Global Drug Development

Development Update

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Neither can there be any guarantee that Novartis will be able to realize any of the potential strategic benefits, synergies or opportunities as a result of the significant reorganizations of recent years, including the creation of the Pharmaceuticals and Oncology business units to form the Innovative Medicines Division, the creation of the Global Drug Development organization and Novartis Operations (including Novartis Technical Operations and Novartis Business Services), the transfer of the Ophthalmic Pharmaceuticals products of our Alcon Division to the Innovative Medicines Division, the transfer of selected mature, non-promoted pharmaceutical products from the Innovative Medicines Division to the Sandoz Division, and the transactions with GSK, Lilly and CSL. Neither can there be any guarantee that shareholders will achieve any particular level of shareholder returns. Nor can there be any guarantee that the Group, or any of its divisions, will be commercially successful in the future, or achieve any particular credit rating or financial results. In particular, management’s expectations could be affected by, among other things: regulatory actions or delays or government regulation generally; the potential that the strategic benefits, synergies or opportunities expected from the significant reorganizations of recent years, including the creation of the Pharmaceuticals and Oncology business units to form the Innovative Medicines Division, the creation of the Global Drug Development organization and Novartis Operations (including Novartis Technical Operations and Novartis Business Services), the transfer of the Ophthalmic Pharmaceuticals products of our Alcon Division to the Innovative Medicines Division, the transfer of selected mature, non-promoted pharmaceutical products from the Innovative Medicines Division to the Sandoz Division, and the transactions with GSK, Lilly and CSL may not be realized or may take longer to realize than expected; the inherent uncertainties involved in predicting shareholder returns or credit ratings; the uncertainties inherent in the research and development of new healthcare products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products which commenced in prior years and will continue this year; safety, quality or manufacturing issues; global trends toward health care cost containment, including ongoing pricing and reimbursement pressures, such as from increased publicity on pharmaceuticals pricing, including in certain large markets; uncertainties regarding actual or potential legal proceedings, including, among others, actual or potential product liability litigation, litigation and investigations regarding sales and marketing practices, intellectual property disputes and government investigations generally; general economic and industry conditions, including uncertainties regarding the effects of the persistently weak economic and financial environment in many countries; uncertainties regarding future global exchange rates; uncertainties regarding future demand for our products; and uncertainties regarding potential significant breaches of data security or data privacy, or disruptions of our information technology systems; and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this presentation as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

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Development priorities

Creating an efficient and agile Development organization

Delivering late stage pipeline: 13 potential blockbusters

Advancing high value, mid stage opportunities

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Strong track record of R&D Excellence

Deep pipeline

200+ projects in the clinic

90+ NMEs in the clinic

High innovation power

13 FDA Breakthrough Therapy designations in the last 5 years

7 FDA Fast Track designations in 2016

Leading success rate

29 approvals[1] in the last 5 years

1. Includes only first approvals for a compound in an indication in any major region/country

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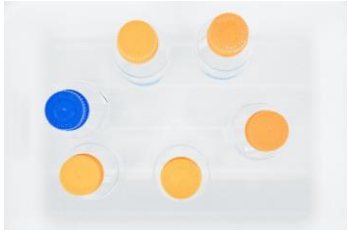
However, we see an opportunity to achieve a step change in performance



Better
portfolio prioritization

Leveraging new
technology

Driving efficiency
and lowering our
cost base

New generation of
leadership

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Creating an efficient and agile organization

5 priorities

Priorities

1. Rigorous portfolio prioritization
2. Measuring performance
3. Driving operational efficiencies
4. Leveraging new technology & capabilities
5. Investing in our people

- Higher return on investment
- Leading cost efficiency
- 20% sustainable R&D spend in Innovative Medicines

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Rigorous disease area and portfolio prioritization

1. Rigorous portfolio prioritization

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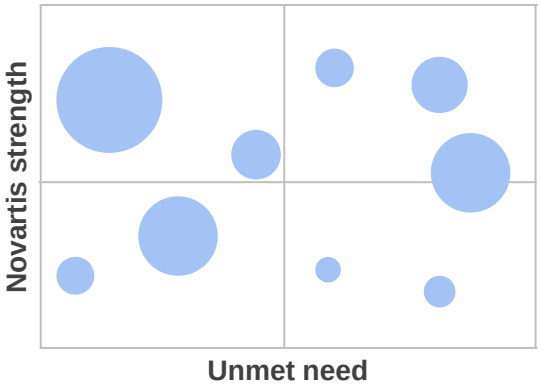
Disease area reviews

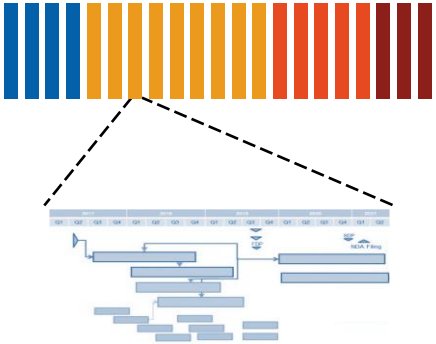


- Evaluation of disease areas, decision on future focus
- Examples: Prioritized liver diseases, de-prioritized transplant

Project prioritization

- Evaluation based on science, risk, and valuation
- Retired 25+ projects based on prioritization; partnering ongoing

Resource allocation



- Consistent with priority categories
- 70% of resources focused on top projects

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Consistent measurement of R&D performance

2. Measuring performance

Metric	Measure	Trend
Output	NMEs, Approvals	Leading
Cycle Times	By Phase, Total cycle time	Leading
Costs	Total spend, cost per NTD	Improving
Quality	Peak sales per NTD, 1st in Class, Late in Class	Improving
Returns	Freshness, Replacement Power, 3/5/10 Return on R&D spend[1]	Improving

1. 3-, 5- and 10-year return as measured by peak sales of new therapeutic drugs divided by R&D spend

