

Amgen Research & Development

Sean Harper

Executive Vice President, Research & Development

AMGEN®

Pioneering science delivers vital medicines™

We Have Refined Our R&D Guiding Principles

- **Focus on innovative medicines for unmet needs in patients with serious illnesses**
- **Emphasis on target validation in humans**
- **Multimodality platform with focus on biologics**
- **Focus on return on investment and operational efficiency**
- **Harness external innovation**
- **Demonstrate the value of our medicines**

Our Discovery Efforts Are Focused On Specific Diseases Within Key Therapeutic Areas

Therapeutic Area
Inflammation/Oncology
Metabolism/Bone
Cardiovascular
Neuroscience

We Have Refocused and Differentiated Discovery Research

- **Unique consolidation of small, medium, and large molecule technologies into one integrated platform**
 - **Brings scientific synergies**
 - **Generation of innovative hybrid modalities**
 - **Application of rigorous molecular modeling and structure-based design to biologics**
- **Focus on immuno-oncology**
- **Identify or validate targets in humans whenever possible**
 - **eg, PCSK9, sclerostin, CGRP**

CGRP = calcitonin gene-related peptide

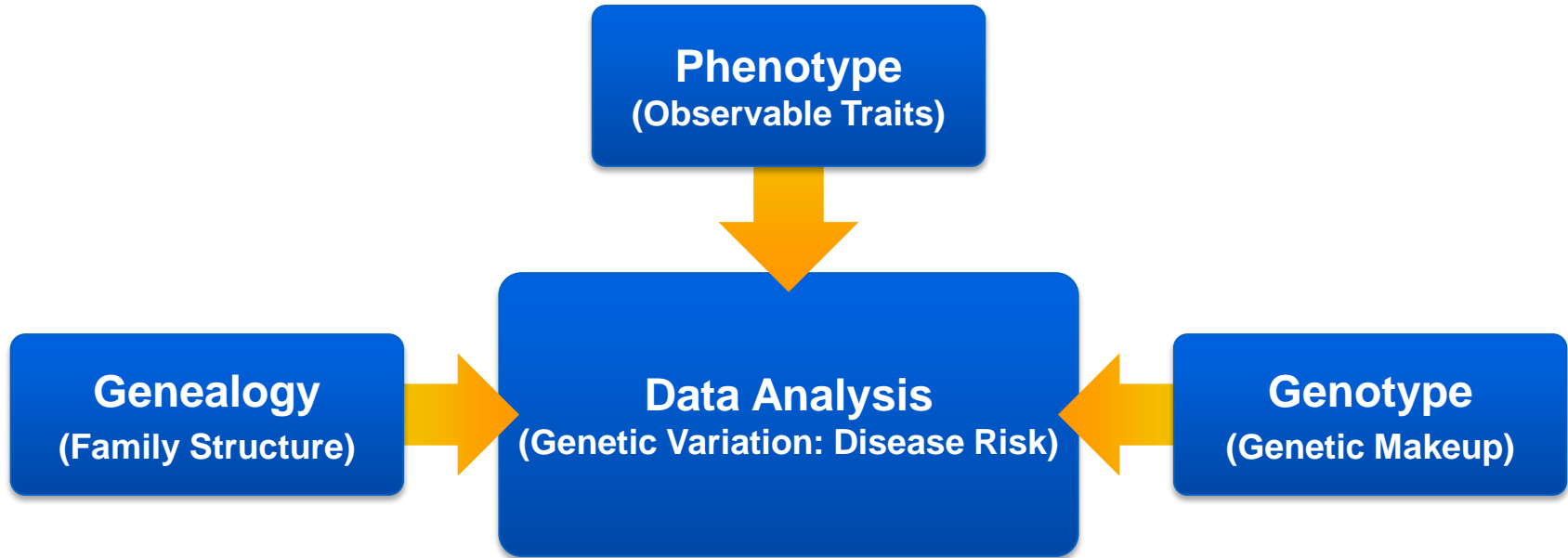
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A New Era In Therapeutic Innovation: Modern Human Population Genetics

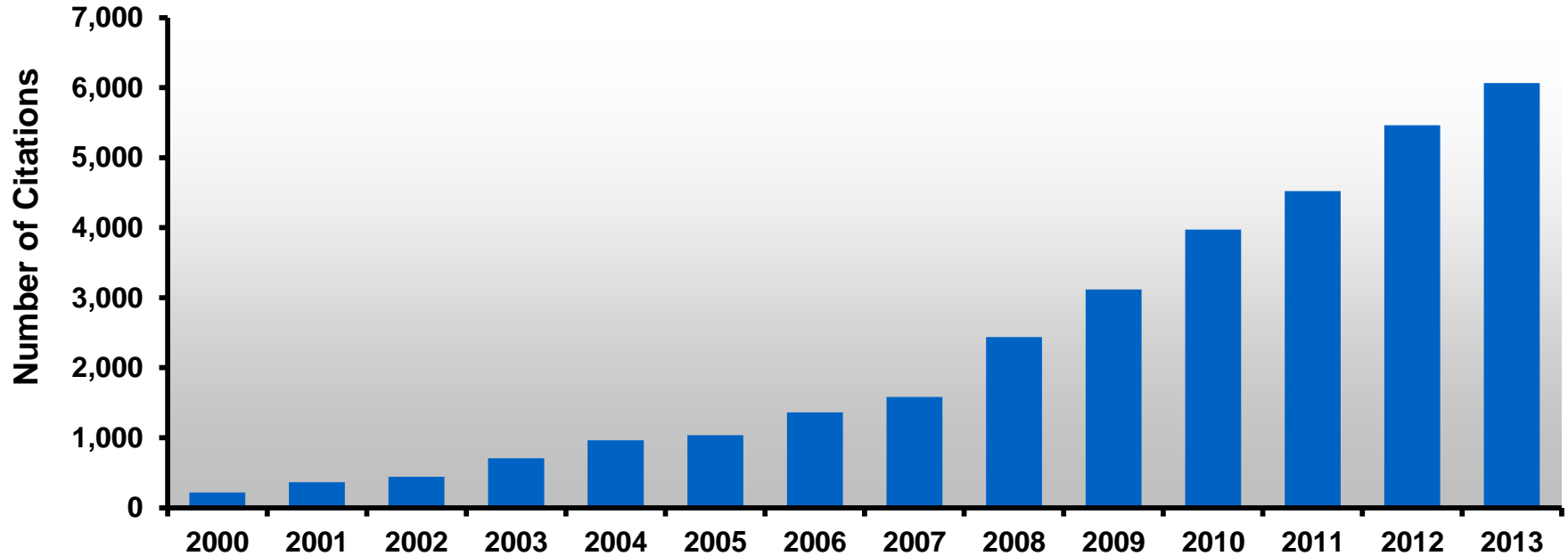
Three Capabilities Are Necessary to Capitalize:

- 1. Ability to discover/validate proprietary genetic targets on an industrial scale**
- 2. Ability to elucidate complex biology in-house**
- 3. Ability to interdict targets via a robust multimodality platform**

deCODE Genetics: The Industry-Leading Capability In Human Population Genetics



deCODE Research Cited In Other Manuscripts



Source: Scopus.com as of October 7, 2014

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Human Population Genetics Strongly Supports Pursuing PCSK9 Inhibition

<i>PCSK9</i> Variant	LDL-C	CHD Risk
Gain-of-Function Mutations	> 300 mg/dL ²	Premature CAD ^{1,2}
R46L	↓ 15% ³	↓ 47% ³
Y142X or C679X	↓ 28%–40% ^{3,4}	↓ 88% ³

LDL-C = low-density lipoprotein cholesterol; CHD = coronary heart disease; CAD = coronary artery disease

1. Haddad L, Day INM, et al. *J Lipid Res.* 1999, 40:1113-1122; 2. Abifadel M, Varret M, Rabes JP, et al. *Nat Genet.* 2003;34:154-156; 3. Cohen JC, Boerwinkle E, Mosley TH, Hobbs HH. *N Engl J Med.* 2006;354:1264-1272; 4. Cohen J, Pertsemlidis A, Kotowski IK, et al. *Nat Genet.* 2005, 37:161-165.

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Humans With Genetic Sclerostin Deficiency Have High Bone Mass

Normal

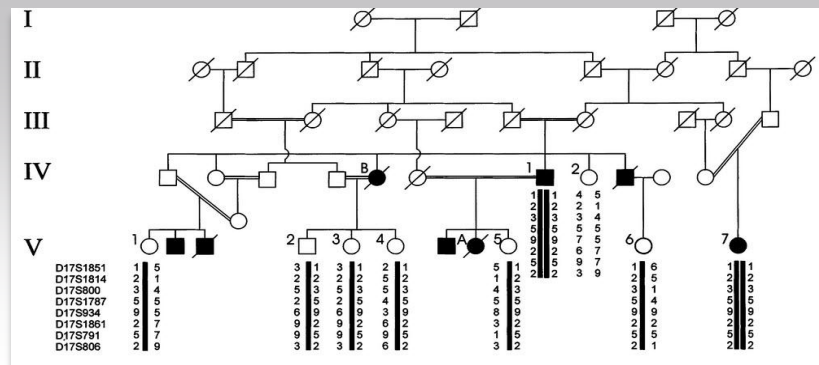


Sclerosteosis



- Rare autosomal recessive disease, < 100 cases
- Robust bone growth evident by mid childhood
- Increased bone density and bone diameter

Genetic Mapping of Sclerosteosis Mutation

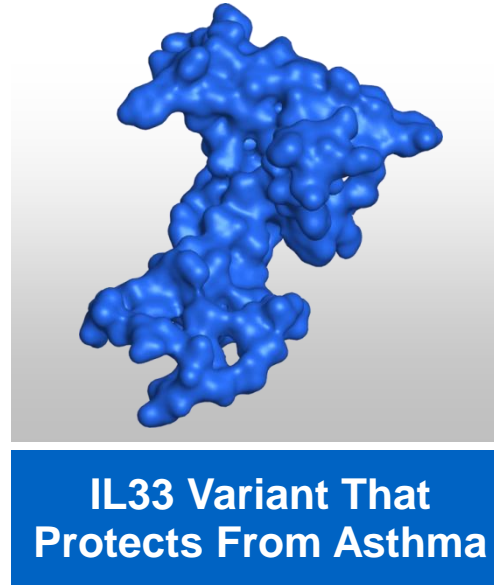
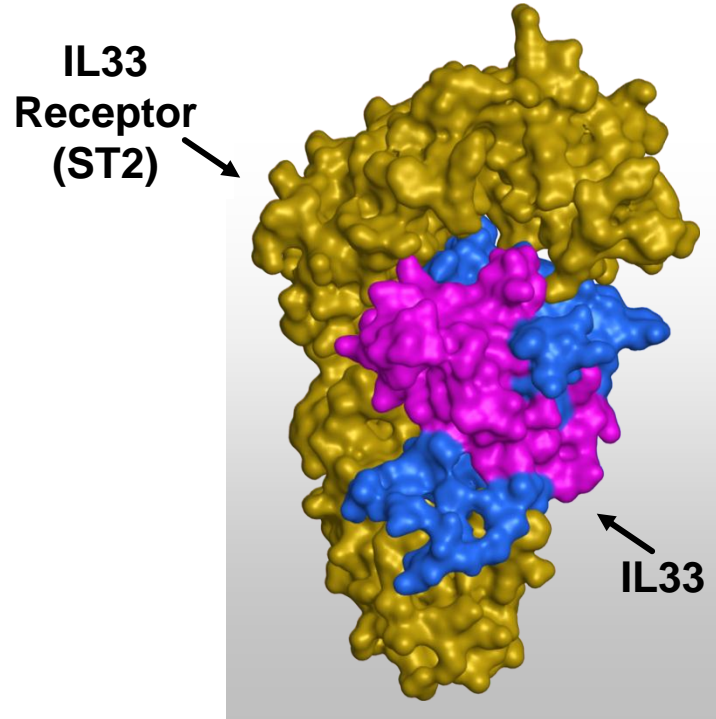


Sclerostin

Balemans, W, et al. *Am. J. Hum. Genet.* 1999;64:1661-1669; Balemans W, et al. *Hum Mol Genet.* 2001;10:537-543; Beighton P, et al. *J Med Genet.* 1988;25:200-203. Brunkow ME, et al. *Am J Hum Genet.* 2001;68:577-589; Hamersma H, et al. *Clin Genet.* 2003;63:192-197. van Lierop A, et al. *J Bone Miner Res.* 2011;26:2804-2811.

