

Amgen's Oncology Clinical Trials



3 **SOLID TUMORS SOLID TUMORS**

GASTRIC/GASTROESOPHAGEAL JUNCTION CANCER

4	Bemarituzumab Monoclonal antibody targeting FGFR2b		
NCT: 05052801	Amgen ID*: 20210096	Status	
FORTITUDE-101: A Phase 3 Study of Bemarituzumab or Placebo Plus Chemotherapy in Gastric Cancers With Fibroblast Growth Factor Receptor 2b (FGFR2b) Overexpression			Phase 3
NCT: 05111626	Amgen ID*: 20210098	Status	
FORTITUDE-102: 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			Phase 1b/3
NCT: 05322577 Amgen ID*: 20210099		Status	
FORTITUDE-103: A Phase 1b Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Bemarituzumab in Combination With Other Anti-cancer Therapies in Subjects With Previously Untreated Advanced Gastric or Gastroesophageal Junction Cancer With FGFR2b Overexpression		R	Phase 1b

GASTROINTESTINAL, PANCREATIC, OR COLORECTAL CANCER



Romiplostim

Protein/peptibody (thrombopoiesis stimulator)

NCT: 03362177 Amgen ID*: 20140346

Study of Romiplostim for Chemotherapy-Induced Thrombocytopenia in Patients With Gastrointestinal, Pancreatic, or Colorectal Cancer

Status

Phase 3



Sotorasib + Panitumumab

Small molecule targeting KRAS G12C + Monoclonal antibody targeting EGFR

NCT: 05198934 Amgen ID*: 20190172

Status

CodeBreak 300: A Phase 3 Multicenter, Randomized, Open-Label, Active-Controlled Study of Sotorasib and Panitumumab Versus Investigator's Choice (Trifluridine with Tipiracil, or Regorafenib) for the Treatment of Previously Treated Metastatic Colorectal Subjects with KRAS G12C Mutation

Phase

LUNG CANCER NON-SMALL CELL LUNG CANCER



AMG 193 MTA-cooperative PRMT5 inhibitor		
NCT: 05094336 Amgen ID*: 20210023	Status	
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	(1)	Phase 1/1b/2
NCT: 05975073 Amgen ID*: 20220127	Status	
A Phase 1/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 in Combination With IDE397 in Subjects With Advanced MTAP-null Solid Tumors	R	Phase 1/2
AMG 794 BiTE® molecule targeting CLDN6		
NCT: 05317078 Amgen ID*: 20210007	Status	
Phase 1 First-In-Human Study to Explore the Safety, Tolerability, and Pharmacokinetics of AMG 794 in Subjects With Claudin 6-positive Advanced/Metastatic Non-squamous Non-small Cell Lung Cancer or Epithelial Ovarian Cancer	R	Phase 1
Sotorasib Small molecule (KRAS G12C inhibitor)		
NCT: 03600883 Amgen ID*: 20170543	Status	
CodeBreaK 100: Open-Label Study Evaluating Sotorasib Monotherapy in Advanced Solid Tumors and in Combination Therapy With Anti-PD-1/L1 in NSCLC With KRAS G12C Mutation	(A)	Phase 1/2
NCT: 04185883 Amgen ID*: 20190135	Status	
CodeBreaK 101 : 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	Phase 1b/2
NCT: 04380753 Amgen ID*: 20190147	Status	
CodeBreaK 105: Open-Label Study Evaluating Sotorasib Monotherapy in Patients of Chinese Descent With Advanced Solid Tumors With KRAS G12C Mutation	A	Phase 1
NCT: 04303780 Amgen ID*: 20190009	Status	
CodeBreaK 200: A Phase 3 Study to Compare Sotorasib With Docetaxel for the Treatment of Previously Treated Locally Advanced and Unresectable or Metastatic NSCLC With KRAS G12C Mutation	A	Phase 3
NCT: 04933695 Amgen ID*: 20190288	Status	
CodeBreaK 201 : Open Label Study of Sotorasib in Untreated Patients with Stage IV KRAS G12C-mutated NSCLC with PD-L1 <1% and/or STK11 Mutation	(A)	Phase 2
NCT: 05920356 Amgen ID*: 20190341	Status	
CodeBreaK 202: Phase 3 Study Evaluating Sotorasib Platinum Doublet	N	Phase

Combination Versus Pembrolizumab Platinum Doublet Combination as Front-Line Therapy in Advanced/Metastatic PD-L1-Negative NSCLC

with KRAS G12C Mutation

3













SOLID TUMORS SOLID TUMORS 5

LUNG CANCER SMALL CELL LUNG CANCER

	Tarlatamab BiTE® molecule targeting DLL3		
NCT: 03319940	Amgen ID*: 20160323	Status	
DeLLphi-300: First-in-Human Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Tarlatamab in SCLC			Phase 1
NCT: 05060016	Amgen ID*: 20200491	Status	
DelLphi-301: A Phase 2 Study Evaluating the Efficacy, Safety, Tolerability, and Pharmacokinetics of Tarlatamab in 2L+ Relapsed/Refractory SCLC		A	Phase 2
NCT: 05361395	Amgen ID*: 20200469	Status	
DelLphi-303: A Phase 1b Study Evaluating the Safety and Efficacy of First-Line Tarlatamab in Combination with Carboplatin, Etoposide, and PD-L1 Inhibitor in Extensive Stage SCLC		R	Phase 1b
NCT: 05740566	Amgen ID*: 20210004	Status	
DelLphi-304: A Randomized, Open-label, Phase 3 Study of Tarlatamab Compared With Standard of Care in Subjects With Relapsed Small Cell Lung Cancer After Platinum-based First-line Chemotherapy		R	Phase 3