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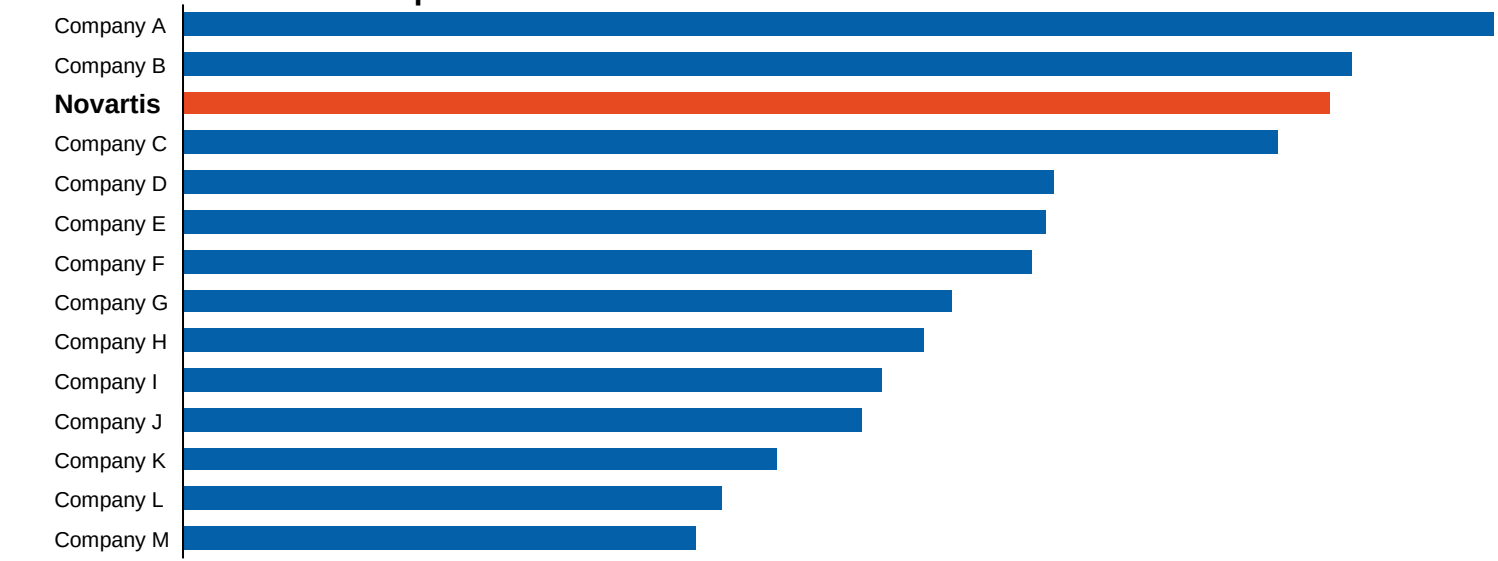
Novartis performs well on replacement power – critical measure

2. Measuring performance

Estimated 2022 sales from products launched between 2010-22



Note: Innovative medicine (incl. biosimilar) product sales excl. vaccines and LCM products (e.g. new formulations, combo's with off-patent molecules); compound-based analysis (marketed, Phase 2 and 3) with add. indications allocated to 1st launch. Source: Novartis peer group analysis based on data from Evaluate Pharma (download from January 16, 2017)

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Driving operational performance across an integrated organization

3. Driving operational efficiencies

Integrated operations
- Harmonized processes
- Driving synergies

Leveraging global scale
- Procurement
- Low cost centers

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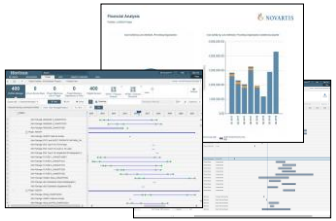
Leveraging leading technology

4. Leveraging new technology & capabilities



Upgrading core systems

- Among largest and most ambitious initiatives in the industry
- Spanning across all resource, document, trial management systems

Scaling digital development

- Establishing advanced, big data analytics and machine learning
- 15+ studies with digital sensors[1]
- 20+ partnerships with digital firms and academic institutions

1. Ongoing or recently completed studies involving digital innovations

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Key external hires to complement strong leadership team

5. Investing in our people

Recent external hires

Eric Hughes

Badhri Srinivasan

Christine Dingivan

Subodh Deshmukh

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Broad and deep late stage pipeline

Selected key assets

Oncology

BYL719+fulv.
CTL019 Ped. ALL+ DLBCL
INC280[2] NSCLC
Jakavi®[2] (Multiple)
LEE011[3] (Multiple)
PKC412 (Multiple)
SEG101 Sickle cell disease
Signifor® LAR Cushing's disease
Tafinlar®+Mekinist® BRAF V600+ NSCLC
Tafinlar®+Mekinist® BRAF V600+ melanoma (adjuvant)
Tasigna® CML treatment free remission
Zykadia® ALK+ NSCLC (brain metastases)

Cardio-Metabolic

RLX030 Acute heart failure
LIK066 Weight loss
ACZ885 CV risk reduction
Entresto® (Multiple)

Ophthalmology

RTH258 (Multiple)
Lucentis® ROP
UNR844 (Presbyopia)

Respiratory

QAW039 Asthma
QMF149 Asthma
QVM149 Asthma

Neuroscience

AMG 334 Migraine
OMB157 Relapsing MS
BAF312 SPMS
CNP520 Alzheimer's disease
EMA401 Neuropathic Pain
CAD106 Alzheimer's disease
FTY720 Pediatric MS
BYM338 Multiple

Immunology & Dermatology

Cosentyx® (Multiple)
VAY736 Prim. Sjoegren's syndr.
Ilaris® Periodic fever syndr.
Emricasan[1] NASH
LJN452 NASH
ZPL389 Atopic dermatitis

Biosimilars

Adalimumab
Pegfilgrastim
Epoetin-alfa
Rituximab
Infliximab
Etanercept

In addition, ~100 projects (70+ NMEs) in exploratory clinical studies

[1] Option to license in [2] licenced in from Incyte [3] "LEE011 was developed by the Novartis Institutes for BioMedical Research (NIBR) under a research collaboration with Astex Pharmaceuticals

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Progressing development of 13 potential blockbusters[1] at Novartis

Onco | CM | NS | I&D | Resp | Oph | Bios

Therapeutic area	Molecule	Indication	MoA	Exp. pivotal trial readout	Exp. order of entry	Potential target population
Oncology	**LEE011** (ribociclib)	HR+ HER2- advanced breast cancer	CDK4/6 inhibitor	✓	2	~0.2m (US, EU)[4]
	CTL019 (CART-T)	r/r B-Cell ALL, DLBCL	CART-T	Q2 2017[6]	1	~0.05m (US, EU)
	SEG101 (crizanlizumab)	Sickle cell pain crises	Anti-P-selectin	2020	1	~0.3m (US, EU, BRA)
Cardio-metabolic	**RLX030** (serelaxin)	Acute heart failure	Relaxin receptor agonist	Q2 2017	1	~1.2m (US, EU5)
	LCZ696 (Entresto®)	Heart failure with preserved EF	ARNI	2019	1	~4.2m (US, EU5)
	ACZ885 (canakinumab)	CV risk reduction	Anti-IL1β	H2 2017	1	~4m (G7)
Neuroscience	**OMB157** (ofatumumab)	Relapsing multiple sclerosis	CD20	2019	2	~0.6m (US, EU5)
	BAF312 (siponimod)[2]	Secondary progressive multiple sclerosis	S1P receptor modulator	✓	1	~0.3m (US, EU5)
	AMG 334 (erenumab)[3]	Prophylaxis of migraine	CGRP receptor antagonist	✓	1	~2.3m (EU5)
Immunology& Dermatology	**AIN457** (Cosentyx®)	Non-radiographic axial SpA	Anti-IL17A	2018	1	~1.1m (US, EU5)
Respiratory	**QVM149** (indacaterol, glycopyrronium, mometasone)	Asthma	LABA + LAMA + ICS	2018	1	~7.0m (EU5+JP)
	QAW039 (fevipiprant)	Asthma	CRTh2 antagonist	2019	1	~4.0m (G7)
Ophthalmology	**RTH258** (brolucizumab)	Neovascular AMD	Anti-VEGF (scFv)	H1 2017	3	~0.9m (US, EU, JP)[5]
Biosimilars	**Multiple**	Multiple	Multiple	Ongoing	Varying	Varying