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Example: Rare Variant In IL-33 That Protects From Asthma



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Example: A Rare Variant In *Gene X* Associates With Markedly Reduced Risk of Cardiovascular Disease

Identification of a Novel, Genetically Validated Atherosclerosis Target

- **deCODE identified a rare variant in *Gene X* associated with reduced risk of coronary artery disease and myocardial infarction (MI)**
- **Variant confers loss of function, suggesting inhibition as therapeutic strategy**
- **Protective effect mediated through both LDL-dependent and LDL-independent mechanisms**
- **No adverse phenotypes associated, suggesting safety of approach**

Variant In *Gene X* Associated With Decreased Risk of CAD and MI

Phenotype	P Value	Effect (OR)
Myocardial infarction (n = 31,720)	2.03×10^{-05}	0.56
Myocardial infarction before age 76	5.88×10^{-05}	0.50
Coronary artery disease (n = 18,764)	2.61×10^{-05}	0.62
Coronary artery disease before age 76	4.01×10^{-04}	0.53
Ischemic stroke excluding AF	1.01×10^{-03}	0.44
Peripheral artery disease	9.43×10^{-02}	0.63

OR = odds ratio

AF = atrial fibrillation

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Protective Effect of *Gene X* Is Mediated Through Both LDL-Dependent and LDL-Independent Mechanisms

Phenotype	Effect of Variant	
	PCSK9	<i>Gene X</i>
LDL Reduction	14.4%	6.7%
Life Span	+8 Months	+18 Months
MI Odds Ratio	0.72	0.58

The Future: A Complete Catalog of Human Genetic Variation



~ 25,000 human genes in total

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Amgen's Strengths In Immunology, Oncology, and Biologics Form a Competitive Position In Immuno-Oncology

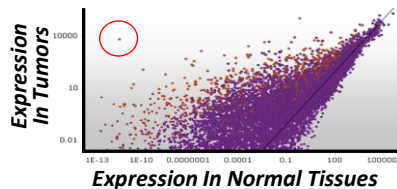
- **PD-1/PDL-1 inhibition will become cornerstone therapy for many tumors; however, many nonresponders will remain**
- **Tumors such as breast, colon, and prostate are currently “non-immune responsive”**
- **Talimogene laherparepvec and BiTE[®] platforms address anticipated needs in a PD-1/PDL-1 world**
- **Combination trials with ipilimumab and pembrolizumab designed to make talimogen laherparepvec another cornerstone of immunotherapy**
 - **Melanoma and head and neck cancer**
- **BiTE[®] platform is clinically validated and also attractive for combination approaches**

BiTE[®] = bispecific T-cell engager

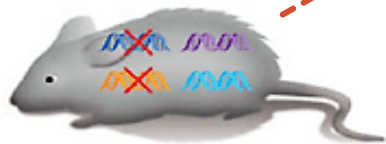
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A Comprehensive Platform for BiTE[®]s

High-Resolution Target Discovery

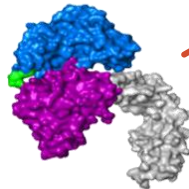
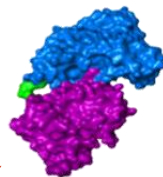


> 20 New Projects



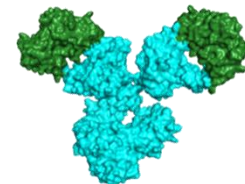
Immunization of XenoMouse[®]

Conversion to BiTE[®]s



Improved Half-Life/ Biodistribution

Efficacy and Safety Evaluation



Plus Additional Immunotherapeutics

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Progress On Operational Efficiency

- Disciplined project prioritization to maintain focus
- Refocused discovery research investment
- Reduced geographic complexity and cost
- Reduced cycle times for biologics and genetically validated targets
- Leaner clinical trial programs
- Partnering strategy to complement core competencies

Continuous improvement culture: Success rate, cycle time, cost

Fast-to-Patient Approach for Monoclonal Antibodies

Cycle Time Improvement

- 1 year faster to clinic
- Raw material and resource savings

Leverages Next-Generation Biomanufacturing Platform



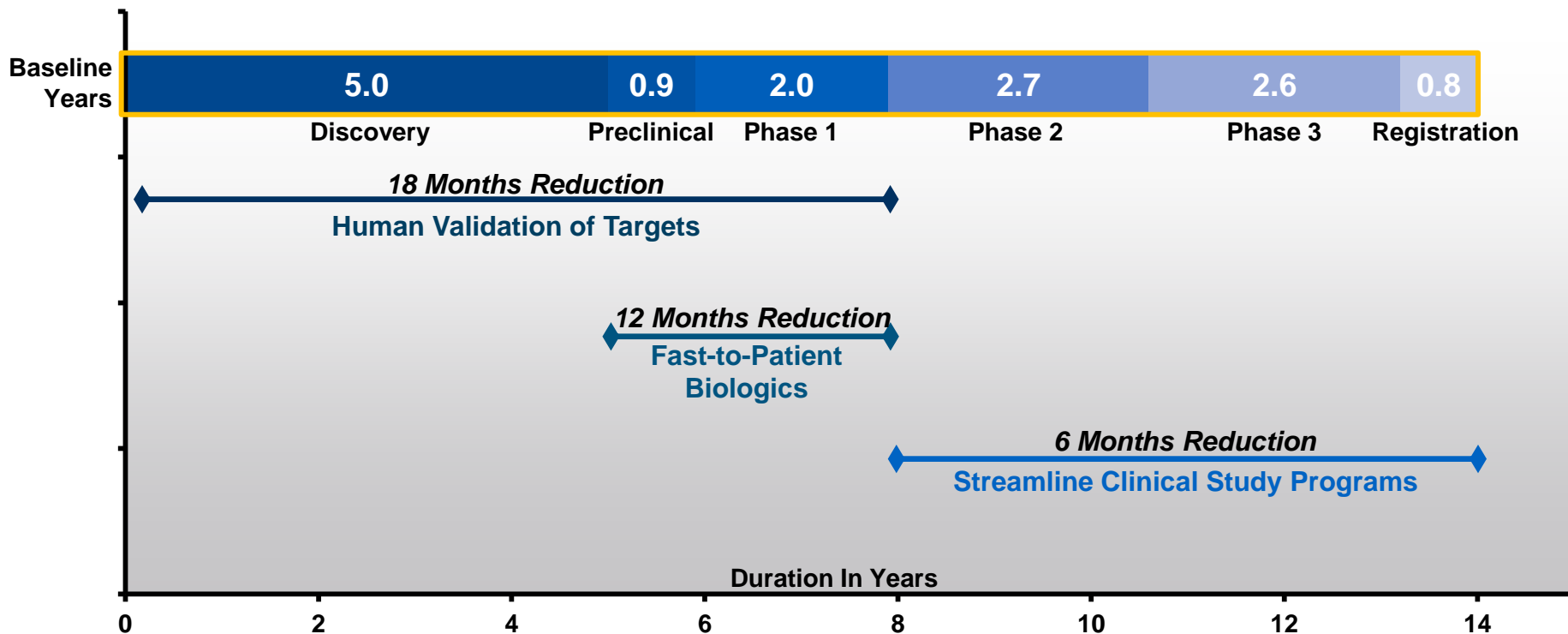
- Meets toxicology and clinical material demands in a single run

We Will Reduce the Cost of Clinical Trials While Improving Cycle Time and Quality



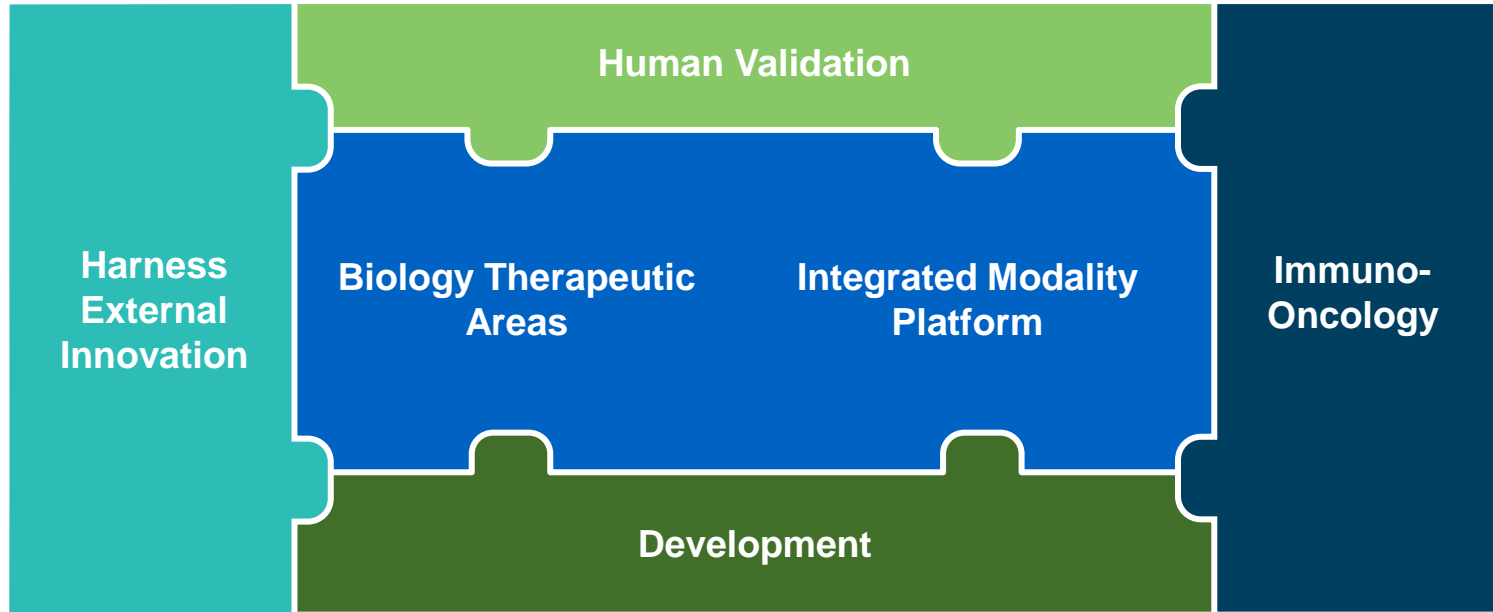
- Design leaner clinical trial programs
- Risk-based quality control
- Fully leveraged outsourcing
- Manage investigational product more efficiently

Meaningful Estimated Reductions In Our Product Development Cycle Time



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How the Pieces Fit Together: The Workings of Our Unique R&D Engine



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Amgen Pipeline Highlights

Projected 2014 Milestones for Innovative Programs

Clinical Program	Lead Indication	Milestone	Timing
Evolocumab	Dyslipidemia	US submission	✓
		EU submission	✓
Ivabradine	Chronic heart failure	US submission	✓
Kyprolis® (carfilzomib)	Multiple myeloma	Phase 3 ASPIRE data	✓
		Phase 3 FOCUS data	✓
Talimogene laherparepvec	Metastatic melanoma	US submission	✓
		EU submission	✓
Blinatumomab	Relapsed/refractory ALL	US submission	✓
		EU submission	✓
AMG 416	Secondary hyperparathyroidism	Phase 3 data	✓
Brodalumab**	Moderate to severe plaque psoriasis	Phase 3 data [‡]	✓, Q4 2014
Trebananib	Recurrent ovarian cancer	Phase 3 data ^{*†}	Q4 2014
AMG 334	Migraine prophylaxis	Phase 2b data (episodic)	Q4 2014

ALL = acute lymphoblastic leukemia; *Event-driven; ✓ Milestone achieved; †Overall survival (secondary endpoint)

**Developed in collaboration with AstraZeneca; ‡Positive data received from first pivotal study

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What We Will Cover Today

Therapeutic Area	Molecule	Phase	Primary Indication
Cardiovascular	Evolocumab	Registration	Dyslipidemia
	Ivabradine	Registration	Chronic heart failure
	Omecamtiv mecarbil*	Phase 2	Heart failure
Bone	Romosozumab†	Phase 3	Postmenopausal osteoporosis
Inflammation	Brodalumab**	Phase 3	Moderate-to-severe plaque psoriasis
	AMG 157‡	Phase 2	Asthma
Neuroscience	AMG 334	Phase 2	Migraine
Oncology	Talimogene laherparepvec	Registration	Metastatic melanoma
	Blinatumomab	Registration	Acute lymphoblastic leukemia
	Kyprolis®	Phase 3	Multiple myeloma

