20180257	Status	
Study of Subcutaneous Blinatumomab Administration in ALL	<b>(R)</b>		Phase 1b
NCT: 04506086	Amgen ID*: 20190014	Status	
Study of Outpatient Blinatumomab in Subjects With Minimal Residual Disease (MRD) of B-precursor ALL	<b>(N)</b>		Phase 4
NCT: 04994717	Amgen ID*: 20190360	Status	
Study Comparing Blinatumomab Alternating With Low-intensity Chemotherapy Versus Standard of Care Chemotherapy for Older Adults With Newly Diagnosed Philadelphia-negative B-cell Precursor Acute Lymphoblastic Leukemia	<b>(N)</b>		Phase 3
	<b>Carfilzomib<sup>†</sup></b> Small molecule (proteasome inhibitor)		
NCT: 02303821	Amgen ID*: CFZ008	Status	
Study of the Safety, Tolerability, and Activity of Carfilzomib, Alone and in Combination With Induction Chemotherapy, in Children With Relapsed or Refractory Acute Lymphoblastic Leukemia	<b>(R)</b>		Phase 1b/2

## OTHER PAROXYSMAL NOCTURNAL HEMOGLOBINURIA

	<b>ABP 959<sup>‡</sup></b> Monoclonal antibody (eculizumab biosimilar)		
NCT: 03818607	Amgen ID*: 20150168	Status	
Efficacy and Safety of ABP 959 Compared With Eculizumab in Adult Participants With PNH (DAHLIA)	<b>(A)</b>		Clinical Comparability

## OTHER CHRONIC GRAFT VERSUS HOST DISEASE

	<b>Efavaleukin alfa (formerly AMG 592)</b> Fusion protein (IL-2 mutein)		
NCT: 03422627	Amgen ID*: 20160283	Status	
Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of Efavaleukin alfa in Adult Patients With Steroid-Refractory Chronic Graft Versus Host Disease	<b>(R)</b>		Phase 1b/2



Potentially may resume



Not yet recruiting



Active, recruiting


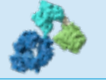



Active, not recruiting

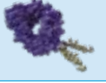


Completed, pending results


## GASTRIC/GASTROESOPHAGEAL JUNCTION CANCER

	<b>Bemarituzumab</b> Monoclonal antibody targeting FGFR2b		
NCT: 03694522 Amgen ID*: FPA144-004 Phase 2	Status		Phase 2
A Phase 2 Study of Bemarituzumab (FPA144) Combined With Modified FOLFOX6 (mFOLFOX6) in Gastric/Gastroesophageal Junction Cancer (FIGHT)	(A)		
NCT: 05052801 Amgen ID*: 20210096	Status		Phase 3
A Phase 3 Study of Bemarituzumab or Placebo Plus Chemotherapy in Gastric Cancers With Fibroblast Growth Factor Receptor 2b (FGFR2b) Overexpression (FORTITUDE-101)	(N)		
NCT: 05111626 Amgen ID*: 20210098	Status		Phase 1b/3
A Phase 1b/3 Study of Bemarituzumab plus Chemotherapy and Nivolumab versus Chemotherapy and Nivolumab Alone in Subjects With Previously Untreated Advanced Gastric/Gastroesophageal Junction Cancer With FGFR2b Overexpression (FORTITUDE-102)	(N)		
	<b>AMG 199</b> HLE BiTE® platform (HLE BiTE® molecule targeting MUC17)		
NCT: 04117958 Amgen ID*: 20180290	Status		Phase 1
A Phase 1 Study of AMG 199 in Subjects With MUC17-Positive Gastric and Gastroesophageal Junction Cancer	(R)		
	<b>AMG 910</b> BiTE® platform (BiTE® molecule targeting CLDN18.2)		
NCT: 04260191 Amgen ID*: 20180292	Status		Phase 1
A Phase 1 Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of AMG 910 in Subjects With Claudin 18.2-Positive Gastric and Gastroesophageal Junction Adenocarcinoma	(R)		