1. Blockbuster potential refers to specified indication 2. Next steps to be evaluated in consultations with health authorities 3. In collaboration with Amgen; Novartis has AMG 334 rights outside of US, Canada and Japan 4. Kantar Health; Novartis analyses 5. Rudnicka et al. Am. J. Ophthalmol. 2015 Jul; 160(1):85-93.e3; Brown et al. Can J Ophthalmol. 2005 Jun;40(3):277-87; – Yasuda M et al. Ophthalmology. 2009 Nov;116(11):2135-40. doi: 10.1016/j.ophtha.2009.04.017. Epub 2009 Sep 10; Novartis analyses 6. Ped. r/r B-cell ALL positive trial readout achieved in 2016; Note: sources for epidemiology information can be found in the respective sections

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Oncology

Onco
CM
NS
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Oph
Bios

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LEE011 - advancing across indications for HR+/HER2- advanced breast cancer

Trial	Indication	Status	Planned next milestone
MONALEESA-2	1st Line in combination with Letrozole	US submission (Priority Review) EU submission	US regulatory decision Q2 EU regulatory decision H2
MONALEESA-3	1st & 2nd line in combination with Fulvestrant	Fully enrolled; readout H2 2017	Filing early 2018 if positive
MONALEESA-7	Pre-menopausal women 1st line in combination	Fully enrolled; readout H1 2018	Filing in H2 2018 if positive
Adjuvant Trials	High risk of recurrence trial Medium risk of recurrence trial	Trial initiation	Trials to start in 2017

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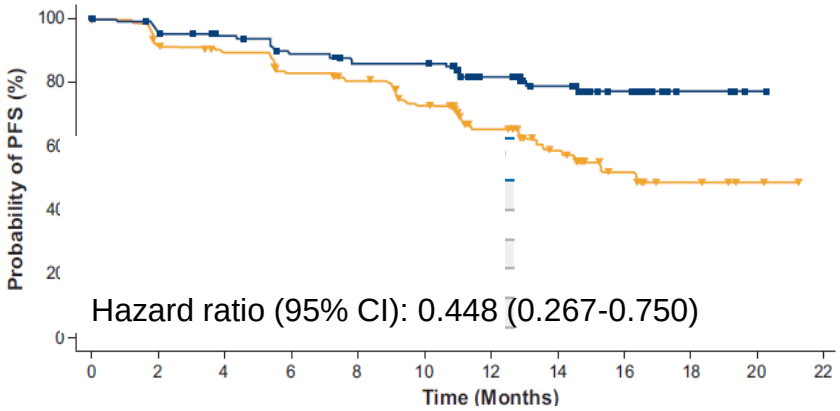
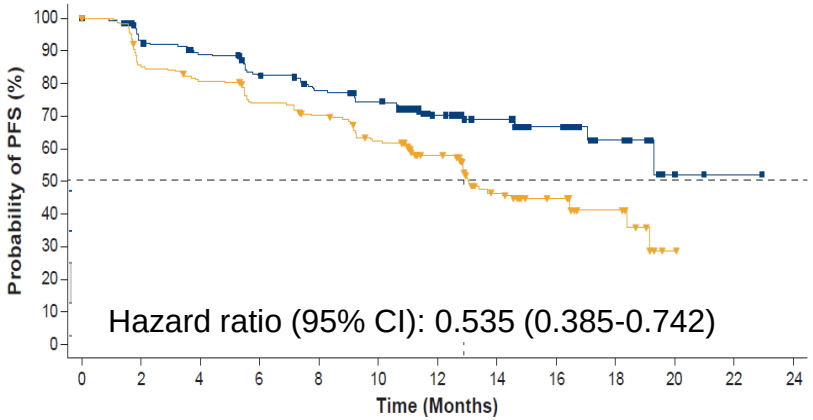
LEE011 + letrozole showed superior PFS vs. letrozole in pre-defined subgroups

Locally Assessed Progression-free Survival in Patients With *De Novo* Advanced Breast Cancer[1]



Progression-free Survival in Patients With Visceral Metastases[2]



1. O'Shaughnessy J., presented at San Antonio Breast Cancer Symposium (SABCS), December 9, 2016, San Antonio, Texas (abstract # P4-22-05) 2. Burris H., presented at San Antonio Breast Cancer Symposium (SABCS), December 9, 2016, San Antonio, Texas (abstract # P4-22-16)

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Safety profile with quickly identifiable, manageable and reversible side effects

Key risks	Exposure related?	Frequency of severe cases	Time to onset[1]
Neutropenia	Yes	~60% grade 3/4	~15 days
QT prolongation	Yes	11 pts (3.3%) with QTcF[2] >480 ms	~15 days (no worsening over time)
Hepatobiliary toxicity	No	4 (1.2%) Hy's Law cases, all reversible	within first 6 months

- Only 7.5% of patients discontinued treatment due to adverse events
- Dose reduction or discontinuation effective in managing adverse events

1. Median in patients with events 2. QT interval corrected according to Fridericia

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Proposed monitoring unlikely to pose additional burden for patients

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Pending approved label

Visits	Cycle 1 Day 1	Cycle 1 Day 15	Cycle 2 Day 1	Cycle 2 Day 15	Cycle "X" Day 1
Neutropenia monitoring currently approved agent	X	X	X	X	X
Proposed EKG[1] monitoring	X	X	X		
Proposed Liver enzyme monitoring		X	X	X	X

1. EKG = Electrocardiography

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CTL019 - data support US submission for pediatric and young adult r/r B-cell ALL in Q1 2017

ELIANA Phase II trial results

Interim efficacy analysis set (N=50)	Response rate (%)	95% CI	*p*-value
Overall remission rate (CR+CRi) within 3 months	**82**	69, 91	*<0.0001†*
Best overall response (BOR)			
CR	**68**		
CRi	**14**		