*Developed in collaboration with Cytokinetics; †Developed in collaboration with UCB

**Developed in collaboration with AstraZeneca; ‡Developed in collaboration with AstraZeneca/MedImmune

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Amgen Cardiovascular

Amgen Cardiovascular: Three Innovative Molecules to Address Unmet Need

	Evolocumab	Ivabradine	Omecamtiv Mecarbil
Class	PCSK9 inhibitor	<i>I_f</i> Channel inhibitor	Cardiac myosin activator
Indications	Dyslipidemia	Chronic heart failure	Heart failure
Phase of Development	Regulatory review in US and EU	Priority review in US	Phase 2b

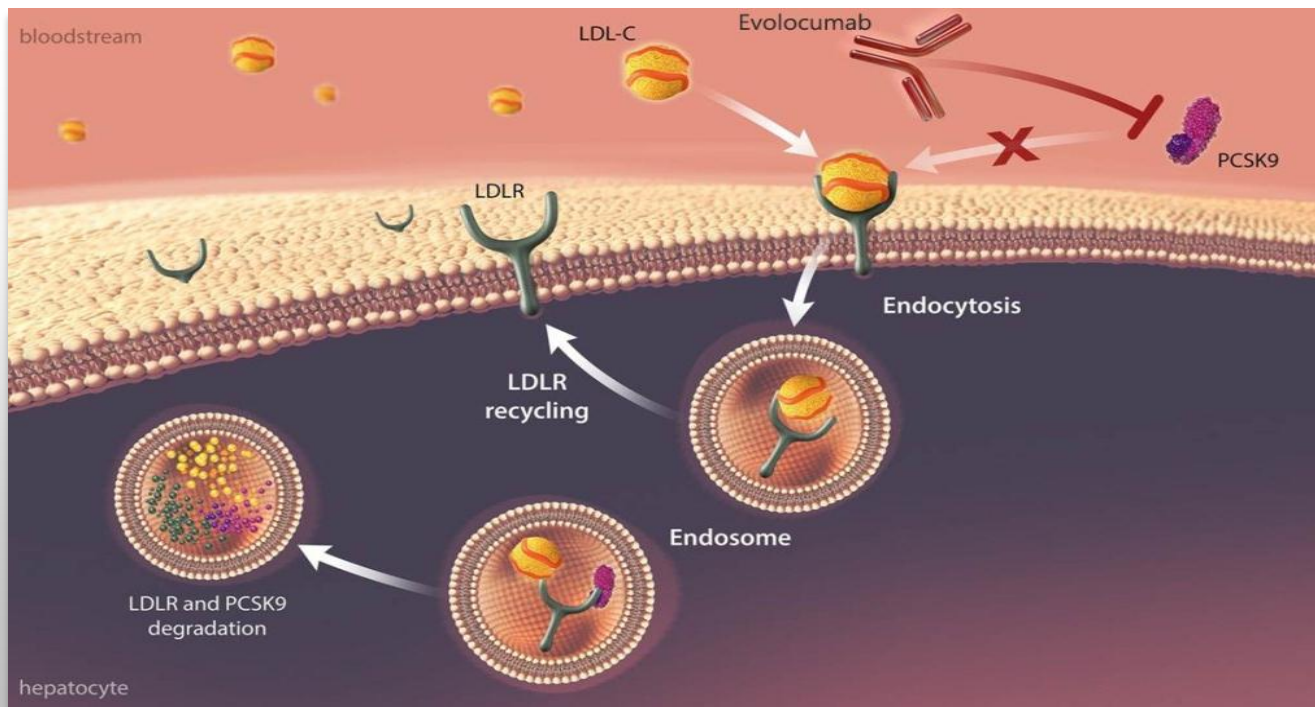
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Evolocumab

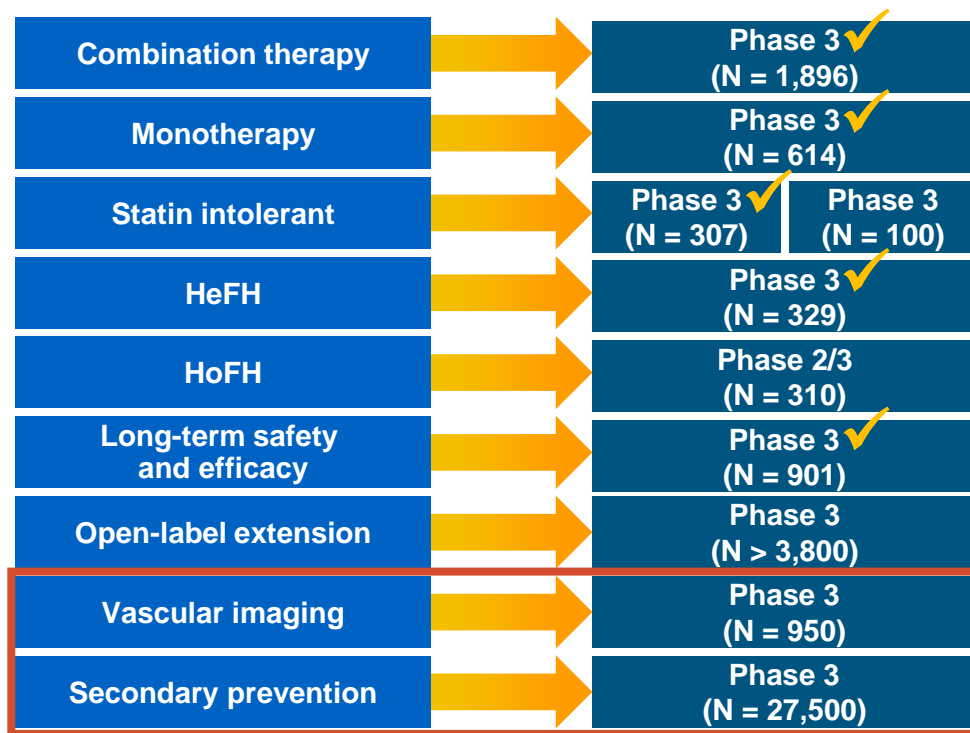
Evolocumab: A Human Monoclonal Antibody That Inhibits PCSK9



LDLR = LDL receptor

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Evolocumab Global Phase 3 Program Evaluates LDL-C; Effect On Plaque Burden; CV Outcomes



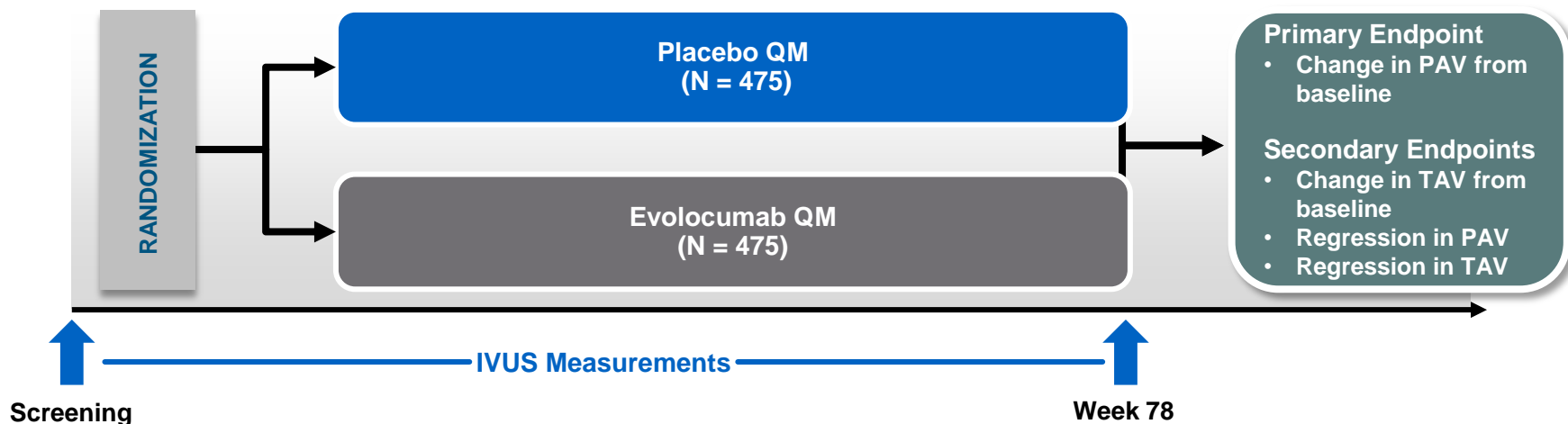
CV = cardiovascular; HeFH = heterozygous familial hypercholesterolemia; HoFH = homozygous familial hypercholesterolemia; ✓ = completed

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Coronary Intravascular Ultrasound (IVUS) Study Schema

Population

- Clinical indication for coronary angiography
- Fasting LDL-C ≥ 60 mg/dL

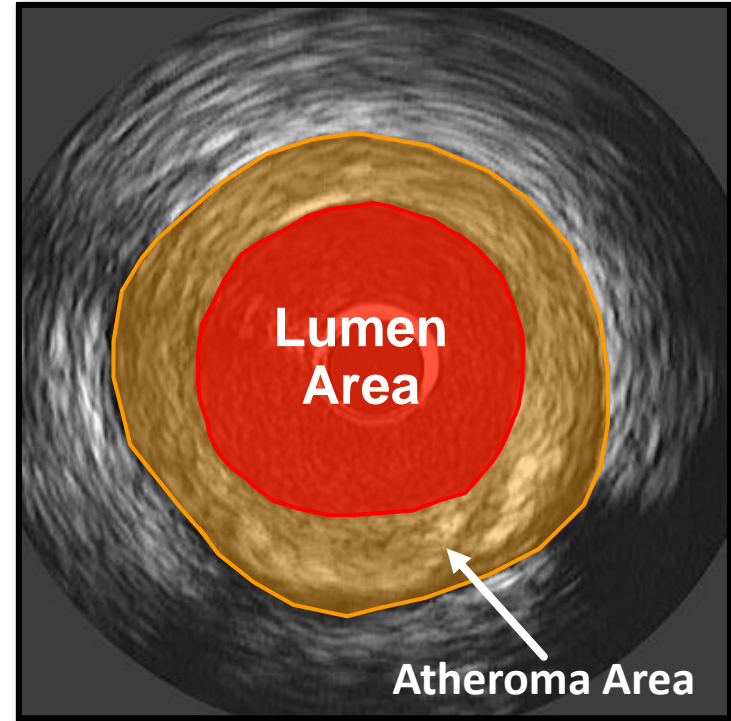
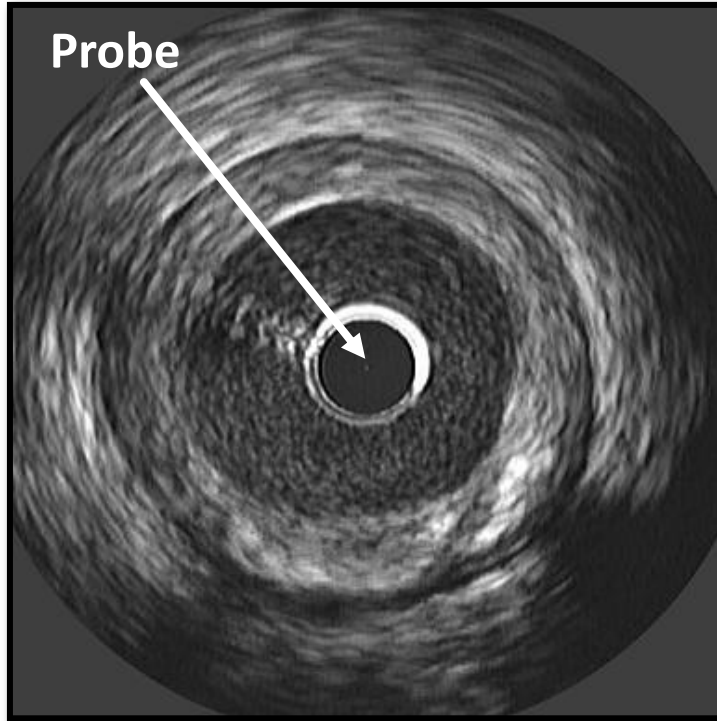