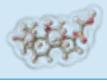
## GASTROINTESTINAL, PANCREATIC, OR COLORECTAL CANCER

	<b>Romiplostim</b> Protein/peptibody (thrombopoiesis stimulator)		
NCT: 03362177 Amgen ID*: 20140346	Status		Phase 3
Study of Romiplostim for Chemotherapy-Induced Thrombocytopenia in Patients With Gastrointestinal, Pancreatic, or Colorectal Cancer	(R)		


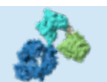
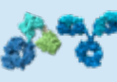
## LUNG CANCER NON-SMALL CELL LUNG CANCER

	<b>Acatamab (AMG 160)</b> HLE BiTE® platform (HLE BiTE® molecule targeting PSMA)		
NCT: 04822298 Amgen ID*: 20180273	Status		Phase 1b
A Phase 1b Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of AMG 160 in Subjects With Non-Small Cell Lung Cancer	(A)		

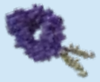
## LUNG CANCER NON-SMALL CELL LUNG CANCER (continued)

	<b>Sotorasib (AMG 510)</b> Small molecule ( <i>KRAS</i> <sup>G12C</sup> inhibitor)		
NCT: 03600883 Amgen ID*: 20170543	Status		Phase 1/2
<b>CodeBreak 100:</b> Open-Label Study Evaluating Sotorasib Monotherapy and in Combination Therapy With Anti-PD-1/L1 in NSCLC With <i>KRAS</i> G12C Mutation	(R)		
NCT: 04185883 Amgen ID*: 20190135	Status		Phase 1b
<b>CodeBreak 101:</b> Open-Label Study Evaluating Sotorasib Monotherapy and in Combination With Other Anti-Cancer Therapies in Advanced Solid Tumors With <i>KRAS</i> G12C Mutation	(R)		
NCT: 04380753 Amgen ID*: 20190147	Status		Phase 1
<b>CodeBreak 105:</b> Open-Label Study Evaluating Sotorasib Monotherapy in Patients of Chinese Descent With Advanced Solid Tumors With <i>KRAS</i> G12C Mutation	(A)		
NCT: 04303780 Amgen ID*: 20190009	Status		Phase 3
<b>CodeBreak 200:</b> A Phase 3 Study to Compare Sotorasib With Docetaxel for the Treatment of Previously Treated Locally Advanced and Unresectable or Metastatic NSCLC With <i>KRAS</i> G12C Mutation	(A)		
NCT: 04933695 Amgen ID*: 20190288	Status		Phase 2
<b>CodeBreak 201:</b> Open Label Study of Sotorasib in Untreated Patients with Stage IV <i>KRAS</i> G12C-mutated NSCLC and PDL1 <1% and/or STK11 mutation	(N)		

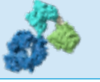
## LUNG CANCER SMALL CELL LUNG CANCER

	<b>AMG 119</b> CAR T-cell therapy (anti-DLL3 CAR-T)		
NCT: 03392064 Amgen ID*: 20170124	Status		Phase 1
First-in-Human Study of AMG 119 to Evaluate the Safety, Tolerability, and Efficacy in Patients With RR SCLC	(P)		
	<b>Tarlatabab (AMG 757)</b> HLE BiTE® platform (HLE BiTE® molecule targeting DLL3)		
NCT: 03319940 Amgen ID*: 20160323	Status		Phase 1
First-in-Human Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of Tarlatabab (AMG 757) in SCLC	(R)		
	<b>Tarlatabab (AMG 757) + AMG 404</b> HLE BiTE® platform (HLE BiTE® molecule targeting DLL3) + Monoclonal antibody (Anti-PD1)		
NCT: 03319940 Amgen ID*: 20200439	Status		Phase 1b
A Phase 1b Study Evaluating the Safety and Efficacy of Tarlatabab (AMG 757) in Combination With AMG 404 in Subjects With SCLC	(R)		


