



33 preclinical and clinical targets with **STRONG** GENETIC SUPPORT

The industry's largest toolkit with **13** MODALITIES*

A mix of **INNOVATIVE MOLECULES, NEW INDICATIONS, AND BIOSIMILARS**

A robust and differentiated pipeline, leveraging state-of-the-art science to create medicines for serious illness. Amgen is focused on high-quality candidates that demonstrate large, clinically-relevant effects. Human genetic validation is used whenever possible to enhance the likelihood of success.

PHASE ONE			PHASE TWO			PHASE THREE		
AMG 176 Hematology/ Oncology	AMG 224 Hematology/ Oncology	AMG 330 Hematology/ Oncology	AMG 301 Neuroscience	AMG 899 Cardiovascular	**Aimovig™ (ereenumab) Neuroscience	AMG 520 Neuroscience	**Aimovig™ (ereenumab) Neuroscience	Aranesp® (darbepoetin alfa) Hematology/ Oncology
AMG 420 Hematology/ Oncology	AMG 529 Cardiovascular	AMG 557 Inflammation	BLINCYTO® (blinatumomab) Hematology/ Oncology	Tezepelumab Inflammation		Enbrel® (etanercept) Inflammation	**EVENTITY™ (romosozumab) Bone Health	IMLYGIC® (talimogene laherparepvec) Hematology/ Oncology
AMG 570 Inflammation	AMG 592 Inflammation	AMG 673 Hematology/ Oncology				KYPROLIS® (carfilzomib) Hematology/ Oncology	Omecamtiv mecarbil Cardiovascular	Prolia® (denosumab) Bone Health
AMG 820 Hematology/ Oncology	AMG 966 Inflammation	AMG 986 Cardiovascular				Repatha® (evolocumab) Cardiovascular	XGEVA® (denosumab) Hematology/ Oncology	
IMLYGIC® (talimogene laherparepvec) Hematology/ Oncology	KYPROLIS® (carfilzomib) Hematology/ Oncology	Oprozomib Hematology/ Oncology						

BIOSIMILARS‡					
ABP 215 (biosimilar bevacizumab) Hematology/ Oncology	ABP 494 (biosimilar cetuximab) Hematology/ Oncology	ABP 710 (biosimilar infliximab) Inflammation	ABP 798 (biosimilar rituximab) Hematology/ Oncology & Inflammation	ABP 959 (biosimilar eculizumab) Hematology /Oncology	ABP 980 (biosimilar trastuzumab) Hematology/ Oncology

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 **Tradename provisionally approved by the United States Food and Drug Administration.

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PHASE ONE

Phase 1 clinical trials investigate safety and proper dose ranges of a product candidate in a small number of human subjects.