Data expected 2016

QM = monthly; PAV = percent atheroma volume; TAV = total atheroma volume

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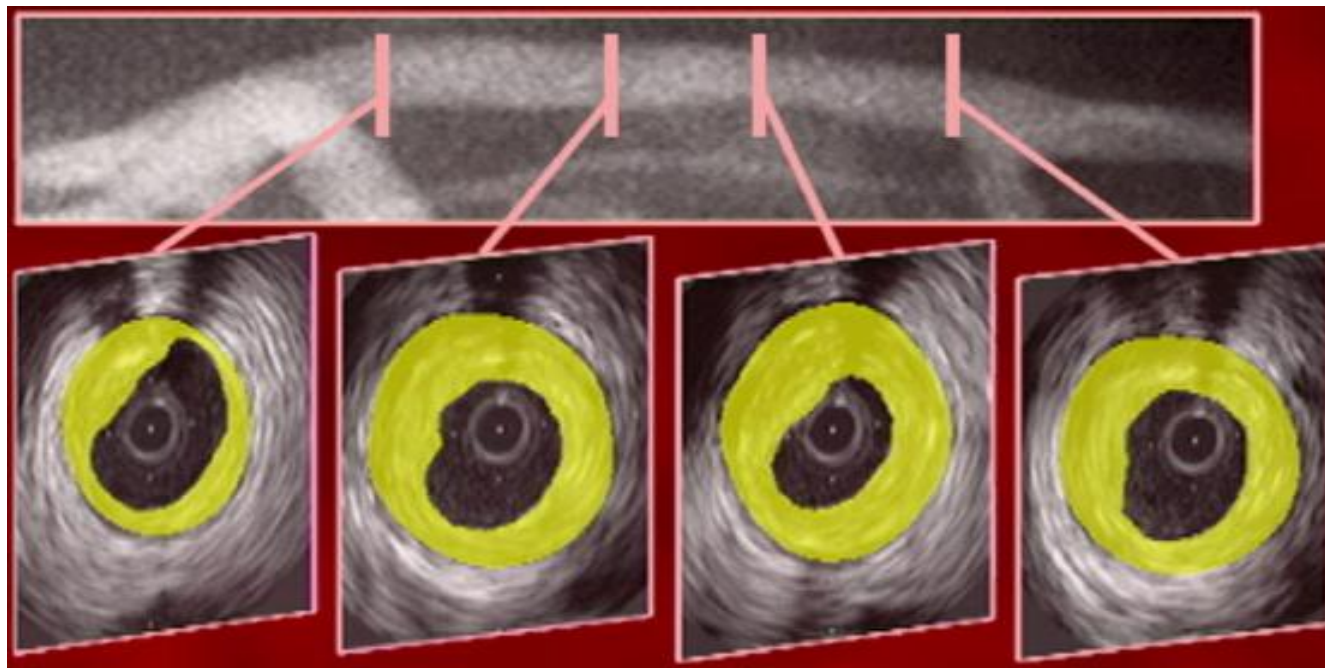
Quantification of Atherosclerotic Plaque Burden by Coronary Intravascular Ultrasound



Source: The Cleveland Clinic Intravascular Ultrasound Research Laboratory

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Quantification of Atherosclerotic Plaque Burden by IVUS Through Volumetric Assessments



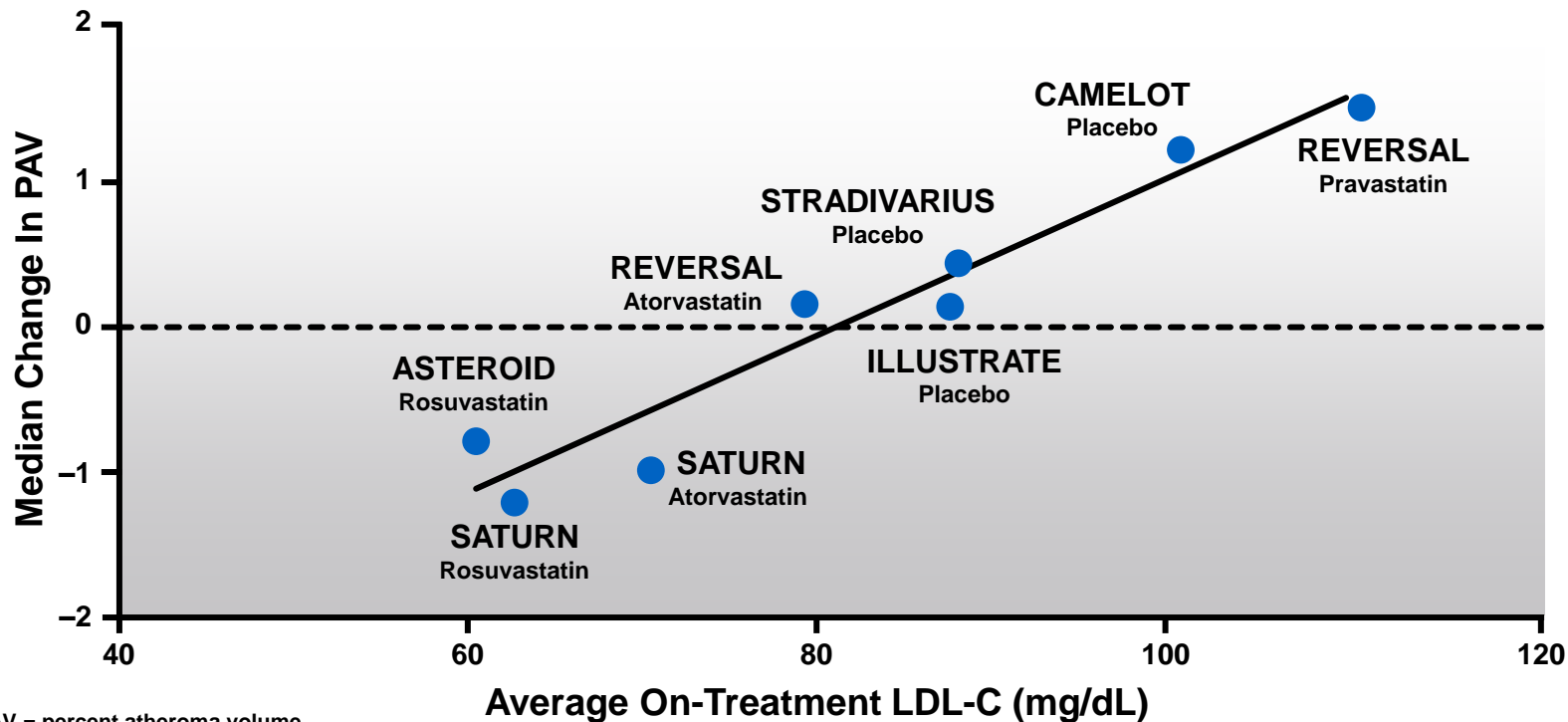
Angiogram

IVUS

Source: The Cleveland Clinic Intravascular Ultrasound Research Laboratory

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Plaque Burden and LDL-C: Testing Hypothesis That “Lower Is Better”



PAV = percent atheroma volume

Puri R, et al. *European Heart J* 2013;13:1818-1825.

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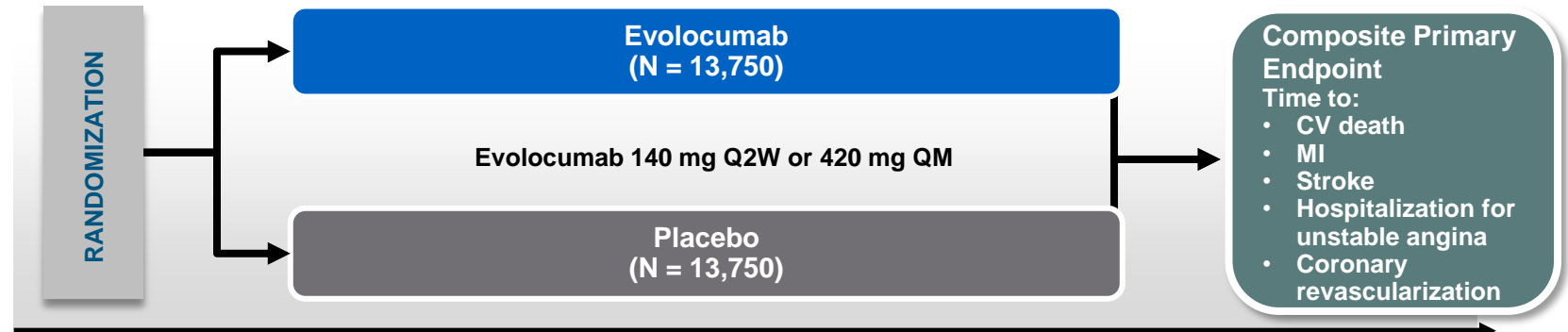
Our Outcomes Study Is Also Exploring Levels of LDL-C Not Previously Achievable

Population

- Clinically evident cardiovascular disease at high risk for a recurrent event
- Median baseline LDL-C expected to be in the range of 90–100 mg/dL

Background Therapy

- Effective statin therapy +/- ezetimibe



Increasing enrollment by 5,000 patients
Outcomes data expected no later than 2017 (event driven)

Q2W = every 2 weeks

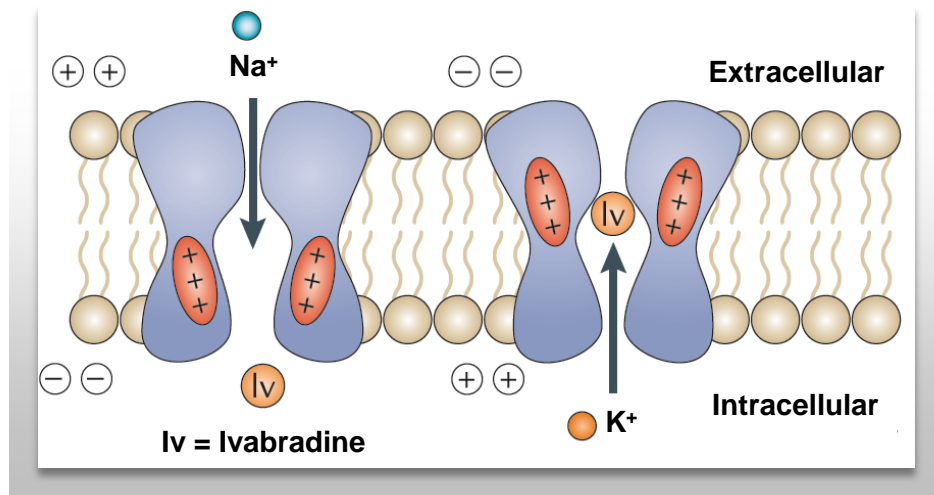
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Ivabradine