## NON-SMALL CELL LUNG, OVARIAN, OR BREAST CANCER


	<b>Romiplostim</b> Protein/peptibody (thrombopoiesis stimulator)	NCT: 03937154 Amgen ID*: 20170770	Status	Phase 3
Study of Romiplostim for Chemotherapy-Induced Thrombocytopenia in Patients With Non-small Cell Lung, Ovarian, or Breast Cancer			(R)	

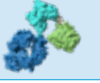
## PROSTATE CANCER

	<b>Acapatamab (AMG 160)</b> HLE BiTE <sup>®</sup> platform (HLE BiTE <sup>®</sup> molecule targeting PSMA)	NCT: 03792841 Amgen ID*: 20180101	Status	Phase 1
Safety, Tolerability, Pharmacokinetics, and Efficacy of Acapatamab (AMG 160) in Patients With mCRPC			(R)	

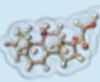
NCT: 04631601 Amgen ID*: 20190505	Status	Phase 1
A Master Protocol Evaluating the Safety and Efficacy of Therapies for Metastatic Castration-resistant Prostate Cancer (mCRPC)		(R)

	<b>AMG 340</b> UniAb <sup>®</sup> platform (bispecific T cell engager targeting PSMA and CD3)	NCT: 04740034 Amgen ID*: 20210249	Status	Phase 1
A Study of AMG 340 (TNB-585) in Subjects with Metastatic Castrate-resistant Prostate Carcinoma			(R)	


	<b>AMG 509</b> XmAb <sup>®</sup> platform (XmAb <sup>®</sup> targeting STEAP1)	NCT: 04221542 Amgen ID*: 20180146	Status	Phase 1
Phase 1 Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of AMG 509 in Subjects With Metastatic Castration-Resistant Prostate Cancer			(R)	


	<b>Taratamab (AMG 757)</b> HLE BiTE <sup>®</sup> platform (HLE BiTE <sup>®</sup> molecule targeting DLL3)	NCT: 04702737 Amgen ID*: 20200040	Status	Phase 1b
Study Evaluating Taratamab (AMG 757) in Patients With De Novo or Treatment-Emergent Neuroendocrine Prostate Cancer			(N)	


## SOLID TUMORS WITH KRAS G12C MUTATION

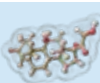
	<b>Sotorasib (AMG 510)</b> Small molecule ( <i>KRAS</i> <sup>G12C</sup> inhibitor)	NCT: 03600883 Amgen ID*: 20170543	Status	Phase 1/2
<b>CodeBreaK 100:</b> Open-Label Study Evaluating Sotorasib Monotherapy in Advanced Solid Tumors With <i>KRAS</i> G12C Mutation			(R)	
NCT: 04185883 Amgen ID*: 20190135	Status	Phase 1b		
<b>CodeBreaK 101:</b> Open-Label Study Evaluating Sotorasib Monotherapy and in Combination With Other Anti-Cancer Therapies in Advanced Solid Tumors With <i>KRAS</i> G12C Mutation			(R)	
NCT: 04380753 Amgen ID*: 20190147	Status	Phase 1		
<b>CodeBreaK 105:</b> Open-Label Study Evaluating Sotorasib Monotherapy in Patients of Chinese Descent With Advanced Solid Tumors With <i>KRAS</i> G12C Mutation			(A)	

## VARIOUS SOLID TUMORS

	<b>AMG 256</b> Bi-functional fusion protein (Targeted IL-21 receptor agonist)	NCT: 04362748 Amgen ID*: 20180144	Status	Phase 1
A Phase 1 Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of AMG 256 in Patients With Advanced Solid Tumors			(R)	

	<b>AMG 404</b> Monoclonal antibody (Anti-PD1)	NCT: 03853109 Amgen ID*: 20180143	Status	Phase 1
Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of AMG 404 in Patients With Advanced Solid Tumors			(R)	