- Current **prevalence**[1] of ped. ALL ~7,000;
  - Potentially eligible patients 2nd line ~1,100 / 3rd line ~700
- **Met primary endpoint** with strong overall response rate (CR/CRi 82%)
- **Acceptable safety profile** with no deaths due to cytokine release syndrome or neurologic toxicities and no cases of cerebral edema reported
- Planned US BLA submission in Q1 2017
- Filing in Europe targeted for late 2017

MRD negative = MRD <0.01%
†One-sided exact p-value threshold 0.0057 (adjusted for interim). Null hypothesis of ORR ≤20% statistically tested and rejected before testing and rejecting null hypothesis of MRD negative remission rate ≤15%.
Source: Grupp, Stephen A. et al. Session 614, December 3, 2016. 58th American Society of Hematology Annual Meeting and Exposition: Abstract 221.
Abbreviations: r/r ALL = relapsed/refractory acute lymphoblastic leukemia; BOR = best overall response; CR = complete remission; CRi = complete remission with incomplete blood count recovery; MRD = minimal residual disease
CI = Confidence interval 1. Prevalence data for US, EU incl. Israel, Canada and Japan; sources: Surveillance, Epidemiology, and End Results Program (SEER); Decision Resources; Novartis analysis

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DLBCL[1] pivotal readout and submission planned for 2017

JULIET Phase II trial (3rd line r/r DLBCL)

- Treatment of 80 patients completed
- Interim analysis of 50 patients with 3 months follow-up planned for Q1 2017
- Primary analysis of 80 patients with 3 months follow-up planned for Q2 2017

Additional program information

- Current DLBCL prevalence ~56,000
  - Potentially eligible patients 2nd line ~25,000 / ≥3rd line ~19,000
- Submissions in US and EU planned in Q4 2017[2]

1. DLBCL = Diffuse large B-cell lymphoma 2. For relapsed/refractory DLBCL (≥3rd line) Epidemiology data for US, EU incl. Israel, Canada and Japan; sources: Surveillance, Epidemiology, and End Results Program (SEER); Decision Resources; Novartis analysis

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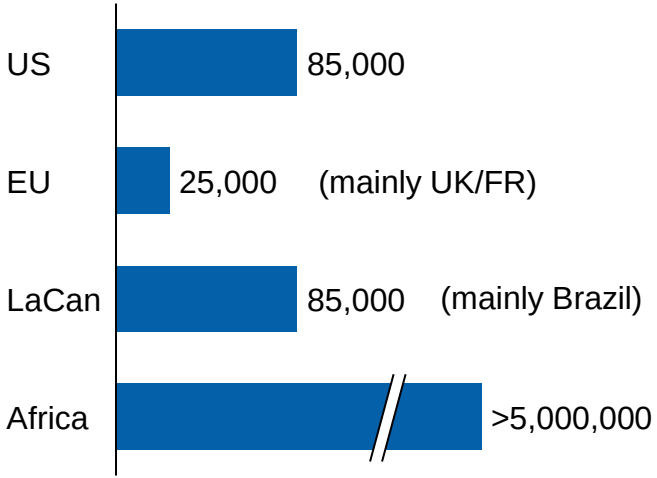
SEG101 (crizanlizumab) – potentially first therapy in over 15 years to address pain crises in Sickle Cell disease

Prevalence[1]



Unmet need

- **Early mortality**: Reduced life expectancy - median age at death 38-42 years[2]
- **Diminished quality of life** due to pain with patients reporting pain in over 50% of days[3]
- Hydroxyurea only approved therapy, but many patients **continue to experience acute painful episodes**; only ~25% on therapy

1. Chaturvedi et al. Am. Journal of Hematology, 91(1), 2016; Piel et al. PLoS Med 10(7): e1001484. doi:10.1371/jounal.pmed.1001484; Gluckman (eurocord) 2013; Novartis analyses 2. Public Health Reports / March–April 2013 / Volume 128
3. J Natl Med Assoc. 2005 Feb; 97(2): 183–193.

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SEG101 significantly reduced Sickle Cell Disease Pain Crises (SCPC)

Results from Phase II SUSTAIN trial

Event	SEG101* (n=67)	Placebo (n=65)	Difference from placebo	*P* value
Median annual rate of pain crises	1.63	2.98	-45.3%	0.010
Median time to first pain crisis (months)	4.07	1.38	+2.9x	0.001
Median time to second pain crisis (months)	10.32	5.09	+2.0x	0.022
Median annual rate of uncomplicated pain crises	1.08	2.91	-62.9%	0.020
Median annual rate of days hospitalized	4.0	6.9	-42%	0.450
N of pts with SCPC rate of zero at end of study	24	11	+2.2x	-

- **Antibody to P-selectin** blocking adhesion of platelets and red blood cells
- Similar effect **regardless of concomitant hydroxyurea usage** or SCD genotype
- Generally **well tolerated**
- Meetings planned with FDA, EMA in early 2017 to discuss next steps

* SEG101 (formerly SelG1) 5mg/kg monthly Source: Ataga et al, NEJM Dec 3, 2016 (online)

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Cardio-metabolic

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Oph Ophthalmology	RTH258 (brolucizumab)	Neovascular AMD	Anti-VEGF (scFv)	H1 2017	3	~0.9m (US, EU, JP)[5]
Bios Biosimilars	Multiple	Multiple	Multiple	Ongoing	Varying	Varying

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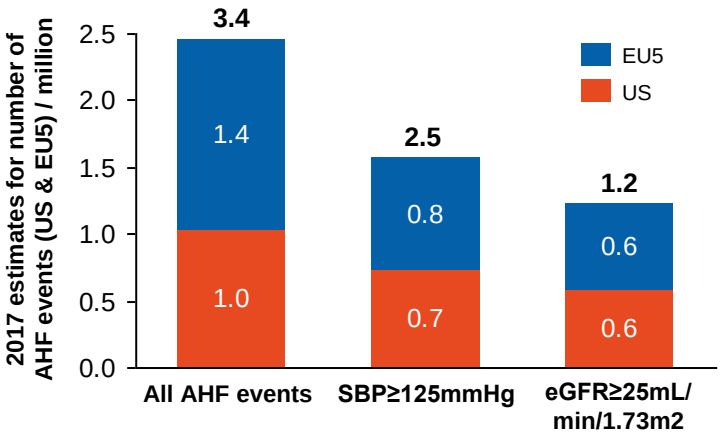
NOVARTIS

RLX030 for Acute Heart Failure addresses a significant unmet need; on track for Q2 readout

Acute Heart Failure Incidence



RLX030 potential first-in-class therapy

- **High mortality**: ~10% in hospital, ~15% in 6 months, 20% in 1 year and 50% in 5 years
- No approved therapies with outcomes benefits
- Targets relaxin receptor to stimulate vasodilation in a range of tissues
- **RELAX-AHF-2** trial fully enrolled (6,610 patients) and on track to read out in Q2 2017
  - Primary endpoints: CV death through Day 180 and worsening heart failure at Day 5

