



OUR CLINICAL TRIALS

Advancing oncology at the speed of life™

AMGEN®

Oncology

APOPTOSIS

AMG 176 (MCL-1 inhibitor)				
Research Area	Description	Phase	Status	NCT/Amgen ID*
AML, Multiple Myeloma	First-in-Human Study of AMG 176 in Relapsed or Refractory Multiple Myeloma and in Relapsed or Refractory AML	1	R	02675452 20150161

AMG 397 (MCL-1 inhibitor)				
Research Area	Description	Phase	Status	NCT/Amgen ID*
AML, Multiple Myeloma, NHL	Safety, Tolerability, Pharmacokinetics and Efficacy of AMG 397, an Oral MCL1 Inhibitor, in Patients With Multiple Myeloma, NHL, and AML	1	R	03465540 20170173

BIOSIMILARS†

ABP 798 (biosimilar rituximab; anti-CD20 antibody)				
Research Area	Description	Phase	Status	NCT/Amgen ID*
NHL	Efficacy and Safety Study of ABP 798 Compared With Rituximab in Treating Non-Hodgkin Lymphoma (JASMINE)	3	A	02747043 20130109

ABP 959 (Biosimilar eculizumab; anti-complement C5 antibody)				
Research Area	Description	Phase	Status	NCT/Amgen ID*
Paroxysmal Nocturnal Hemoglobinuria	Efficacy and Safety of ABP 959 Compared With Eculizumab in Adult Participants With PNH (DAHLIA)	3	N	03818607 20150168

ABP 980 (Biosimilar trastuzumab; anti-HER2 antibody)				
Research Area	Description	Phase	Status	NCT/Amgen ID*
Breast Cancer	Efficacy and Safety Study of ABP 980 Compared With Trastuzumab in Subjects With HER2 Positive Early Breast Cancer (Lilac)	3	C	01901146 20120283

BONE METASTASES AND METABOLISM

Denosumab (RANK-ligand inhibitor)				
Research Area	Description	Phase	Status	NCT/Amgen ID*
Multiple Myeloma	Denosumab Compared to Zoledronic Acid in the Treatment of Bone Disease in Patients With Multiple Myeloma	3	A	01345019 20090482
Giant Cell Tumor of Bone	Long-term Safety Follow-up of Subjects With Giant Cell Tumor of Bone Treated With Denosumab in Study 20062004	4	A	03301857 20140114
Osteonecrosis of the Jaw	Osteonecrosis of the Jaw (ONJ) Case Registry	Registry	A	01666106 20101102
	Osteonecrosis of the Jaw (ONJ) and Infection Among Nordic Cancer Patients Treated With XGEVA™ or Zoledronic Acid	Observational	A	01967160 20101363

HEMATOPOIESIS

Romiplostim (thrombopoiesis stimulator)				
Research Area	Description	Phase	Status	NCT/Amgen ID*
ITP	Single-Arm, Open-Label, Long-Term Study of Romiplostim in Thrombocytopenic Pediatric Patients With ITP	3	A	02279173 20101221
Solid Tumors	Study of Romiplostim for Chemotherapy Induced Thrombocytopenia in Patients With Gastrointestinal or Colorectal Cancer	3	N	03362177 20140346

Pegfilgrastim (granulocyte colony-stimulating factor)				
Research Area	Description	Phase	Status	EU PAS/Amgen ID*
FN	Prospective Observational Study to Estimate Incidence of Febrile Neutropenia in High Risk Patients with Non-myeloid Malignancies Receiving Pegfilgrastim OBI (Onbody Injector) or Physician Choice for Febrile Neutropenia Prophylaxis	Observational	R	24626 20170758

IMMUNOTHERAPY

AMG 119 (Anti-DLL3 CAR T)				
Research Area	Description	Phase	Status	NCT/Amgen ID*
SCLC	First-in-Human Study of AMG 119 in Patients With RR SCLC	1	R	03392064 20170124

AMG 160 (Half-life extended BiTE® molecule targeting PSMA)				
Research Area	Description	Phase	Status	NCT/Amgen ID*
Prostate Cancer	Safety, Tolerability, Pharmacokinetics, and Efficacy of AMG 160 in Patients with mCRPC	1	R	03792841 20180101