Ivabradine: Under Priority Review by FDA



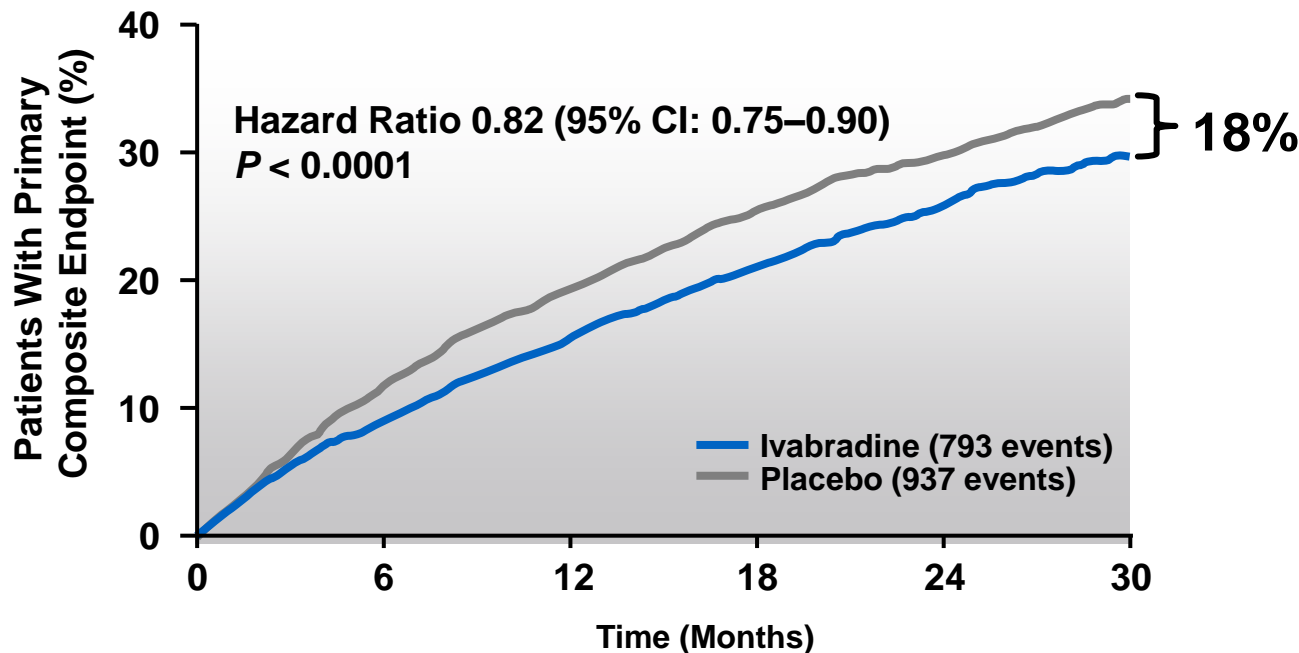
- Treatment goals are not met in all heart failure patients with currently approved therapies
 - > 10% of elderly CHF patients are contraindicated or cannot tolerate beta blockers*
- Ivabradine significantly reduces heart rate
 - Benefit > risk supported by robust clinical data, including heart failure outcomes study

CHF = chronic heart failure

*Hernandez AF, et al. *J Am Coll Cardiol*. 2009;53:184-192.

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SHiFT*: Ivabradine Significantly Reduced Risk of CV Death or First Hospitalization for Worsening Heart Failure



The most common adverse events were phosphenes and bradycardia, which occurred more frequently with ivabradine

*Phase 3 cardiovascular outcomes trial in patients with chronic heart failure and left ventricular systolic dysfunction

Adapted from: Swedberg K, et al. Lancet. 2010;376:875-885.

CI = confidence interval

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SHIfT: Major Outcomes

	Hazard Ratio	P Value
Primary composite endpoint		
CV death or hospitalization for worsening HF	0.82	< 0.0001
Secondary endpoints		
CV death	0.91	0.128
Hospitalization for worsening HF	0.74	< 0.0001
Death from any cause	0.90	0.092
Death from HF	0.74	0.0140
Hospitalization for CV reason	0.85	0.0002
Hospitalization for any cause	0.89	0.0027

HF = heart failure

Swedberg K, et al. *Lancet*. 2010;376:875-885.

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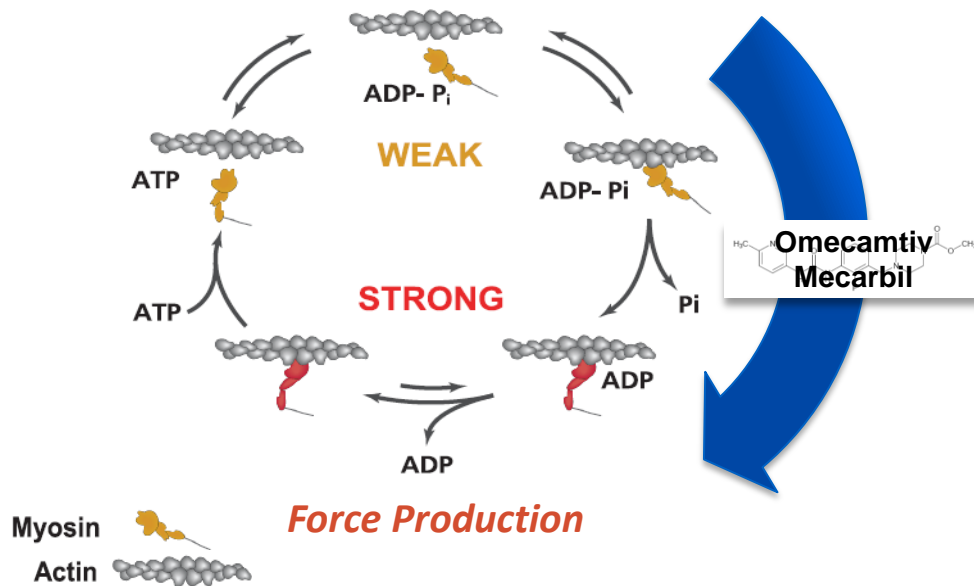


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Omecamtiv Mecarbil

Omecamtiv Mecarbil (OM) Is a Novel Selective Cardiac Myosin Activator

Mechanochemical Cycle of Myosin



Increases duration of systole

Increases stroke volume

No increase in myocardial O_2 consumption

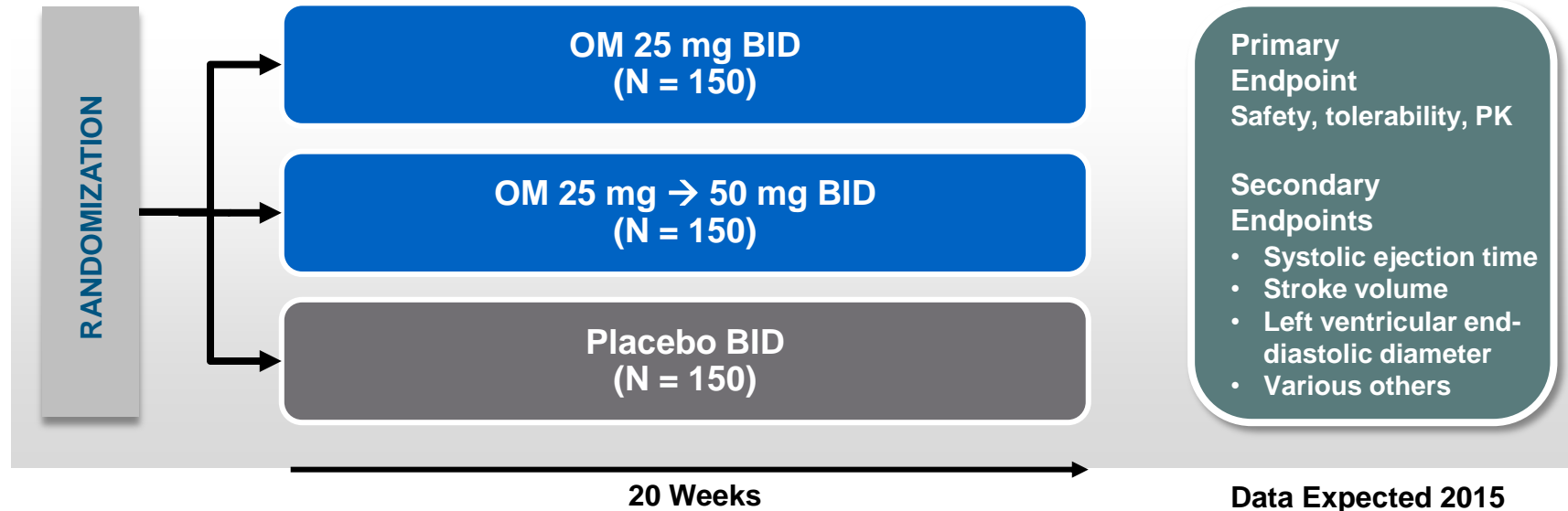
Malik FI, et al. *Science*. 2011;331:1439-1443.

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OM: Phase 2 Oral Study—Expansion Phase

Population

- Patients with chronic NYHA class II to III HF with reduced LVEF



NYHA = New York Heart Association; LVEF = left ventricular ejection fraction; BID = twice a day; PK = pharmacokinetics

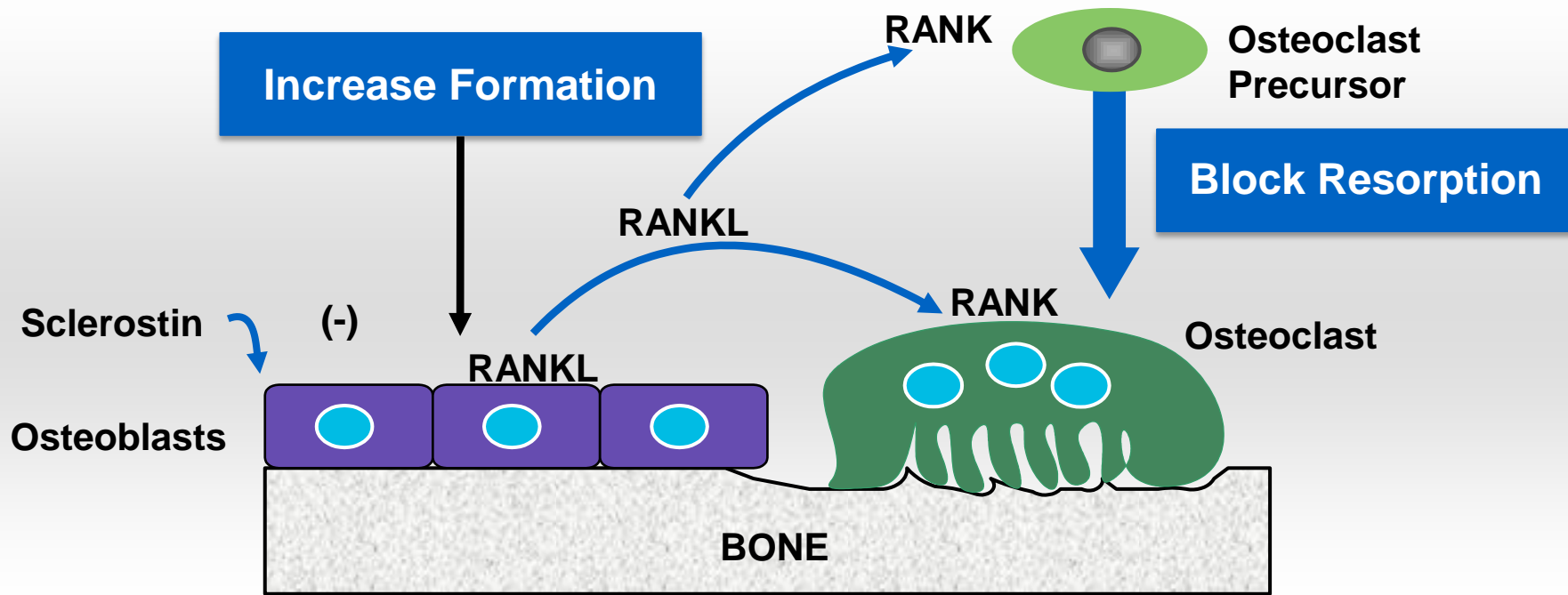
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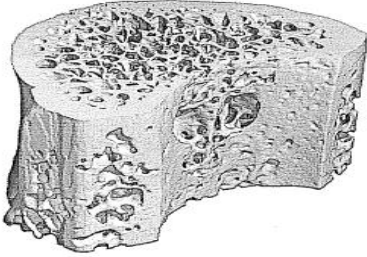
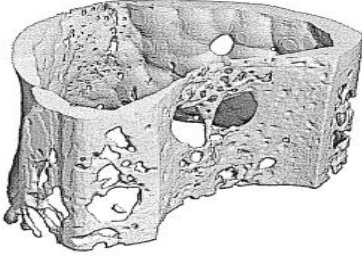
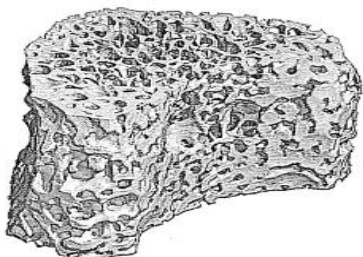
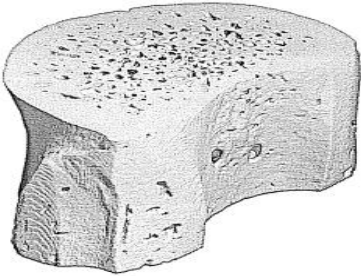
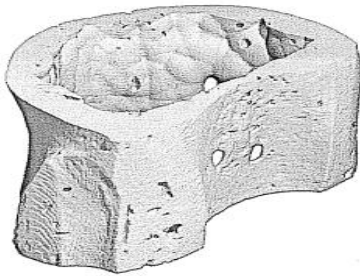
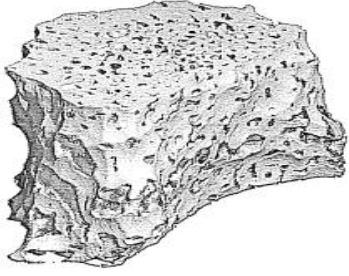
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Amgen Bone Health