Source: Decision Resources Patient Base 2016; estimates for SBP and eGFR based on patient population studied in RELAX-AHF-2 trial – potentially eligible population pending final label
Abbreviations: AHF=acute heart failure; CV=cardiovascular; eGFR=estimated glomerular filtration rate; SBP=systolic blood pressure

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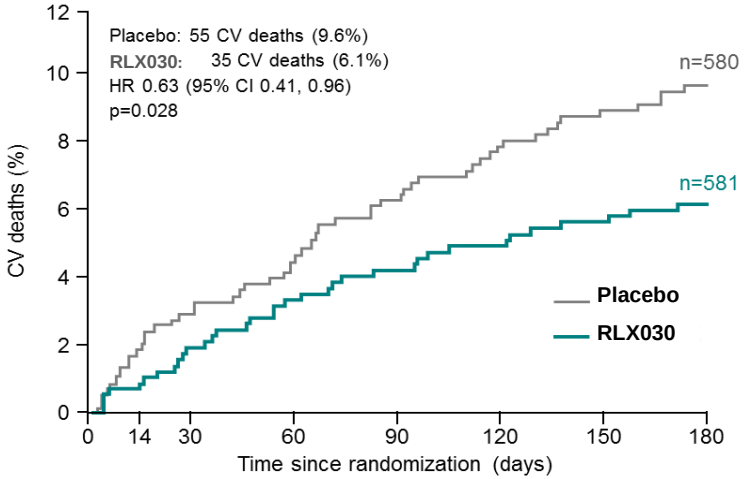
Early and significant reduction in CV mortality observed in RELAX-AHF trial

RELAX-AHF: CV deaths through Day 180



- Significant reduction in all-cause and CV mortality through Day 180
- Benefit seen as early as Day 5
- Favorable safety and tolerability profile compared with placebo

Teerlink et al. Lancet 2013;381:29–39

NOVARTIS

Totality of Phase II/III efficacy data supports potential beneficial effects of RLX030

Efficacy Parameter	Measure	Statistically significant result favoring RLX030
Relief of Dyspnea	VAS, PCWP, mPAP	✓
Decreased Length of Stay	Hospital stay, ICU stay	✓
Prevention of WHF	Day 5 Hazard Ratio	✓
Reduction of Organ Damage (Day 2)	Troponin-T, Cystatin-C, NT-proBNP, Creatinine	✓
Reduction of Mortality	Survival	✓
Re-hospitalization for Heart Failure or Renal Failure	Re-admission	Neutral for RLX030

VAS=visual analogue scale, PCWP=pulmonary capillary wedge pressure, mPAP=mean pulmonary artery pressure

NOVARTIS

Entresto® - investigating potential treatment for ~9m chronic HF patients without effective therapy

	Chronic Heart Failure		
	HF-rEF (Approved)	HF-pEF	Post-AMI
Potentially eligible patients[1]	~8.5m	~8.5m	~0.3m
Pivotal trials	PARADIGM	PARAGON	PARADISE
Key supportive trials	TRANSITION PIONEER HF		

1. Potential patients are defined by the indications studied in the ongoing / planned trials in HFpEF and post acute MI. Potentially eligible population dependent on trial results and label. Estimate for US+EU5 is ~4.2m Current estimates based on Decision Resources; Diller et al. Archives of Family Medicine. 1999; 8(5):414-420; Novartis analyses;
Abbreviations: HF-rEF=heart failure-reduced ejection fraction; HF-pEF=heart failure-preserved ejection fraction; AMI=acute myocardial infarction

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Entresto® - expansion studies all on track

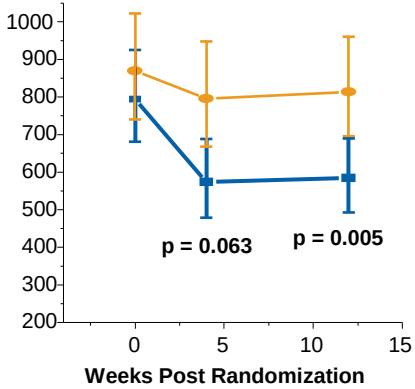
Trial	Indication	Status	Next expected milestone
PARAGONHF	HF-pEF[1]	Fully enrolled 4 months ahead of plan	Interim analysis 2018 Filing in 2019
PARADISE-MI	Post-AMI[2]	Enrolling	Completion 2019 Filing in 2020
TRANSITION	Pre- vs. post-discharge following ADHF (HF-REF)	Enrollment on track	Completion 2018
PIONEERHF	In hospital initiation vs. Enalapril following ADHF[3]	Enrollment on track	Completion 2018

1. HF-pEF: heart failure with preserved ejection fraction 2. AMI: acute myocardial infarction 3. ADHF: acute decompensated heart failure

Entresto® - PARAMOUNT Phase II data[1] strongly support potential of PARAGON trial in HF-pEF

Hemodynamic

Cardiac stress – prognostic of outcome[2]

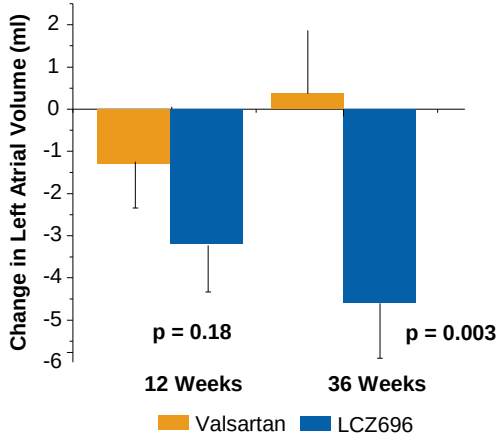


Prim. Endpoint: NT-proBNP

23% reduction by week 12

Structural

Left ventricular pressures – prognostic of outcome[3]