AMG 330 (BiTE® molecule targeting CD33)				
Research Area	Description	Phase	Status	NCT/Amgen ID*
AML	First-in-Human Study of AMG 330 in Adult Patients With Relapsed or Refractory AML	1	R	02520427 20120252

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

N Not yet recruiting **R** Active, recruiting **A** Active, not recruiting **C** Completed, pending results

IMMUNOTHERAPY, continued

AMG 420[®] (BiTE[®] molecule targeting BCMA)

Research Area	Description	Phase	Status	NCT/Amgen ID [*]
Multiple Myeloma	Dose Escalation Study of IV BI 836909 (AMG 420) Monotherapy in Patients With Relapsed and/or Refractory Multiple Myeloma**	1	A	02514239 N/A
	Assessment of AMG 420 in Subjects With Relapsed and/or Refractory Multiple Myeloma	1	R	03836053 20160370

AMG 424 (Anti-CD38 XmAb[®])

Research Area	Description	Phase	Status	NCT/Amgen ID [*]
Multiple Myeloma	First-in-Human Study of AMG 424 in Patients With Multiple Myeloma	1	R	03445663 20160445

AMG 427 (Half-life extended BiTE[®] molecule targeting FLT3)

Research Area	Description	Phase	Status	NCT/Amgen ID [*]
AML	First-in-Human Study of AMG 427 in Patients With Relapsed/Refractory Acute Myeloid Leukemia	1	R	03541369 20170528

AMG 553 (Anti-FLT3 CAR T)

Research Area	Description	Phase	Status	NCT/Amgen ID [*]
AML	First in Human Study of AMG 553 in Patients With Acute Myeloid Leukemia	1	A	03904069 20180091

AMG 562 (Half-life extended BiTE[®] molecule targeting CD19)

Research Area	Description	Phase	Status	NCT/Amgen ID [*]
NHL	First-in-Human Study of AMG 562 in Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma, Mantle Cell Lymphoma, or Follicular Lymphoma	1	R	03571828 20170533

AMG 596 (BiTE[®] molecule targeting EGFRvIII)

Research Area	Description	Phase	Status	NCT/Amgen ID [*]
Glioblastoma	First-in-Human Study of AMG 596 in Adult Patients With EGFRvIII Positive Glioblastoma	1	R	03296696 20160132

AMG 673 (Half-life extended BiTE[®] molecule targeting CD33)

Research Area	Description	Phase	Status	NCT/Amgen ID [*]
AML	First-in-Human Study of AMG 673 in Adult Patients With Relapsed or Refractory AML	1	R	03224819 20160377

AMG 701 (Half-life extended BiTE[®] molecule targeting BCMA)

Research Area	Description	Phase	Status	NCT/Amgen ID [*]
Multiple Myeloma	First-in-Human Study of AMG 701 in Multiple Myeloma	1	R	03287908 20170122

IMMUNOTHERAPY, continued

AMG 757 (Half-life extended BiTE[®] molecule targeting DLL3)

Research Area	Description	Phase	Status	NCT/Amgen ID [*]
SCLC	First-in-Human Study of AMG 757 in SCLC	1	R	03319940 20160323

Blinatumomab (BiTE[®] molecule targeting CD19)

Research Area	Description	Phase	Status	NCT/Amgen ID [*]
ALL	Study of Blinatumomab in Japanese Patients With Relapsed or Refractory B-Precursor ALL	1b/2	A	02412306 20130265
	Blinatumomab vs Standard Chemotherapy in Pediatric Patients With High Risk First Relapse B-Precursor ALL	3	R	02393859 20120215
	Study of Blinatumomab in Chinese Adult Patients With Relapsed or Refractory B-precursor ALL	3	R	03476239 20130316
	Observational Study of Patients With Philadelphia Chromosome-Negative Relapsed or Refractory ALL in the US	Registry	R	02783651 20150253
	Expanded Access Protocol of Blinatumomab in Pediatric and Adolescent Patients With Relapsed or Refractory B-Precursor ALL (RIALTO)	4	Available	02187354 20130320
	Observational Study of Blinatumomab	4	R	03117621 20150136
NHL	Safety and PK of Subcutaneous Blinatumomab in Relapsed or Refractory Indolent NHL	1b	R	02961881 20140286
	Efficacy and Safety of Blinatumomab in Combination With Pembrolizumab in Adult Patients With Relapsed or Refractory DLBCL (KEYNOTE-348)	1b	R	03340766 20150290
	Efficacy and Safety of Blinatumomab in Patients With Newly Diagnosed High-Risk DLBCL	2	A	03023878 20150288
	Effect of Blinatumomab on Minimal Residual Disease in Patients With DLBCL Post-Autologous Hematopoietic Stem-Cell Transplantation	2	R	03298412 20150291
	Efficacy and Safety of Blinatumomab in Patients With Relapsed or Refractory Aggressive B-Cell NHL	2/3	R	02910063 20150292