Romosozumab Inhibits Sclerostin to Increase Bone Formation Mediated by Osteoblasts



Romosozumab Improved Bone Architecture In Preclinical Models

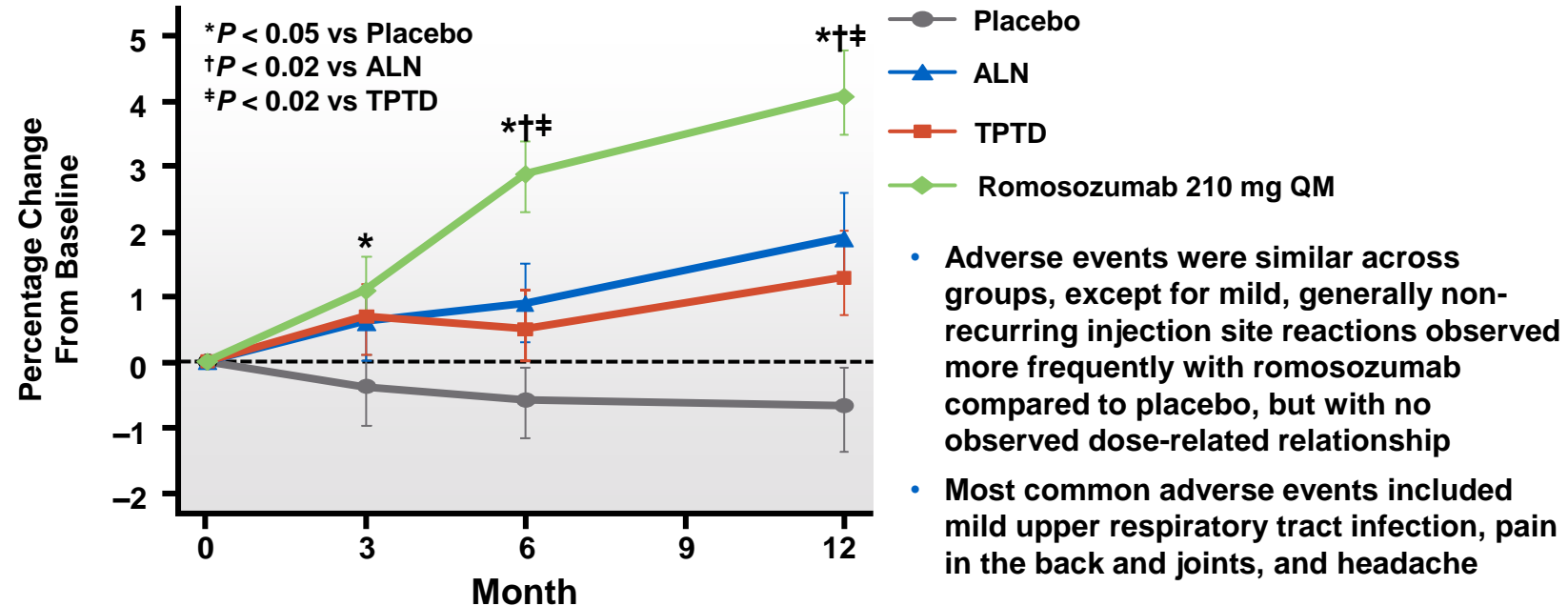
	Whole Body	Cortical Shell	Trabecular Bone
Vehicle			
Romosozumab			

Source: Data on file, Amgen

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Phase 2: Treatment With Romosozumab Increased Total Hip Bone Mineral Density

Total Hip Bone Mineral Density



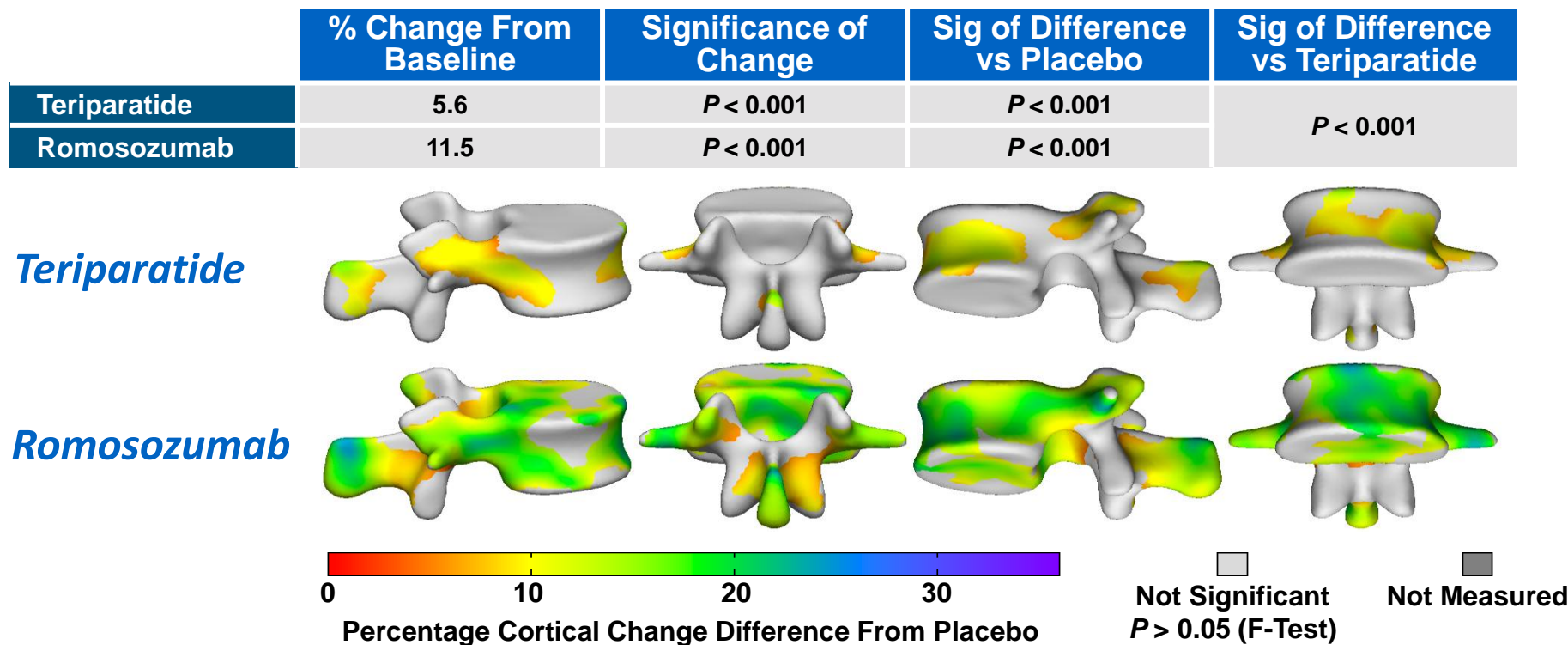
ALN = alendronate; TPTD = teriparatide

McClung, et al. *N Engl J Med*. DOI: 10.1056/NEJMoa1305224. <http://www.nejm.org/doi/full/10.1056/NEJMoa1305224SO>

ALN and TPTD were administered open label; Data are least-squares means and 95% confidence intervals

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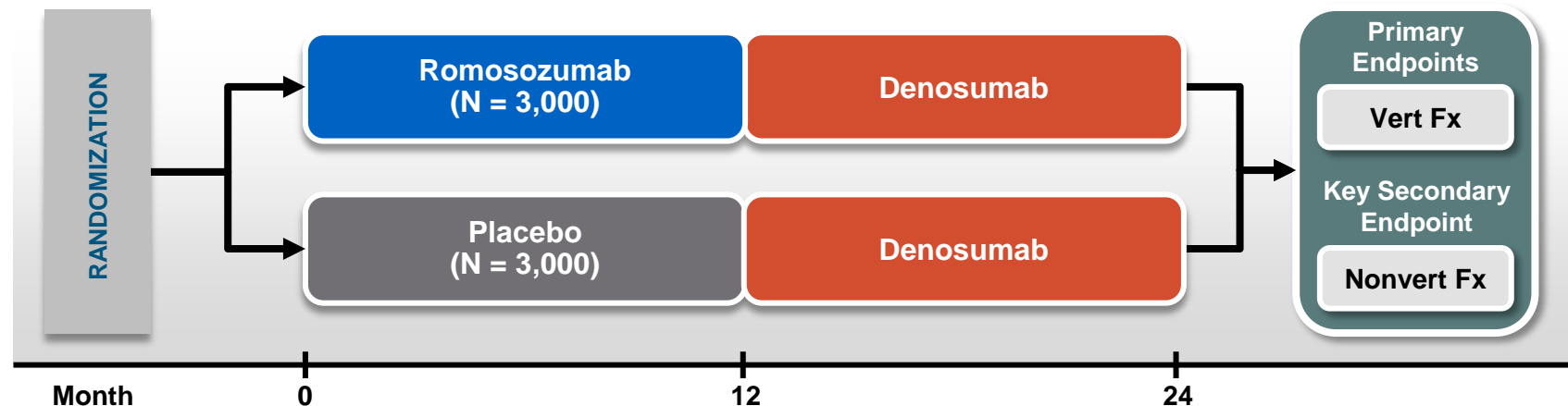
Phase 2: Cortical Thickness Was Significantly Greater With Romosozumab Than Teriparatide at 12 Months



Exploratory analysis

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Romosozumab: Placebo-Controlled Fracture Study In Postmenopausal Women With Osteoporosis

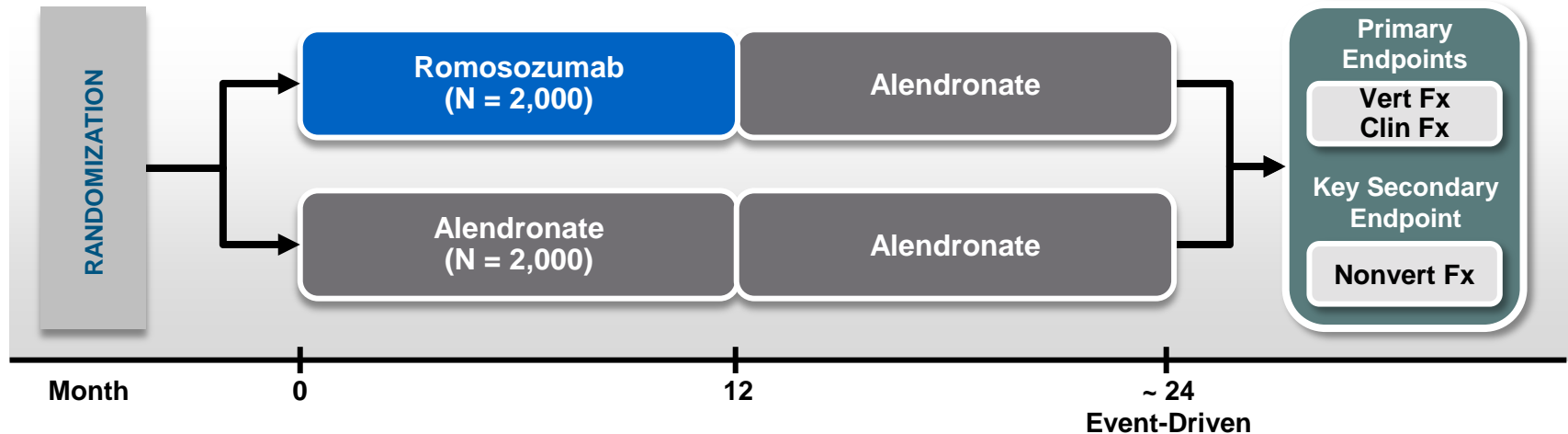


Co-Primary Endpoints	<ul style="list-style-type: none"> • New vertebral fractures at month 12 and 24
Secondary Endpoints	<ul style="list-style-type: none"> • Clinical fractures • Nonvertebral fractures • Major nonvertebral fractures • Major osteoporotic fractures