Sec. Endpoint: Atrial size

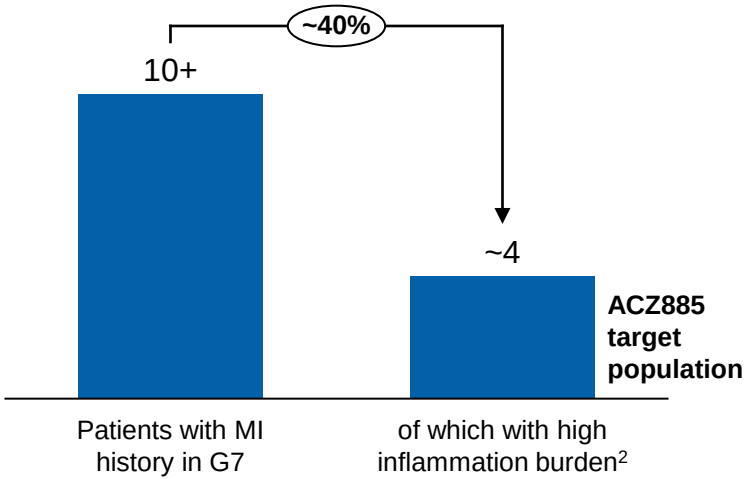
7.6% reduction by week 36

1. Solomon et al. LANCET 2012 2. Komajda 2011; Anand 2003; Massie 2008; 3.Zile 2011; Brenyo 2011; Meris 2009; Geris 2007

NOVARTIS

ACZ885 could address the need for anti-inflammatory therapies to lower CV risk post MI

Post-MI Prevalence[1] in millions



Unmet Need: Moving beyond LDL

- New approaches to reduce excess mortality
- Addressing inflammation's role in plaque formation and disruption
- Addressing other genetically validated risk factors
  - Lp(a)
  - ApoCIII / Triglycerides

1. US AHA (Heard Disease & Stroke Stats 2016 update – e255), EU5 & JP Kantar Health EPI database 2. CANTOS trial baseline

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CANTOS has reached the protocol defined number of events, on track for mid-2017 readout

CANTOS trial design

Population	• History of MI • hsCRP≥2mg/L • On SoC treatment
Primary endpoint	• Composite of CV death, MI or Stroke
Key secondary endpoints	• Primary + unplanned revascularization • New onset of Type 2 Diabetes
Sample size	• 1,400 primary events provides ~90% power to detect 20% RRR *vs*. placebo • 10,065 patients randomized

On track for readout mid-2017

- 1,400 events reached as agreed with regulatory authorities
- Passed 3 futility analyses and 20 DMC safety reviews

NOVARTIS

Neuroscience

Onco | CM | NS | I&D | Resp | Oph | Bios

Therapeutic area	Molecule	Indication	MoA	Exp. pivotal trial readout	Exp. order of entry	Potential target population
Oncology	LEE011 (ribociclib)	HR+ HER2- advanced breast cancer	CDK4/6 inhibitor	✓	2	~0.2m (US, EU)[4]
	CTL019 (CART-T)	r/r B-Cell ALL, DLBCL	CART-T	Q2 2017[6]	1	~0.05m (US, EU)
	SEG101 (crizanlizumab)	Sickle cell pain crises	Anti-P-selectin	2020	1	~0.3m (US, EU, BRA)
Cardio-metabolic	RLX030 (serelaxin)	Acute heart failure	Relaxin receptor agonist	Q2 2017	1	~1.2m (US, EU5)
	LCZ696 (Entresto®)	Heart failure with preserved EF	ARNI	2019	1	~4.2m (US, EU5)
	ACZ885 (canakinumab)	CV risk reduction	Anti-IL1β	H2 2017	1	~4m (G7)
Neuroscience	**OMB157** (ofatumumab)	Relapsing multiple sclerosis	Anti-CD20	2019	2	~0.6m (US, EU5)
	BAF312 (siponimod)[2]	Secondary progressive multiple sclerosis	S1P receptor modulator	✓	1	~0.3m (US, EU5)
	AMG 334 (erenumab)[3]	Prophylaxis of migraine	CGRP receptor antagonist	✓	1	~2.3m (EU5)
Immunology& Dermatology	AIN457 (Cosentyx®)	Non-radiographic axial SpA	Anti-IL17A	2018	1	~1.1m (US, EU5)
Respiratory	QVM149 (indacaterol, glycopyrronium, mometasone)	Asthma	LABA + LAMA + ICS	2018	1	~7.0m (EU5+JP)
	QAW039 (fevipiprant)	Asthma	CRTh2 antagonist	2019	1	~4.0m (G7)
Ophthalmology	RTH258 (brolucizumab)	Neovascular AMD	Anti-VEGF (scFv)	H1 2017	3	~0.9m (US, EU, JP)[5]
Biosimilars	Multiple	Multiple	Multiple	Ongoing	Varying	Varying

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Novartis continues to be a leader in innovation for Multiple Sclerosis patients

ESTIMATES

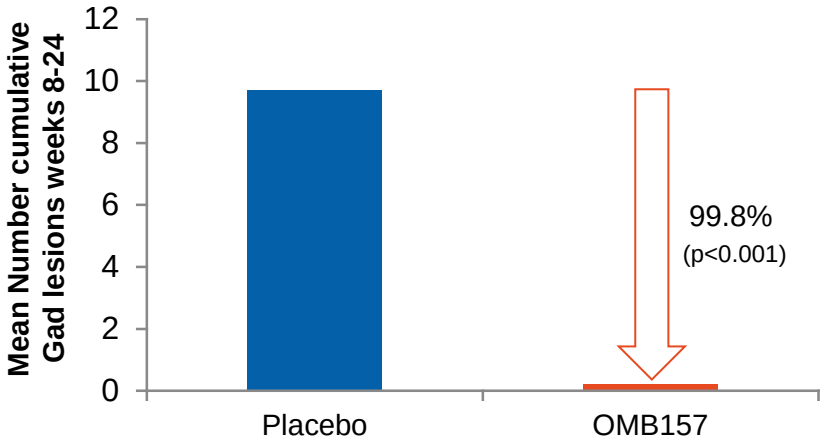
Patient Profiles	**Age 25-35** EDSS: 1-2	**Late 30s – Late 40s** EDSS: 3-6	**> Late 40s** EDSS:>6
MS patients (share%) [2]	**~530k (~60%)**	**~127.5k (~15%)**	**~127.5k (~15%)**

1. Based on US label (relapsing MS); 2. Atlas of MS, Decision Resources epidemiology data, Novartis analysis; remaining portion of market: ~10% PPMS

NOVARTIS

OMB157 (ofatumumab) demonstrated strong efficacy in Phase II studies in RRMS

OMB157 suppressed >90% of new MS lesions in the brain as measured by MRI[1]



- Two parallel Phase III studies vs. oral teriflunomide (Aubagio®[2]) in relapsing MS started 3Q16
- Planned filing 2019

1 Sorensen PS et al., Neurology 2014;82(7):573-81; MRI = Magnetic Resonance Imaging; Pooled analysis of all doses levels in the Sorensen study (Ph IIa); 100 mg, 300 mg, 700 mg - i.v.
2 Aubagio® is a registered trademark of Sanofi