MOLECULE NAME & PRONUNCIATION	MODALITY	THERAPEUTIC AREA	DESCRIPTION
AMG 176	Small Molecule	Hematology/Oncology	AMG 176 is a small molecule being investigated as a treatment for multiple myeloma.
AMG 224	Antibody Drug Conjugate	Hematology/Oncology	AMG 224 is an antibody drug conjugate being investigated as a treatment for multiple myeloma.
AMG 330	BiTE® Antibody	Hematology/Oncology	AMG 330 is an anti-CD33 x anti-CD3 (BiTE®) bispecific antibody construct. It is being investigated as a treatment for acute myeloid leukemia.
AMG 420	BiTE® Antibody	Hematology/Oncology	AMG 420 is an anti-BCMA x anti-CD3 (BiTE®) bispecific antibody construct. It is being investigated as a treatment for multiple myeloma.
AMG 529	Monoclonal Antibody	Cardiovascular	AMG 529 is a human monoclonal antibody that inhibits asialoglycoprotein receptor 1 (ASGR1). It is being investigated as a treatment for cardiovascular disease.
AMG 557	Monoclonal Antibody	Inflammation	AMG 557 is a human monoclonal antibody that inhibits the action of B7 related protein (B7RP-1). It is being investigated as a treatment for systemic lupus erythematosus. AMG 557 is being jointly developed in collaboration with AstraZeneca.
AMG 570	Bispecific Antibody	Inflammation	AMG 570 is a bispecific antibody-peptide conjugate that targets BAFF and ICOSL. It is being investigated as a treatment for systemic lupus erythematosus. AMG 570 is being jointly developed in collaboration with AstraZeneca.
AMG 592	Fusion Protein	Inflammation	AMG 592 is an IL-2 mutein Fc fusion protein. It is being investigated as a treatment for inflammatory diseases.
AMG 673	BiTE® Antibody	Hematology/Oncology	AMG 673 is an extended half-life anti-CD33 x anti-CD3 (BiTE®) bispecific antibody construct. It is being investigated as a treatment for relapsed or refractory acute myeloid leukemia.
AMG 820	Monoclonal Antibody	Hematology/Oncology	AMG 820 is a human monoclonal antibody that inhibits c-fms and decreases tumor-associated macrophage (TAM) function. It is being investigated as a treatment for various cancer types.
AMG 966	Monoclonal Antibody	Inflammation	AMG 966 is a monoclonal antibody being investigated for the treatment of Crohn's disease.
AMG 986	Small Molecule	Cardiovascular	AMG 986 is a small molecule agonist of the Apelin receptor (APJ). It is being investigated for the treatment of heart failure.
IMLYGIC® (talimogene laherparepvec) <i>tal im' oh jeen la her'' pa rep' vek</i>	Oncolytic Immunotherapy	Hematology/Oncology	IMLYGIC® is an oncolytic immunotherapy derived from HSV-1. It is being investigated as a combination treatment in patients with mid- to late-stage metastatic melanoma (3) and in other cancer types (Phase 1).

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Phase 1 clinical trials investigate safety and proper dose ranges of a product candidate in a small number of human subjects.

MOLECULE NAME & PRONUNCIATION	MODALITY	THERAPEUTIC AREA	DESCRIPTION
KYPROLIS® (carfilzomib) <i>car fil' zoe mib</i>	Small Molecule	Hematology/ Oncology	<p>KYPROLIS® is a proteasome inhibitor. It is being investigated in a variety of combinations and patient populations for multiple myeloma and as a treatment for small-cell lung cancer (Phase 1b/2).</p> <p>In August 2017, Amgen announced that the U.S. Food and Drug Administration (FDA) has accepted for review a supplemental New Drug Application (sNDA) based on the overall survival (OS) data from the Phase 3 head-to-head ENDEAVOR study. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of April 30, 2018.</p> <p>In July 2017, Amgen announced the submission of a variation to the marketing application to the European Medicines Agency to include OS data from the Phase 3 head-to-head ENDEAVOR study in the product label for KYPROLIS®.</p>
Oprozomib <i>oh proz' oh mib</i>	Small Molecule	Hematology/ Oncology	Oprozomib is an oral proteasome inhibitor. It is being investigated for the treatment of multiple myeloma.

PHASE TWO

Phase 2 clinical trials investigate side effect profiles and efficacy of a product candidate in a large number of patients who have the disease or condition under study.