PROSTATE CANCER



VARIOUS SOLID TUMORS



ABP 206

Monoclonal antibody (nivolumab biosimilar)

A Study to Evaluate Pharmacokinetic Similarity of ABP 206 Compared With Nivolumab in Subjects With Resected Stage III or IV Melanoma

Phase 3

Status

R

Status

(R)



AMG 193

MTA-cooperative PRMT5 inhibitor

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

Phase

NCT: 05975073 Amgen ID*: 20220127

NCT: 05094336 Amgen ID*: 20210023

A Phase 1/2 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 193 in Combination With IDE397 in Subjects With Advanced MTAP-null Solid Tumors

Status Phase (R) 1/2



AMG 256

Bi-functional fusion protein (Targeted IL-21 receptor agonist)

NCT: 04362748 Amgen ID*: 20180144

Status

Status

A Phase 1 Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of AMG 256 in Patients With Advanced Solid Tumors





AMG 305

Dual-targeting bispecific T cell engager (BiTE) molecule

Study to Explore the Safety, Tolerability, and Pharmacokinetics of AMG 305 in Subjects With Advanced Solid Tumors.

(R)





AMG 794

BiTE® molecule targeting CLDN6

Status

NCT: 05317078 Amgen ID*: 20210007

NCT: 05800964 Amgen ID*: 20220073

Phase 1 First-In-Human Study to Explore the Safety, Tolerability, and Pharmacokinetics of AMG 794 in Subjects With Claudin 6-positive Advanced/Metastatic Non-squamous Non-small Cell Lung Cancer or Epithelial Ovarian Cancer.

(R)

Phase

















Bemarituzumab

Monoclonal antibody targeting FGFR2b

NCT: 05325866 Amgen ID*: 20210104

Status

FORTITUDE-301: A Phase 1b/2, Multicenter, Open-label Basket Study Evaluating the Safety and Efficacy of Bemarituzumab Monotherapy in Solid Tumors With FGFR2b Overexpression



Phase 1b/2



Romiplostim

Protein/peptibody (thrombopoiesis stimulator)

NCT: 03937154 Amgen ID*: 20170770

Status (R)

Study of Romiplostim for Chemotherapy-Induced Thrombocytopenia in Patients With Non-small Cell Lung, Ovarian, or Breast Cancer





Sotorasib

Small molecule (KRAS G12C inhibitor)

NCT: 03600883 Amgen ID*: 20170543

Status **(A)**

CodeBreaK 100: Open-Label Study Evaluating Sotorasib Monotherapy in Advanced Solid Tumors With KRAS G12C Mutation Phase 1/2

NCT: 04185883 Amgen ID*: 20190135

Status (R)

Status

(A)

CodeBreak 101: Open-Label Study Evaluating Sotorasib Monotherapy and in Combination With Other Anti-Cancer Therapies in Advanced Solid Tumors With KRAS G12C Mutation

Phase 1b/2

NCT: 04380753 Amgen ID*: 20190147

CodeBreak 105: Open-Label Study Evaluating Sotorasib Monotherapy in Patients of Chinese Descent With Advanced Solid Tumors With KRAS G12C Mutation

Phase

LEUKEMIA



AMG 176

NCT: 02675452 Amgen ID*: 20150161 AMG 176 First in Human Trial in Participants with Relapsed or Refractory Multiple Myeloma and Participants with Relapsed or Refractory Acute Myeloid Leukemia



Phase

NCT: 05209152 Amgen ID*: 20200392

AMG 176 with Azacitidine in subjects with Higher-Risk Myelodysplastic Syndrome /Chronic Myelomonocytic Leukemia



(R)

Status

(R)

Phase



Blinatumomab BiTE® molecule targeting CD19

NCT: 04506086 Amgen ID*: 20190014 Study of Outpatient Blinatumomab in Subjects With Minimal Residual Disease (MRD) of B-precursor ALL

Status

Phase 4

NCT: 04994717 Amgen ID*: 20190360

Golden Gate Study: Study Comparing Blinatumomab Alternating With Low-intensity Chemotherapy Versus Standard of Care Chemotherapy for Older Adults With Newly Diagnosed

Phase 3

Philadelphia-negative B-precursor ALL NCT: 04521231 Amgen ID*: 20180257

Study of Subcutaneous Blinatumomab Administration in ALL

Status

Phase R 1/2



Carfilzomib[‡]

Small molecule (proteasome inhibitor)

NCT: 02303821 Amgen ID*: 20140106 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



Phase 1b/2













MULTIPLE MYELOMA



Carfilzomib‡ Small molecule (proteasome inhibitor)