NOVARTIS

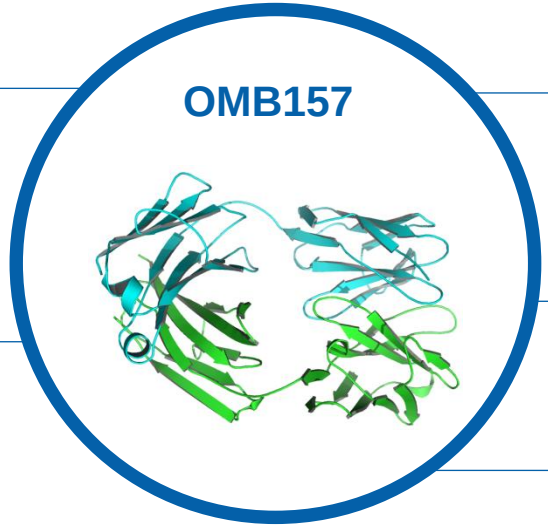
OMB157 has the potential to be a differentiated anti-CD20 therapy with subcutaneous dosing

Selective binding

Targets distinct epitope on human CD20 expressed on B cells[1-3]

Low immunogenicity

Fully Human antibody; efficacy less likely to diminish on prolonged treatment[1-3]



Crystal structure of ofatumumab including the CD20 binding region*

Good safety

Faster B cell recovery and low frequency of post-injection systemic reactions vs. other anti-CD20 therapies[4,5]

Subcutaneous dosing

Every 4 weeks subcutaneous application as maintenance therapy[2,4,5]

Low dose

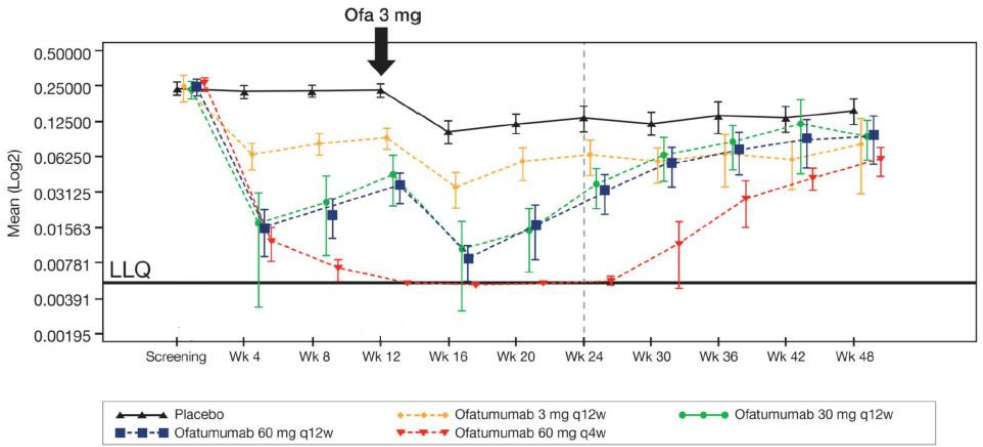
Low dose of ofatumumab expected to be as effective as other high-dose anti-CD20 antibodies[4,5]

1. Ruuls SR et al., Biotechnol J. 2008;3:1157-71 2. Ofatumumab Investigational brochure. Novartis data on file 3. Sorensen PS et al., Neurology 2014;82(7):573-81 4. MIRROR Study CSR, Novartis Data on file 5. Bar-Or A et al., presented at AAN April 2014. B-cell recovery and post-injection systemic reaction safety statements based on Ph II data. Ph III trials ongoing. * mAb Fab portion; Protein Data Bank: 3giz

NOVARTIS

OMB157 demonstrated potent response but also rapid reversibility of B-cell depletion

B-cell depletion and repletion Phase IIb data

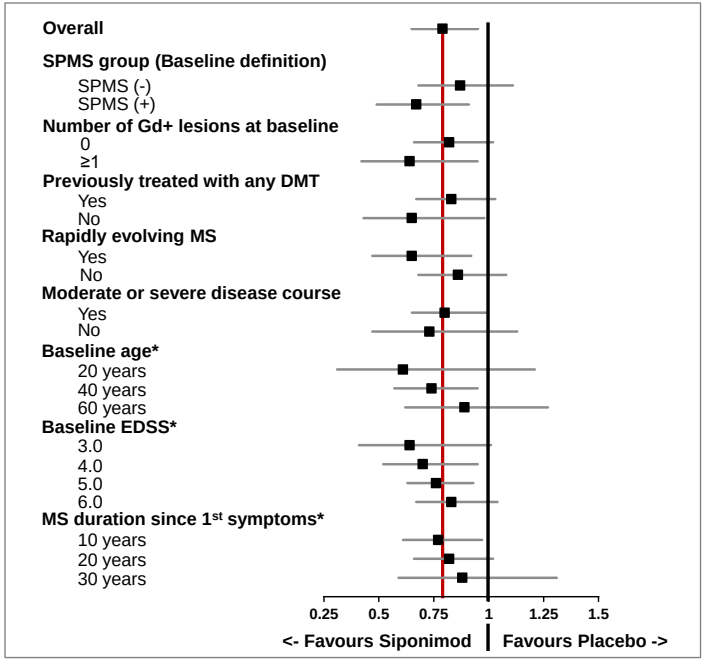


- Given long duration of therapy, reversibility of B cell depletion important should safety issues arise
- 80% B-cell repletion achieved ~5 months after treatment discontinuation

Source: Bar-Or et al, American Academy of Neurology (AAN), 2014; the MIRROR study was sponsored by GSK

NOVARTIS

BAF312 (siponimod) - consistent effect demonstrated across all subgroups[1]; awaiting regulatory feedback



- All predefined subgroups demonstrated positive effect vs. placebo, effects sustained at 6 months
- 13% effect on CDP seen in patients without relapse in past 2 years
- Safety profile of BAF312 was comparable to other drugs in the same class
- Regulatory discussions ongoing

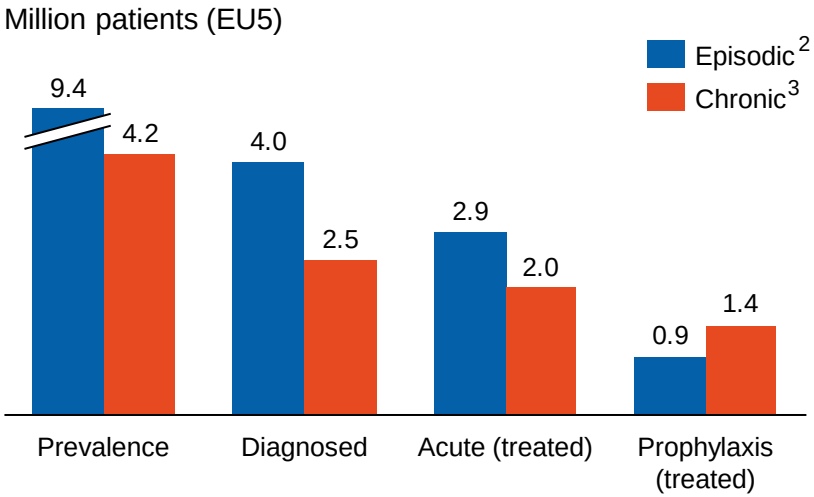
1. CDP: Confirmed Disability Progression