MOLECULE NAME & PRONUNCIATION	MODALITY	THERAPEUTIC AREA	DESCRIPTION
AMG 301	Monoclonal Antibody	Neuroscience	<p>AMG 301 is a human monoclonal antibody that inhibits the type 1 receptor of the pituitary adenylate cyclase-activating polypeptide (PAC1). It is being investigated for migraine prevention.</p> <p>AMG 301 is being jointly developed in collaboration with Novartis.</p>
AMG 899	Small Molecule	Cardiovascular	AMG 899 is a small molecule cholesteryl ester transfer protein (CETP) inhibitor. It is being investigated for the treatment of dyslipidemia.
Aimovig™ (erenumab)	Monoclonal Antibody	Neuroscience	<p>Aimovig™ (erenumab) is a human monoclonal antibody that inhibits the receptor for calcitonin gene-related peptide. It is being investigated for the treatment of episodic migraine (Phase 3) and chronic migraine (Phase 2).</p> <p>In July 2017, Amgen announced that the U.S. Food and Drug Administration (FDA) accepted for review the Biologics License Application (BLA) for Aimovig™ for the prevention of migraine in patients experiencing four or more migraine days per month. The FDA has set a PDUFA target action date of May 17, 2018.</p> <p>Aimovig™ is being jointly developed in collaboration with Novartis.</p>
BLINCYTO® (blinatumomab) <i>blin" a toom' oh mab</i>	BiTE® Antibody	Hematology/ Oncology	<p>BLINCYTO® is an anti-CD19 x anti-CD3 (BiTE®) bispecific antibody construct. It is being investigated as a treatment for adult patients with diffuse large B cell lymphoma (DLBCL) (Phase 2).</p> <p>BLINCYTO® is being developed in Japan by Amgen Astellas BioPharma K.K., a joint venture between Amgen and Astellas Pharma Inc., a pharmaceutical company headquartered in Tokyo.</p>
Tezepelumab	Monoclonal Antibody	Inflammation	Tezepelumab is a human monoclonal antibody that inhibits the action of TSLP. It is being investigated as a treatment for asthma and atopic dermatitis. Tezepelumab is being jointly developed in collaboration with AstraZeneca.

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PHASE THREE

Phase 3 clinical trials investigate the safety and efficacy of a product candidate in a large number of patients who have the disease or condition under study.

MOLECULE NAME & PRONUNCIATION	MODALITY	THERAPEUTIC AREA	DESCRIPTION
AMG 520	Small Molecule	Neuroscience	<p>AMG 520 (CNP520) is a small molecule inhibitor of beta-site APP-cleaving enzyme-1 (BACE). It is being investigated for the prevention of Alzheimer's Disease.</p> <p>AMG 520 (CNP520) is being jointly developed in collaboration with Novartis.</p>
Aimovig™ (erenumab)	Monoclonal Antibody	Neuroscience	<p>Aimovig™ (erenumab) is a human monoclonal antibody that inhibits the receptor for calcitonin gene-related peptide. It is being investigated for the treatment of episodic migraine (Phase 3) and chronic migraine (Phase 2).</p> <p>In July 2017, Amgen announced that the U.S. Food and Drug Administration (FDA) accepted for review the Biologics License Application (BLA) for Aimovig™ for the prevention of migraine in patients experiencing four or more migraine days per month. The FDA has set a PDUFA target action date of May 17, 2018.</p> <p>Aimovig™ is being jointly developed in collaboration with Novartis.</p>
Aranesp® (darbepoetin alfa) <i>dar" be poe' e tin al fa</i>	Therapeutic Protein	Hematology/ Oncology	<p>Aranesp® is a recombinant human protein agonist of the erythropoietin receptor. It is being investigated as a treatment for low risk myelodysplastic syndromes.</p>
Enbrel® (etanercept)	Fusion Protein	Inflammation	<p>ENBREL is a fusion protein that inhibits tumor necrosis factor. It is being investigated as a monotherapy for psoriatic arthritis, as well as a monotherapy in maintaining remission of rheumatoid arthritis.</p>
EVENTIY™ (romosozumab) <i>roe" moe soz' ue mab</i>	Monoclonal Antibody	Bone Health	<p>EVENTIY™ is a humanized monoclonal antibody that inhibits the action of sclerostin. It is being investigated as a treatment for postmenopausal osteoporosis and male osteoporosis. EVENTIY™ is being jointly developed in collaboration with UCB.</p> <p>In September, results were published from the Phase 3 ARCH study in postmenopausal women with osteoporosis demonstrating superior fracture reduction with EVENTIY followed by alendronate, compared to alendronate alone, with additional details on the observed cardiovascular safety signal. Amgen is currently evaluating all EVENTIY Phase 3 data to ensure a comprehensive understanding of the cardiovascular safety results, and will be working in close collaboration with the FDA within the timeline of the complete response letter received in July 2017.</p> <p>In July 2017, Amgen and UCB announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter for the Biologics License Application (BLA) for EVENTIY™ as a treatment for postmenopausal women with osteoporosis. The original submission included data from the pivotal Phase 3 placebo-controlled FRAME study of postmenopausal women with osteoporosis. With the availability of data from the Phase 3 active-comparator ARCH study, the FDA asked that the efficacy and safety data from the study be integrated into the application. The resubmission will also include data from the Phase 3 BRIDGE study evaluating EVENTIY™ in men with osteoporosis. Approval of EVENTIY™ in the United States is not expected to occur in 2017.</p> <p>EVENTIY™ is being developed in Japan by Amgen Astellas BioPharma K.K., a joint venture between Amgen and Astellas Pharma Inc., a pharmaceutical company headquartered in Tokyo.</p>