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)

Phase 3

NCT: 04191616 Amgen ID*: 20180117

Status

Study of Carfilzomib Plus Pomalidomide and Dexamethasone in **(A)** Patients With First or Second Relapse of Multiple Myeloma (SELECT)

Phase 2

OTHER PAROXYSMAL NOCTURNAL HEMOGLOBINURIA



ABP 959§

Monoclonal antibody (eculizumab biosimilar)

NCT: 03818607 Amgen ID*: 20150168

Status

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Efficacy and Safety of ABP 959 Compared With Eculizumab in Adult Participants With PNH (DAHLIA)

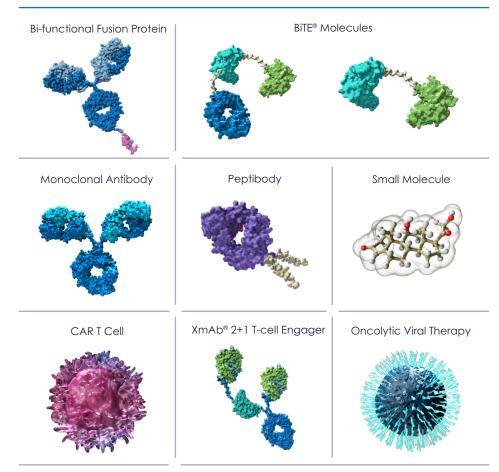
Clinical Comparability

*For more detailed information about the trial, visit www.clinicaltrials.gov or www.amgenpipeline.com. †Previously referred to as OncoVEXGM-CSF. XmAb® is a registered trademark of Xencor. ¹Sponsored by Onyx Pharmaceuticals, an Amgen subsidiary. The regulatory approval pathway for biosimilars requires study of a single indication and permits extrapolation to other reference indications with scientific justification.

ALL – acute lymphoblastic leukemia; BiTE® – bispecific T-cell engager; CAR = Chimeric Antigen Receptor; CD – cluster of differentiation; CLDN6 - claudin-6 protein; CLDN18.2 – claudin-18 isoform 2; DARPin® – designed anklyrin repeat proteins; DLL3 - delta-like ligand 3; EGFR - epidermal growth factor receptor; EGFRVIII - epidermal growth factor receptor variant III; FGFR2b - fibroblast growth factor receptor 2b; IL-21 - interleukin-21; IV - intravenous; KRAS - Kirsten rat sarcoma viral oncogene homolog; mAb - monoclonal antibody; mCRPC - metastatic castration-resistant prostate cancer; MCL-1 - myeloid cell leukemia sequence 1; MM - multiple myeloma; MRD - minimal residual disease; MTA - methylthioadenosine; MTAP - methylthioadenosine phosphorylase; NSCLC - non-small cell lung cancer; PD-1 - programmed cell death protein-1; PNH – paroxysmal nocturnal hemoglobinuria; PRMT5 – protein arginine methyltransferase 5; PSMA – prostate-specific membrane antigen; RR - relapsed or refractory. SCLC - small cell lung cancer; STK11 - serine/threonine kinase 11; STEAP1 six-transmembrane epithelial antigen of the prostate; T-VEC - talimogene laherparepvec; 3L+ - third-line or later treatments.

Information as of October 10, 2023, 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.

MULTISPECIFICS AND OTHER MODALITIES



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; XmAb® is a registered trademark of Xencor.

AMGEN'S RESEARCH AND DEVELOPMENT STRATEGY

OUR VISION

A world where science defeats all disease.

OUR PRIORITIES

Improve our success rates. Focus our people and investments more intensely on the most promising technologies and 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, but there is still ample room for improvements.

Broaden 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 cardiovascular and metabolic, inflammation and cancer therapeutic areas. Rapidly expand the scale and diversity of our human omics platforms to move towards a precision medicine approach to drug discovery and development.
- Expand our human data resources to include proteomics, transcriptomics and clinical/real world data. This will generate deeper insights into disease biology, find new drug targets and speed up clinical trials.
- Use our molecular engineering strength combined with the power of Al/machine learning to expand on the success of current drug platforms, including multispecifics such as BiTE® molecules, and pioneer novel modalities to address targets now seen as undruggable.

Innovate in Clinical Development

- Increase the speed and efficiency of clinical trials and improve success rates through greater use of modelling and simulation, adaptive designs and real-world evidence.
- Increase recruitment of patients who will potentially benefit most from new therapies, design smaller and faster studies with larger response rates by using human data, including genetics and omics.

Address access and use at all stages of drug development

- Engage with healthcare professionals, regulators and payors to enable broader and faster access to therapies.
- Accelerate bringing molecules from the lab, through the clinic, to approval and to
 patients around the world because of the immense interconnected R&D ecosystem
 so the patients who need our medicines most are getting them as fast as possible.

SUPPORT OUR PEOPLE

Our past and future success relies on our people – they form the foundation for all
that we do. We will continue to build an R&D culture that supports, develops and
nurtures a diverse talent base energized by the rapid scientific progress and new
technology we are using to push the boundaries of science. Our teams are vested
in a collective accountability for our success.