Data expected in H1 2016

Vert Fx = vertebral fracture; Nonvert Fx = nonvertebral fracture
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Romosozumab: Active Controlled Fracture Study In Postmenopausal Women With Osteoporosis at High Risk of Fracture



Co-Primary Endpoints

- Vertebral fractures at month 24
- Clinical fractures (event driven)

Secondary Endpoints

- Nonvertebral fractures
- Major nonvertebral fractures
- Major osteoporotic fractures (event driven)

Clin Fx = clinical fractures

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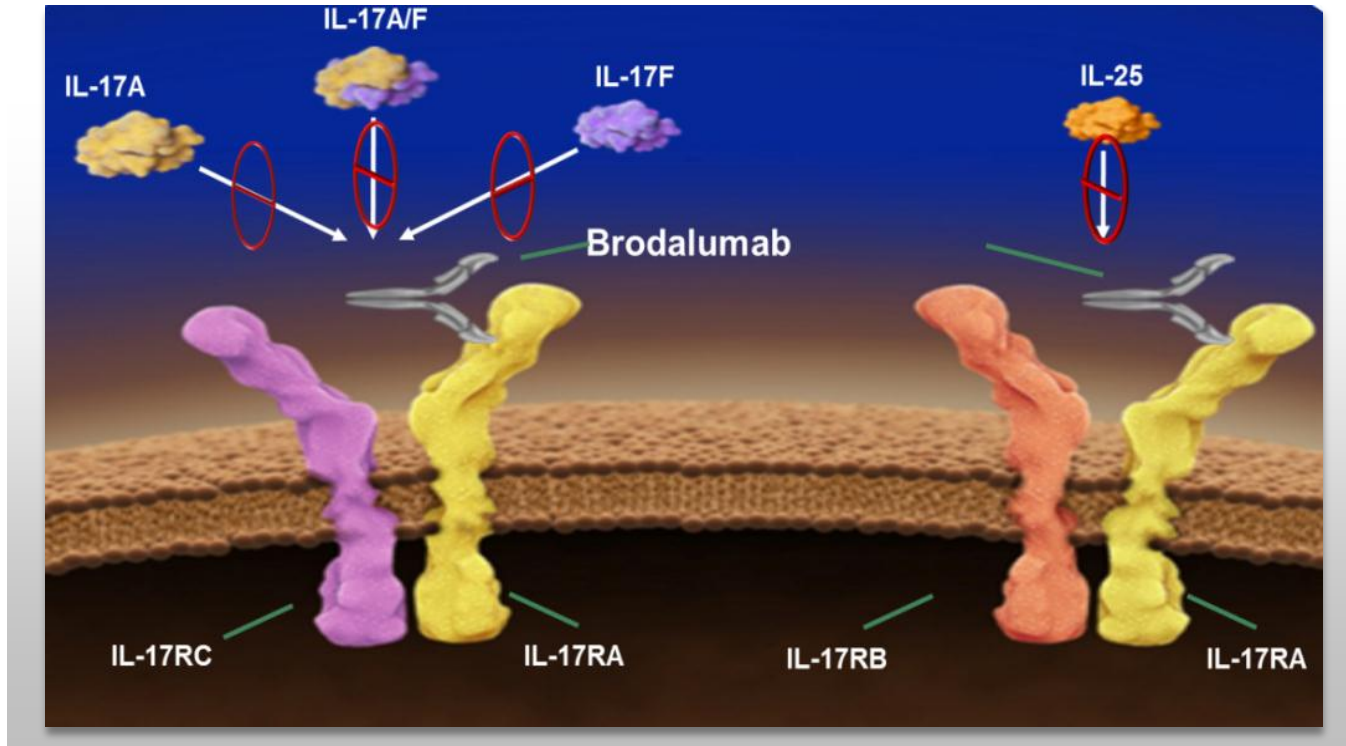
Amgen Inflammation



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Brodalumab

Brodalumab: A Human IL-17RA Monoclonal Antibody That Blocks the IL-17 Receptor



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Phase 3 Psoriasis Study of Brodalumab vs Placebo

Met All Primary and Secondary Endpoints

Patients Achieving Responses at Week 12

	PASI 75	PASI 90	PASI 100
210 mg Brodalumab	83.3%	70.3%	41.9%
140 mg Brodalumab	60.3%	42.5%	23.3%
Placebo	2.7%	0.9%	0.5%

- The most common adverse events that occurred in the brodalumab group (> 5% of participants) were nasopharyngitis, upper respiratory tract infection, and headache
- Serious adverse events occurred in 1.8% of patients in the 210 mg group and 2.7% of patients in the 140 mg group compared to 1.4% for placebo

Moderate-to-severe plaque psoriasis

Primary endpoints were patients achieving at least a 75% improvement from baseline in disease severity at week 12, as measured by the psoriasis area and severity index (PASI 75), and patients achieving clear or almost clear skin at week 12, according to the Static Physician's Global Assessment of Psoriasis (sPGA 0 or 1)

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Brodalumab Development Update

- **Moderate-to-severe plaque psoriasis**
 - Met all primary and secondary endpoints in placebo-controlled Phase 3 study
 - Two placebo-controlled studies of brodalumab vs ustekinumab expected in Q4 2014
- **Psoriatic arthritis**
 - Two placebo-controlled Phase 3 studies currently enrolling
- **Asthma**
 - Phase 2 study enrolling inadequately controlled subjects with high bronchodilator reversibility

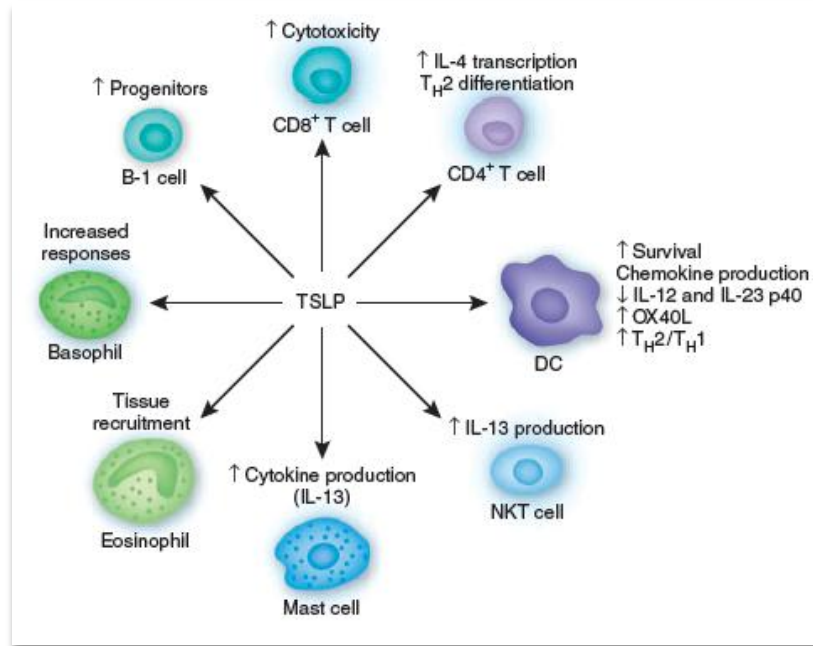


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AMG 157

AMG 157: A Human Monoclonal Antibody That Inhibits Thymic Stromal Lymphopoietin (TSLP)

- Promotes inflammation by influencing dendritic cell, mast cell, and lymphocyte populations
- Induced by disease exacerbating environmental factors and proinflammatory stimuli
- AMG 157 prevents signaling through the TSLP receptor complex



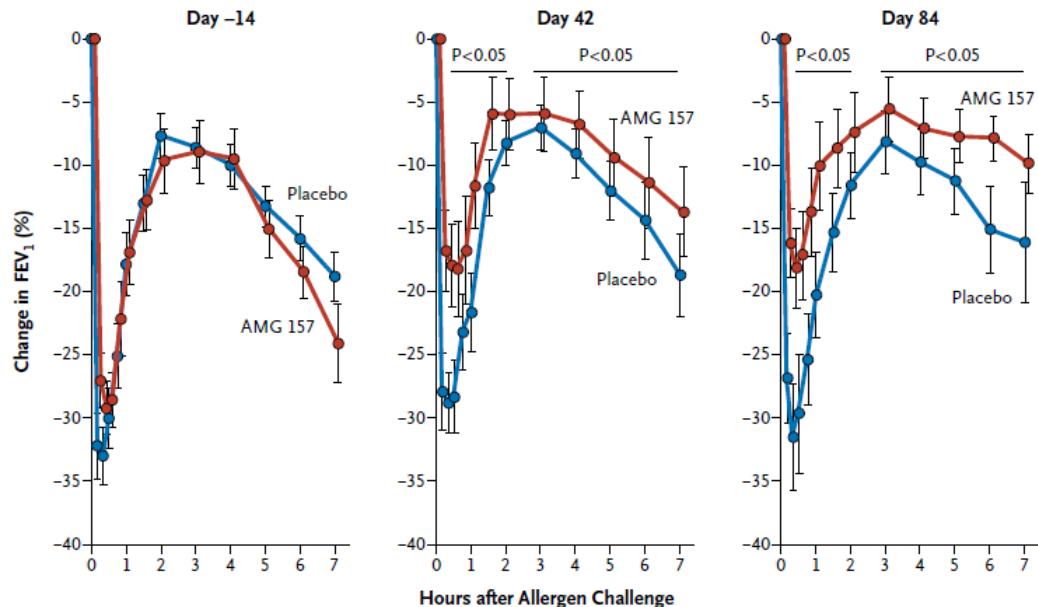
Nat Immunol. 2010;11(4):289-293

Partnered with AstraZeneca/MedImmune as Medi9929/AMG 157

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Phase 1: Encouraging Effect of AMG 157 On Allergen-Induced Asthmatic Responses

Allergen-Induced Percent Reduction In the Forced Expiratory Volume In 1 Second (FEV₁)



- Desirable changes observed in the following:
 - Eosinophil levels
 - Exhaled nitric oxide
 - Th2:Th1 ratio
- There were 15 adverse events in the AMG 157 group and 12 adverse events in the placebo group

Gauvreau, GM et al. *NEJM*. 2014.

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Amgen Neuroscience

AMG 334 Has the Potential to Address the Significant Unmet Need In Migraine Prophylaxis

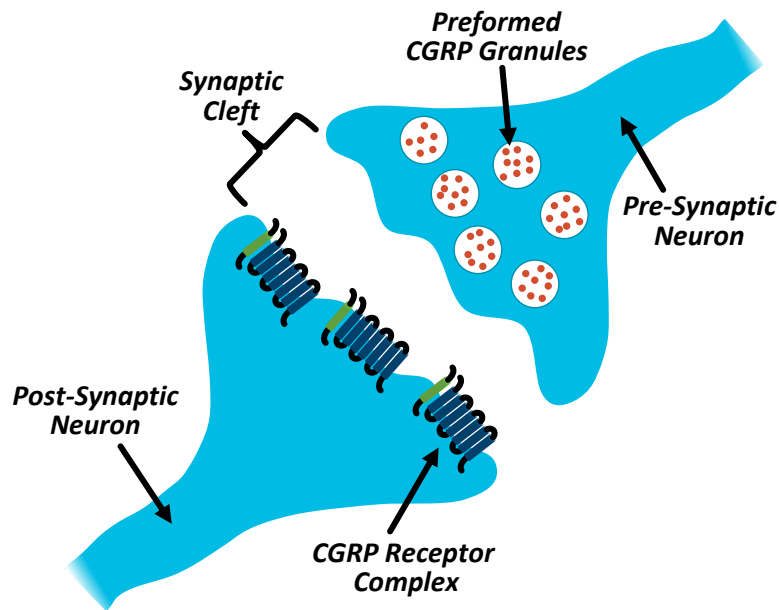
- ~ 26M Americans suffer from migraine,
~ 8M > 2 days/month^{1,2}
- Options for prophylaxis are limited by poor efficacy and significant side effects
- Migraine affects patients in prime working years
 - Most have reduced ability to function during the attack, one third require bed rest
 - Disability increases with increased attack frequency

1. Lipton RB, et al. *Neurology*. 2007;68:343-349.

2. Lipton RB, Chronic Migraine, Classification, Differential Diagnosis, and Epidemiology. *Headache: The Journal of Head and Face Pain*. 2011;51:77-83.