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<p>IMLYGIC® (talimogene laherparepvec) <i>tal im' oh jeen la her" pa rep' vek</i></p>	<p>Oncolytic Immunotherapy</p>	<p>Hematology/Oncology</p>	<p>IMLYGIC® is an oncolytic immunotherapy derived from HSV-1. It is being investigated as a combination treatment in patients with mid- to late-stage metastatic melanoma (3) and in other cancer types (Phase 1).</p>
<p>KYPROLIS® (carfilzomib) <i>car fil' zoe mib</i></p>	<p>Small Molecule</p>	<p>Hematology/Oncology</p>	<p>KYPROLIS® is a proteasome inhibitor. It is being investigated in a variety of combinations and patient populations for multiple myeloma and as a treatment for small-cell lung cancer (Phase 1b/2).</p> <p>In August 2017, Amgen announced that the U.S. Food and Drug Administration (FDA) has accepted for review a supplemental New Drug Application (sNDA) based on the overall survival (OS) data from the Phase 3 head-to-head ENDEAVOR study. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of April 30, 2018.</p> <p>In July 2017, Amgen announced the submission of a variation to the marketing application to the European Medicines Agency to include OS data from the Phase 3 head-to-head ENDEAVOR study in the product label for KYPROLIS®.</p>
<p>Omecamtiv mecarbil <i>om" e kam' tiv me kar' bil</i></p>	<p>Small Molecule</p>	<p>Cardiovascular</p>	<p>Omecamtiv mecarbil is a small molecule activator of cardiac myosin. It is being investigated for the treatment of chronic heart failure.</p> <p>Omecamtiv mecarbil is being jointly developed in collaboration with Cytokinetics. Amgen has also entered into an alliance with Servier for exclusive commercialization rights in Europe as well as the Commonwealth of Independent States, including Russia.</p>
<p>Prolia® (denosumab) <i>den oh sue' mab</i></p>	<p>Monoclonal Antibody</p>	<p>Bone Health</p>	<p>Prolia® is a human monoclonal antibody that inhibits RANKL. It is being investigated for the treatment of glucocorticoid-induced osteoporosis.</p> <p>In October 2017, Amgen announced that the U.S. Food and Drug Administration (FDA) accepted for review the supplemental Biologics License Application (sBLA) for Prolia® for the treatment of patients with glucocorticoid-induced osteoporosis. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of May 28, 2018.</p>
<p>Repatha® (evolocumab) <i>e" voe lok' ue mab</i></p>	<p>Monoclonal Antibody</p>	<p>Cardiovascular</p>	<p>Repatha® is a human monoclonal antibody that inhibits Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9). It is being evaluated as a treatment for patients with hyperlipidemia.</p> <p>In July 2017, Amgen announced that the U.S. Food and Drug Administration (FDA) granted priority review for Amgen's supplemental Biologics License Application (sBLA) for Repatha®. If approved by the FDA, the U.S. Prescribing Information for Repatha will be updated to include risk reduction of major cardiovascular events based on data from the large cardiovascular outcomes study (FOURIER). The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of Dec. 2, 2017.</p> <p>In June 2017, Amgen announced the submission of a variation to the marketing authorization to the European Medicines Agency (EMA) for Repatha® based on the FOURIER study.</p> <p>Repatha® is being developed in Japan by Amgen Astellas BioPharma K.K., a joint venture between Amgen and Astellas Pharma Inc., a pharmaceutical company headquartered in Tokyo.</p>

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XGEVA®
(denosumab)
den oh sue' mab

**Monoclonal
Antibody**

**Hematology/
Oncology**

XGEVA® is a human monoclonal antibody that inhibits RANKL. It is being investigated as a treatment for the delay or prevention of bone metastases in patients with adjuvant breast cancer (Phase 3).