	<b>AMG 506**</b> (also known as MPO310) DARPin <sup>®</sup> protein targeting FAP x 4-1BB	NCT: 04049903 Study ID*: MPO310-CP101	Status	Phase 1
A First-In-Human, Single-Arm, Multi-Center, Open-Label, Repeated-Dose, Dose-Escalation Study of MPO310 in Patients With Advanced Solid Tumors			(R)	

	<b>AMG 650</b> Small molecule targeting KIF18A being evaluated in advanced solid tumors	NCT: 04293094 Amgen ID*: 20190131	Status	Phase 1
A Phase 1, Multicenter, Open-label, Dose-Exploration and Dose-Expansion Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of AMG 650 in Subjects With Advanced Solid Tumors			(R)	

<b>AMG193</b> MTA cooperative PRMT5 inhibitor	NCT: 05094336 Amgen ID*: 20210023	Status	Phase 1/1b/2
A Phase 1/1b/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 Alone and in Combination With Docetaxel in Subjects With Advanced MTAP-null Solid Tumors			(N)

 <b>Talimogene Laherparepvec<sup>§</sup></b> Oncolytic immunotherapy (oncolytic viral therapy)		Status	
NCT: 02756845	Amgen ID*: 20110261		Phase 1
Study of Talimogene Laherparepvec in Children With Advanced Non-CNS Tumors		®	1
NCT: 03064763	Amgen ID*: 20140270		Phase 1
Study to Evaluate the Safety/Efficacy of T-VEC in Japanese Subjects With Unresectable Stage IIIB-IV Malignant Melanoma		Ⓐ	1
NCT: 02509507	Amgen ID*: 20140318		Phase 1b/2
Safety Study of Talimogene Laherparepvec Injected Into Liver Tumors Alone and in Combination With Systemic Pembrolizumab (MASTERKEY-318)		®	1b/2
NCT: 03256344	Amgen ID*: 20140299		Phase 1b
Safety Study of Talimogene Laherparepvec Combined With Atezolizumab for Triple Negative Breast Cancer and Colorectal Cancer With Liver Metastases		Ⓐ	1b
NCT: 04068181	Amgen ID*: 20180115		Phase 2
T-VEC With Pembrolizumab in Melanoma Following Progression on Prior Anti-PD-1 Based Therapy (MASTERKEY-115)		Ⓐ	2
NCT: 02211131	Amgen ID*: 20110266		Phase 2
Efficacy and Safety of Talimogene Laherparepvec Neoadjuvant Treatment Plus Surgery Versus Surgery Alone for Melanoma		Ⓐ	2
NCT: 02910557	Amgen ID*: 20130193		Phase 4
Postmarketing Prospective Study of Melanoma Patients Treated With Talimogene Laherparepvec to Characterize Risk of Herpetic Infection		®	4
NCT: 02173171	Amgen ID*: 20120139		Observational
Registry Study to Evaluate the Survival and Long-Term Safety of Patients With Melanoma Who Previously Received Talimogene Laherparepvec		Registry	

\*For more detailed information about the trial, visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) or [www.amgenpipeline.com](http://www.amgenpipeline.com). <sup>§</sup>Sponsored by Onyx Pharmaceuticals, an Amgen subsidiary.

<sup>†</sup>The regulatory approval pathway for biosimilars requires study of a single indication and permits extrapolation to other reference indications with scientific justification. <sup>‡</sup>Previously referred to as OncoVEX<sup>™</sup>GM-CSF. <sup>¶</sup>AMG 506 (also known as MPO310) is being developed in collaboration with Molecular Partners AG.

DARPin<sup>®</sup> is a registered trademark owned by Molecular Partners AG.