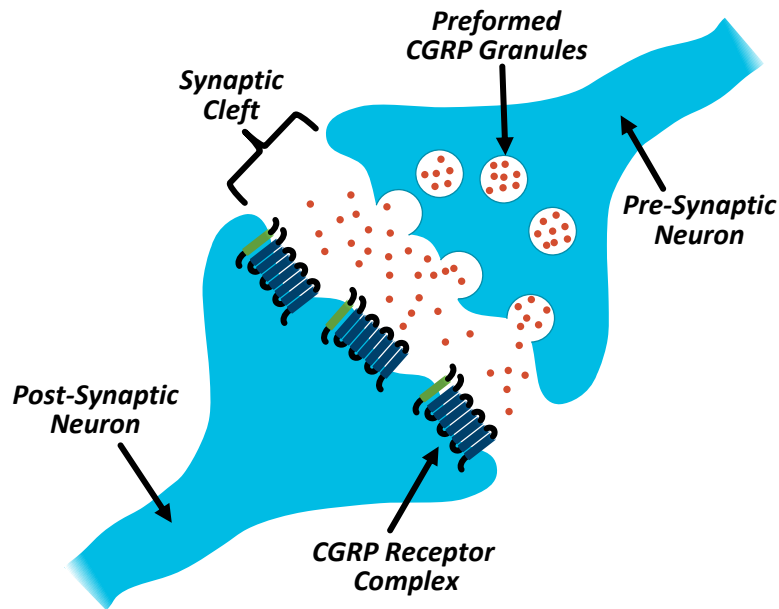
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AMG 334: Only CGRP Receptor Monoclonal Antibody in the Clinic



- **CGRP is a validated target for migraine**
- **CGRP receptors at interface of neurovascular junction**
- **Receptor antagonism is independent of CGRP release and concentration**
- **Currently in Phase 2b for episodic and chronic migraine**
 - **Dosed monthly**
 - **Data from episodic study expected in Q4 2014**

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Amgen Oncology

Amgen Oncology Portfolio

Immuno-Oncology

- **Talimogene laherparepvec**
 - Metastatic melanoma
- **Blinatumomab**
 - Relapsed/refractory B-precursor ALL

Multiple Myeloma

- **XGEVA® (denosumab)**
- **Kyprolis® (carfilzomib)**
- **Oprozomib**

mCRC = metastatic colorectal cancer

AML = acute myeloid leukemia

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Solid Tumors

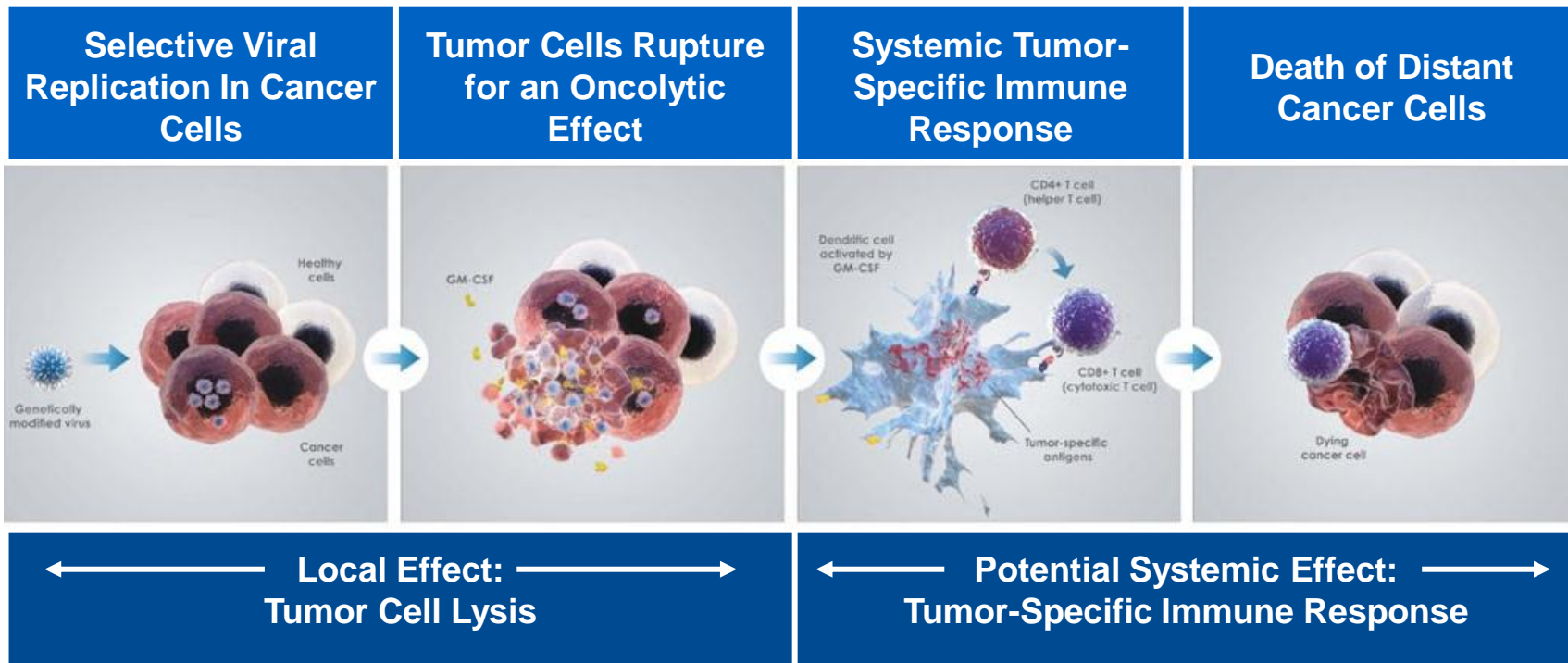
- **Vectibix® (panitumumab)**
 - mCRC
- **XGEVA® (denosumab)**
 - Adjuvant breast cancer
- **Rilotumumab and AMG 337**
 - MET-positive (rilotumumab) and MET-amplified (AMG 337) gastric cancer
- **Trebananib**
 - Ovarian cancer
- **AMG 232**
 - Solid tumors and AML



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Talimogene Laherparepvec

Talimogene Laherparepvec



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Talimogene Laherparepvec Development Program

- Submitted in US and EU for the treatment of regionally or distantly metastatic melanoma
- Combination Phase 1b melanoma study with ipilimumab (N = 18)
 - Overall response 56% (95% CI: 31%–79%)
 - Complete response 33%; Partial response 22%
 - No unexpected toxicities identified
 - Most common AEs were chills, fever, rash, and fatigue
 - Progressing in Phase 2
- Phase 1b/2 melanoma study with pembrolizumab initiated
- Head and neck study with pembrolizumab in design phase

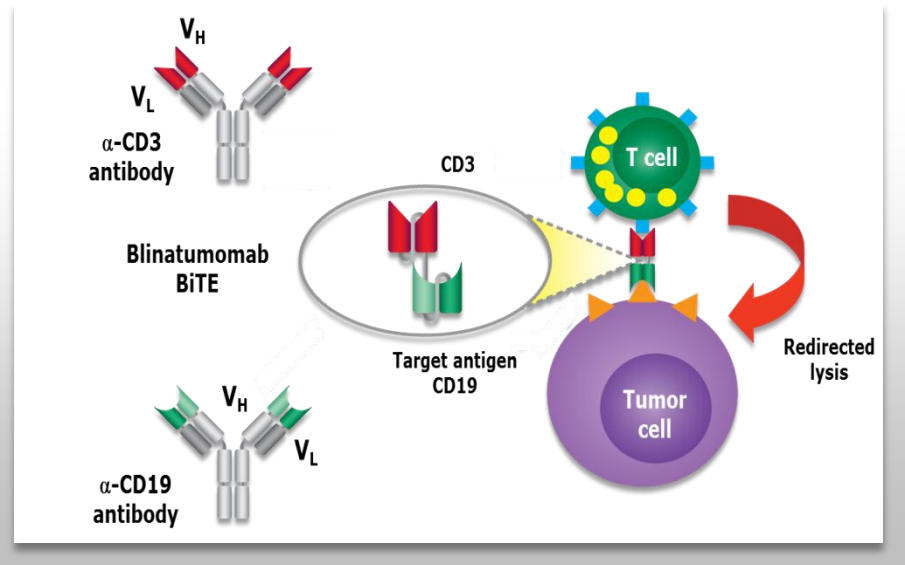


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Blinatumomab

Blinatumomab: Potential to Address Significant Unmet Need In Relapsed/Refractory ALL

Blinatumomab Is a BiTE® Antibody Construct That Directs Cytotoxic T Cells to CD-19 Expressing Cancer Cells



- The average 5-year survival rate for adult ALL patients after first relapse is 7%*
- Breakthrough therapy designation granted by FDA
- US and EU submissions completed
- Under priority review by FDA

Bargou R, et al. *Science*. 2008;321:974-977.

*Fielding A, et al. *Blood*. 2007;109:944-950.

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Confirmatory Phase 2 Study of Blinatumomab In Adult Patients With Relapsed/Refractory B-Precursor ALL

Hematologic and Molecular Remission Rates Within Two Cycles of Treatment

	%
Complete response/complete response with partial hematologic recovery* (primary endpoint)	43
Complete response (CR)	33
Complete response with partial hematologic recovery (CRh)	10
MRD response during first two cycles CR/CRh*†	82
Hematopoietic stem cell transplant after CR/CRh*	40

- Most frequent grade \geq three adverse events were febrile neutropenia (25%), neutropenia (16%), and anemia (14%)
- Serious adverse events included cytokine release syndrome and nervous system adverse events
- Three (2%) patients had grade 5 adverse events considered possibly treatment related (sepsis, n = 2; candida infection, n = 1)

* \leq 5% blasts in the bone marrow, no evidence of circulating blasts or extramedullary disease, partial recovery of peripheral blood counts (at least platelets $> 50,000/\mu\text{L}$, and ANC $> 500/\mu\text{L}$); †MRD = minimal residual disease $< 10^{-4}$ by polymerase chain reaction (PCR)

Topp M, et al. ASCO Annual Meeting, 2014

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Key Blinatumomab Clinical Development Programs

- **B-precursor ALL**
 - Adult relapsed/refractory—Phase 3
 - Adult relapsed/refractory Philadelphia-positive—Phase 2
 - Pediatric relapsed/refractory—Phase 1/2
 - Adult frontline—Phase 3
 - Minimal residual disease positive—Phase 2
- **Diffuse large B-cell lymphoma**
 - Adult relapsed/refractory—Phase 2

Innovative Programs With Key Readouts

Product	Indication	'14	'15	'16	'17
Brodalumab	Psoriasis (PsO) Psoriatic arthritis (PsA)	★ Phase 3 PsO vs Ustekinumab		★ Phase 3 PsA	
AMG 334	Migraine prophylaxis	★ Phase 2b Episodic		★ Phase 2b Chronic	
Trebananib	Ovarian cancer	★ Phase 3 Recurrent OS*	★ Phase 3 1st-Line PFS*		
Blinatumomab	B-precursor ALL	★ Phase 2 Adult MRD+*		★ Phase 3 Adult R/R*	
Omecamtiv mecarbil	Heart failure		★ Phase 2b Oral		
AMG 416	Secondary hyperparathyroidism		★ Phase 3 vs Cinacalcet		
Rilotumumab	Gastric cancer		★ Phase 3*		
Evolocumab	Dyslipidemia			★ Phase 3 Imaging	★ Phase 3 Outcomes*
Romosozumab	Postmenopausal osteoporosis			★ Phase 3 vs Placebo	★ Phase 3 vs ALN
Talimogene laherparepvec	Melanoma			★ Phase 2 + Ipilimumab	★ Phase 2 + Pembrolizumab
Kyprolis®	Multiple myeloma			★ Phase 3 2nd-Line MM vs Bortezomib*	★ Phase 3 1st-Line MM vs Bortezomib*

OS = overall survival; PFS = progression-free survival; *Event-driven

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Projected Data Availability