Talimogene Laherparepvec^{††} (oncolytic viral immunotherapy)

Research Area	Description	Phase	Status	NCT/Amgen ID [*]
Advanced Non CNS Tumors	Study of Talimogene Laherparepvec in Children With Advanced Non-CNS Tumors	1	R	02756845 20110261

IMMUNOTHERAPY, continued

Talinogene Laherparepvec ^{††} (oncolytic viral immunotherapy)				
Research Area	Description	Phase	Status	NCT/Amgen ID [*]
Melanoma	Study to Evaluate the Safety/Efficacy of T-VEC in Japanese Subjects With Unresectable Stage IIIB-IV Malignant Melanoma	1	R	03064763 20140270
	Ipilimumab With or Without Talinogene Laherparepvec in Unresected Melanoma	1b/2	A	01740297 20110264
	Efficacy and Safety of Talinogene Laherparepvec Neoadjuvant Treatment Plus Surgery Versus Surgery Alone for Melanoma	2	A	02211131 20110266
	Single-Arm Trial to Evaluate the Biodistribution and Shedding of Talinogene Laherparepvec	2	C	02014441 20120324
	Single-Arm Trial to Evaluate the Role of the Immune Response to Talinogene Laherparepvec in Unresected Melanoma	2	A	02366195 20120325
	Pembrolizumab With or Without Talinogene Laherparepvec in Unresected Melanoma	3	A	02263508 20110265
	Postmarketing Prospective Study of Melanoma Patients Treated With Talinogene Laherparepvec to Characterize Risk of Herpetic Infection	4	R	02910557 20130193
	Registry Study to Evaluate the Survival and Long-Term Safety of Patients With Melanoma Who Previously Received Talinogene Laherparepvec	Registry	Enrolling by invitation only	02173171 20120139
HNSCC	Talinogene Laherparepvec With Pembrolizumab for Recurrent Metastatic Squamous Cell Carcinoma of the Head and Neck (MASTERKEY232/KEYNOTE-137)	1b	A	02626000 20130232
Solid Tumors	Safety Study of Talinogene Laherparepvec Injected into Hepatocellular Carcinoma and Metastatic Liver Tumors	1b	R	02509507 20140318
	Safety Study of Talinogene Laherparepvec Combined With Atezolizumab for Triple Negative Breast Cancer and Colorectal Cancer With Liver Metastases	1b	R	03256344 20140299

PROTEIN DEGRADATION

Carfilzomib ^{††} (proteasome inhibitor)				
Research Area	Description	Phase	Status	NCT/Amgen ID [*]
ALL	Carfilzomib in Combination With Induction Chemotherapy in Children With Relapsed or Refractory ALL	1b	R	02303821 CFZ008

PROTEIN DEGRADATION, continued

Carfilzomib ^{††} (proteasome inhibitor) continued				
Research Area	Description	Phase	Status	NCT/Amgen ID [*]
Multiple Myeloma	Real-world Use of Carfilzomib Among Patients With Relapsed MM in Europe	Observational	R	03091127 20150262
	Study of Carfilzomib Administered Once Weekly in Combination With Lenalidomide and Dexamethasone in Patients With Multiple Myeloma	1b	A	02335983 CFZ013
	A Study of Carfilzomib Plus Dexamethasone in Subjects With Relapsed or Refractory Multiple Myeloma at US Community Oncology Centers	2	R	03512353 20170596
	Study Comparing Carfilzomib, Dexamethasone, and Daratumumab to Carfilzomib and Dexamethasone in Relapsed or Refractory Multiple Myeloma (CANDOR)	3	A	03158688 20160275