In June 2017, Amgen announced that the U.S. Food and Drug Administration (FDA) accepted the XGEVA® supplemental Biologics License Application (sBLA) that seeks to expand the current approved indication for the prevention of fractures and other skeletal-related events in patients with bone metastases from solid tumors to include patients with multiple myeloma. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of February 3, 2018

BIOSIMILARS

A biosimilar, or follow-on biologic, is a biologic medicine designed to have active properties similar to one that has previously been licensed. Biosimilars follow a different regulatory review pathway than innovative products and indications.

MOLECULE NAME	MODALITY	THERAPEUTIC AREA	DESCRIPTION
ABP 215 (biosimilar bevacizumab)	Monoclonal Antibody	Hematology/ Oncology	<p>ABP 215 (biosimilar bevacizumab) is an anti-vascular endothelial growth factor A (anti-VEGF) monoclonal antibody.</p> <p>The reference product primary conditions are colorectal cancer, non-squamous non-small cell lung cancer, glioblastoma, renal cell carcinoma, breast cancer and ovarian cancer.</p> <p>In December 2016, Amgen and Allergan announced that they a submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for ABP 215.</p> <p>Amgen is developing ABP 215 in collaboration with Allergan.</p>
ABP 494 (biosimilar cetuximab)	Monoclonal Antibody	Hematology/ Oncology	<p>ABP 494 (biosimilar cetuximab) is an anti-epidermal growth factor receptor (anti-EGFr) monoclonal antibody. It is in pre-clinical development.</p> <p>The reference product primary conditions are colorectal cancer and head and neck cancer.</p> <p>Amgen is developing ABP 494 in collaboration with Allergan.</p>
ABP 710 (biosimilar infliximab)	Monoclonal Antibody	Inflammation	<p>ABP 710 (biosimilar infliximab) is an anti-tumor necrosis factor-alpha (anti-TNF) monoclonal antibody.</p> <p>The reference product primary conditions are rheumatoid arthritis, plaque psoriasis, Crohn's disease, ulcerative colitis, psoriatic arthritis and ankylosing spondylitis.</p>
ABP 798 (biosimilar rituximab)	Monoclonal Antibody	Hematology/ Oncology & Inflammation	<p>ABP 798 (biosimilar rituximab) is an anti-CD20 monoclonal antibody. The reference product primary conditions are non-Hodgkin's lymphoma, chronic lymphocytic leukemia and rheumatoid arthritis.</p> <p>Amgen is developing ABP 798 in collaboration with Allergan.</p>
ABP 959 (biosimilar eculizumab)	Monoclonal Antibody	Hematology/ Oncology	<p>ABP 959 (biosimilar eculizumab) is a monoclonal antibody that specifically binds to the complement protein C5. The reference product primary conditions are Paroxysmal Nocturnal Hemoglobinuria (PNH) and Atypical Hemolytic Uremic Syndrome (aHUS).</p>

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MOLECULE NAME	MODALITY	THERAPEUTIC AREA	DESCRIPTION
ABP 980 (biosimilar trastuzumab)	Monoclonal Antibody	Hematology/ Oncology	<p>ABP 980 (biosimilar trastuzumab) is an anti-HER2 monoclonal antibody.</p> <p>The reference product primary conditions are HER2+ breast cancer and HER2+ gastric cancer.</p> <p>In July 2017, Amgen and Allergan announced that they submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for ABP 980. The FDA has set a Biosimilar User Fee Act target action date of May 28, 2018.</p> <p>Amgen is developing ABP 980 in collaboration with Allergan.</p>

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