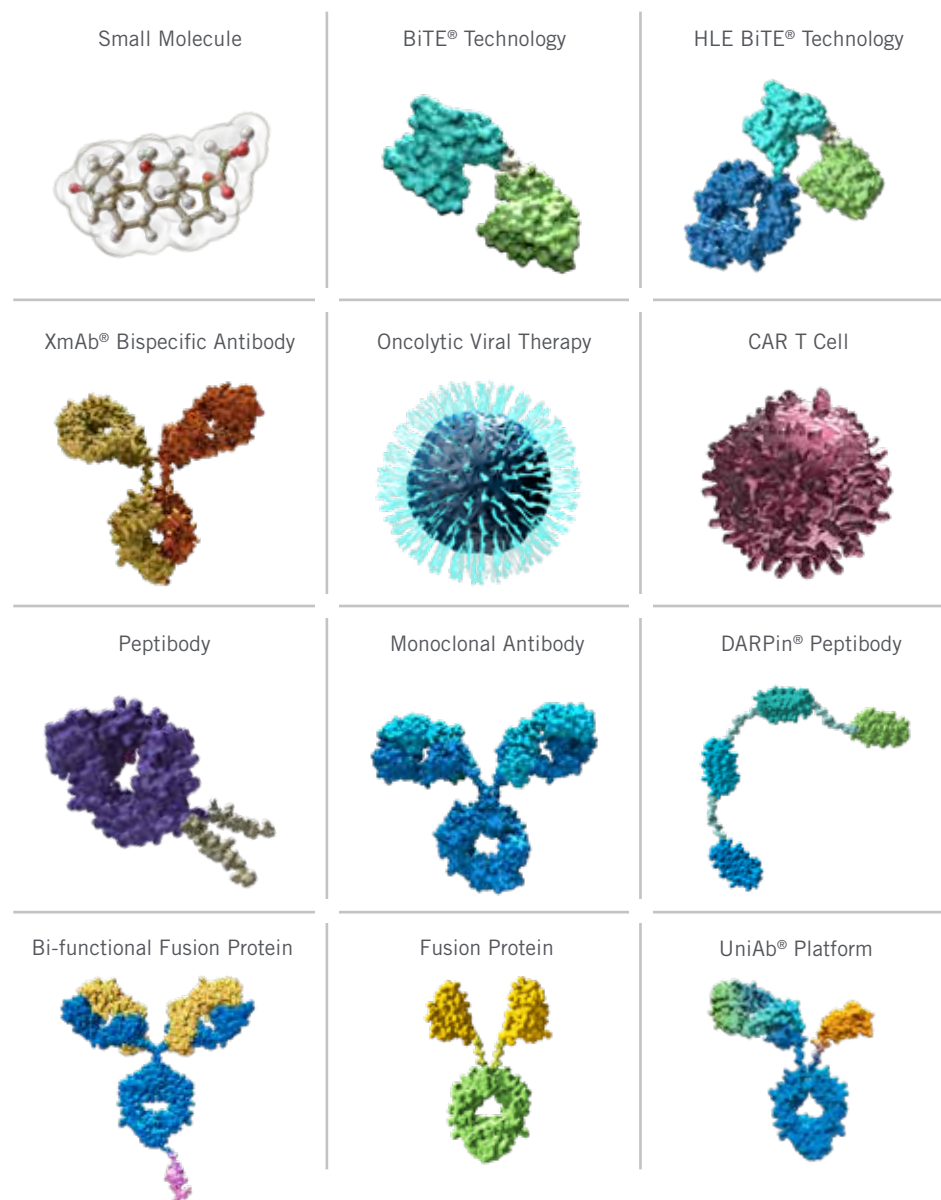
XmAb<sup>®</sup> is a registered trademark of Xencor.