TUMOR REGULATION

AMG 510 (KRAS G12C Inhibitor)				
Research Area	Description	Phase	Status	NCT/Amgen ID [*]
Solid Tumors	First-in-Human Study of AMG 510 in Patients With Solid Tumors With KRAS G12C Mutation	1	R	03600883 20170543

IMMUNE MODULATION

AMG 592 (IL-2 mutein)				
Research Area	Description	Phase	Status	NCT/Amgen ID [*]
Chronic Graft Versus Host Disease	Open-label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 592 in Adult Patients With Steroid Refractory Chronic Graft Versus Host Disease	1b/2	R	03422627 20160283

*For more detailed information about the trial, visit www.clinicaltrials.gov or www.amgen.com.

[†]The regulatory approval pathway for biosimilars requires study of a single indication and permits extrapolation to other reference indications with scientific justification.

^{††}For detailed information on this study please visit <http://www.encepp.eu/encepp/studiesDatabase.jsp>.

[§]As of September 1, 2016, Amgen has acquired global development and commercial rights from Boehringer Ingelheim for BI 836909 (AMG 420).

**This study is sponsored by Boehringer Ingelheim

^{†††}Previously referred to as OncoVEX^{GM-CSF}.

^{††††}Sponsored by Onyx Pharmaceuticals, an Amgen subsidiary.

XmAb[®] is a registered trademark of Xencor.

ALL – acute lymphoblastic leukemia; AML – acute myelogenous leukemia; BiTE[®] – bispecific T cell engager; CNS – central nervous system; DLBCL – diffuse large B-cell lymphoma; EGFR – epidermal growth factor receptor; EGFRvIII – epidermal growth factor receptor variant III; FN – febrile neutropenia; HNSCC – head and neck squamous cell carcinoma; ITP – immune thrombocytopenic purpura; IV – intravenous; mAb – monoclonal antibody; mCRC – metastatic colorectal cancer; NHL – non-hodgkin lymphoma; ORR – objective response rate; PK – pharmacokinetics; QoL – quality of life; SCLC – small cell lung cancer.

Information as of April 5, 2019. 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.

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Amgen's Research and Development Guiding Principles

Amgen aspires to be the best human therapeutics company. Achieving this goal starts with building the world's premier R&D organization. Amgen's R&D Guiding Principles were inspired by this pursuit and designed to reinforce our strategic priorities.

Focus on innovative medicines for unmet needs in patients with serious illnesses.

While Amgen is always pursuing new opportunities and adapting to challenges, we retain an enduring commitment to the same mission. That mission is to enhance and extend the lives of patients facing serious illness.

Pursue targets that are validated in humans. We believe we are on the threshold of a revolution in science in which population genetics will help to reveal new targets that clearly drive disease risk in humans. By focusing on targets supported by human genetics or other strong human evidence, we aim to increase our clinical success rates, reduce development timelines, and lower the cost of delivering new medicines to patients.

Maintain an expansive toolkit of drug modalities with a focus on biologics. Amgen pursues a “biology-first” approach to drug discovery. We strive to select drug targets based on a deep understanding of disease biology, and then choose the drug modality, or structural template, best suited to the target. We recognize our strength in biologics and the higher clinical success rates for biologic medicines. We also maintain a broad toolkit of modalities, including small molecules, in order to have the right tool for any target we pursue.

Focus on return on investment and operational efficiency. To maximize the value of Amgen's R&D investment, we focus resources on programs that offer a large effect size and more likelihood of success. We maximize the value of lower-priority assets by partnering and out-licensing. Amgen also strives to continually identify operational efficiencies, such as reduced cycle times, leaner clinical trials, and centralized monitoring of clinical study sites.

Harness external innovation. At Amgen, we pursue great innovation wherever we can find it, and roughly half of our current late-stage pipeline comes from collaborations or acquisitions. We appreciate the synergy between in-house and external innovation: To identify and add value to the best external inventions, we need to maintain a high level of in-house scientific talent and capabilities.

Demonstrate the value of our medicines. Patients will not benefit from medicines they cannot access, and increasingly, access depends on meeting evolving standards from regulators and payers. To meet these expectations, we strive to deliver major therapeutic advances—medicines that offer compelling benefits for patients and sound health economics for society.