ALL – acute lymphoblastic leukemia; AMG 193 – placeholder for now; AML – acute myelogenous leukemia; BiTE<sup>®</sup> – bispecific T-cell engager; BCMA – B-cell maturation antigen; CD – cluster of differentiation; CLDN18.2 – claudin-18 isoform 2; CNS – central nervous system; DARPin<sup>®</sup> – designed ankyrin repeat proteins; DLL3 – delta-like ligand 3; EGFR – epidermal growth factor receptor; EGFRvIII – epidermal growth factor receptor variant III; FAP – fibroblast activation protein; FGFR2b – fibroblast growth factor receptor 2b; FLT-3 – FMS-like tyrosine kinase 3; G-CSF – granulocyte colony-stimulating factor; HLE – half-life extended; ITP – immune thrombocytopenic purpura; IL-21 – interleukin-21, IV – intravenous; KRAS – Kirsten rat sarcoma 2 viral oncogene homolog; mAb – monoclonal antibody; mCRPC – metastatic castration-resistant prostate cancer; MCL-1 – myeloid cell leukemia sequence 1; MM – multiple myeloma; MUC – mucin; PD-1 – programmed cell death protein-1; PD L1 – programmed death-ligand 1; PK – pharmacokinetics; PNH – paroxysmal nocturnal hemoglobinuria; PSMA – prostate-specific membrane antigen; RR – relapsed or refractory; SCLC – small cell lung cancer; STEAP – six-transmembrane epithelial antigen of the prostate.

Information as of November 8, 2021. Statements are based on the company's current beliefs and Amgen disclaims any duty to update. For more information about Amgen and its business, including risks and uncertainties, please refer to Amgen's filings with the SEC. Products under investigational study have not been approved by regulatory agencies for the use under investigation. This information is provided only for purposes of providing general information on clinical trials and stages of development on the select candidates identified. This information should not be construed as a recommendation for use of any product for unapproved uses.

## MODALITIES

Amgen has built an array of drug modalities that is unsurpassed in the biopharmaceutical industry.



Disclaimer: Amgen's product pipeline will change over time as molecules move through the drug development process, including progressing to market or failing in clinical trials, due to the nature of the development process. BiTE = bispecific T-cell engager; CAR = chimeric antigen receptor; HLE = half-life extended.

# Amgen's Research and Development Strategy

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## Our Vision

Benefit patients and societies through transformative medicines.

## Our Priorities

**Improve our success rates:** Focus our people and investments more intensely on the activities most likely to lead to new therapies.

**Reduce cycle times:** The industry's standard timeline of 12 to 14 years from project start to drug approval is not viable. Amgen has already reduced its drug development timelines by about three years, but there is still ample room for improvements.

**Enable access and use:** Gaining regulatory approval for new therapies is only half the battle. In the end, only one metric matters: Are the patients who need Amgen medicines actually getting them?

## Our Strategic Imperatives

### Make focused investment in innovative research platforms:

- Focus research investments in cardiometabolic, inflammation, and cancer therapeutic areas. Rapidly expand the scale and diversity of our human genetic platform.
- Expand our human data resources to include proteomics, transcriptomics, and allied data to generate deeper insights into disease biology.
- Use our strength in molecular engineering to expand on the success of current drug platforms, including BiTE<sup>®</sup> molecules, and pioneer novel modalities to address targets now seen as undruggable.

### Innovate in clinical development:

- Reduce the durations and cost of clinical trials and improve success rates through greater use of modelling and simulation, adaptive designs, and real-world evidence.
- Design smaller and faster studies with larger response rates by using genetics and omics to identify patients who will potentially benefit most from new therapies.

### Address access and use at all stages of drug development:

- Ensure that representatives from our medical, clinical development, commercial, and manufacturing functions are partnering with research teams very early in each drug discovery program to define the attributes a new medicine will need to gain future access and use.
- Leverage our Global Medical organization and its external network of research collaborators to generate insights into the evidence our drug development teams must generate in order to support access and use.
- Invest in biomarkers, diagnostics, and other tools that can enhance the value of our medicines and support Amgen's commitment to empower doctors to go beyond a traditional "one size fits all" approach to treat patients in a more precise, personalized way.

## Our Strategic Enablers

- Maintain our long-standing and successful commitment to continuous improvement and operational efficiency in all aspects of R&D by challenging the way we work, speeding up decision making, and delivering better productivity to free resources to drive our science and innovation to deliver transformative medicines.
- The foundation for our past and future success is our people – they form the foundation for all we do. We will continue to build an R&D culture that recruits, develops, and retains the best talent excited by the opportunities arising from rapid scientific progress and new technologies to push the boundaries of science as part of a collaborative team vested in a collective accountability for our success.