Source: Kappos et al. ECTRIMS 2016 (oral presentation); SPMS (+)/(-): with or without superimposed relapses in the 2 years prior to study start; * Model estimate

NOVARTIS

Migraine: Disabling condition without effective therapies – AMG 334* could be first new therapy

Migraine prevalence and target patients[1]



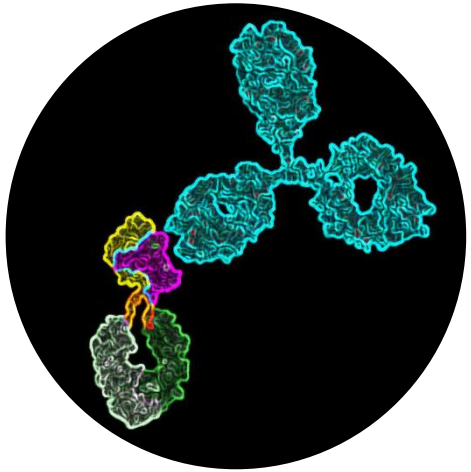
Unmet need: No new therapies in a decade

- Migraine is sixth highest cause worldwide of years lost due to disability[4]
- Major prophylactic anti-migraine drugs are repurposed with incomplete efficacy[5]
- Most prescribed drugs produce adverse effects resulting in limited adherence[6]

1. Patients in EU top 5; Decision Resources Group; Novartis analysis 2. Chronic Migraine: 15+ migraine headache days per month 3. Episodic Migraine: 4-14 migraine headache days per month 4. Global Burden of Disease Study 2013
5. Major prophylactic anti-migraine drugs include beta-blockers, tricyclic anti-depressants, anti-epileptic drugs; Pringsheim T. et al. CMAJ 2010 6. Hepp Z. et al. Cephalalgia 2015; 35: 478-88 CGRP=calcitonin gene related peptide
* Development in collaboration with Amgen; Novartis has AMG 334 rights outside of US, Canada and Japan

NOVARTIS

AMG 334[1] (erenumab) is a fully human, potent and selective CGRP receptor antagonist



AMG 334 unique profile

- Targets receptor (competitors target ligand)
- Highly specific to receptor associated with migraine
- Inhibits CGRP function regardless of CGRP circulating levels

1. Development in collaboration with Amgen; Novartis has AMG 334 rights outside of US, Canada and Japan

NOVARTIS

AMG 334[1] – positive data for chronic and episodic migraine

Study	Indication	MMD[2] reduction vs. placebo	Share of pts. achieving ≥50% reduction	Safety
ARISE[3]	Episodic migraine	-1.1 for 70 mg	*Not yet reported*	Similar to placebo across all three studies
STRIVE[3]	Episodic migraine	-1.4 for 70 mg -1.9 for 140 mg	*Not yet reported*	
20120295 study[4]	Chronic migraine	-2.4 for 70 mg -2.4 for 140 mg	40% for 70 mg 41% for 140 mg	

- Planned filing in Q2 2017
- Potential first-in-class CGRP receptor antagonist

1. Development in collaboration with Amgen; Novartis has AMG 334 rights outside of US, Canada and Japan 2. MMD = mean monthly migraine days 3. Novartis press release 28 Sep and 16 Nov 2016 4.Tepper S et al. EHMTIC 2016 poster 057

NOVARTIS

Immunology & Dermatology

	Therapeutic area	Molecule	Indication	MoA	Exp. Pivotal Trial Readout	Exp. order of entry	Potential target population
Onco	Oncology	**LEE011** (ribociclib)	HR+ HER2- advanced breast cancer	CDK4/6 inhibitor	✓	2	~0.2m (US, EU)[4]
		CTL019 (CART-T)	r/r B-Cell ALL, DLBCL	CART-T	Q2 2017[6]	1	~0.05m (US, EU)
		SEG101 (crizanlizumab)	Sickle cell pain crises	Anti-P-selectin	2020	1	~0.3m (US, EU, BRA)
CM	Cardio-metabolic	**RLX030** (serelaxin)	Acute heart failure	Relaxin receptor agonist	Q2 2017	1	~1.2m (US, EU5)
		LCZ696 (Entresto®)	Heart failure with preserved EF	ARNI	2019	1	~4.2m (US, EU5)
		ACZ885 (canakinumab)	CV risk reduction	Anti-IL1β	H2 2017	1	~4m (G7)
NS	Neuroscience	**OMB157** (ofatumumab)	Relapsing multiple sclerosis	Anti-CD20	2019	2	~0.6m (US, EU5)
		BAF312 (siponimod)[2]	Secondary progressive multiple sclerosis	S1P receptor modulator	✓	1	~0.3m (US, EU5)
		AMG 334 (erenumab)[3]	Prophylaxis of migraine	CGRP receptor antagonist	✓	1	~2.3m (EU5)
I&D	**Immunology& Dermatology**	**AIN457** (Cosentyx®)	Non-radiographic Axial SpA	Anti-IL17A	2018	1	~1.1m (US, EU5)
Resp	Respiratory	**QVM149** (indacaterol, glycopyrronium, mometasone)	Asthma	LABA + LAMA + ICS	2018	1	~7.0m (EU5+JP)
		QAW039 (fevipiprant)	Asthma	CRTh2 antagonist	2019	1	~4.0m (G7)
Oph	Ophthalmology	**RTH258** (brolucizumab)	Neovascular AMD	Anti-VEGF (scFv)	H1 2017	3	~0.9m (US, EU, JP)[5]
Bios	Biosimilars	**Multiple**	Multiple	Multiple	Ongoing	Varying	Varying

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NOVARTIS

Cosentyx® (secukinumab)

Cosentyx® has shown unprecedented strong and sustained efficacy across indications

	Psoriasis	Psoriatic Arthritis	Ankylosing Spondylitis
Efficacy[1-5,15-24]			
1 year	✓ vs. Enbrel® and Stelara®	✓	✓
2 year	✓	✓	✓
3 year	✓	✓	
4 year	✓		
Safety			
Adverse events	Favorable safety profile similar to etanercept and ustekinumab[1,2,6] No new or unexpected long-term safety signals across indications[4,7-11]		
Injection site reactions	Almost zero injection site reactions[1]		
Immunogenicity	Very low immunogenicity[12,13]		
Re-treatment	95% recapture of response[14]		

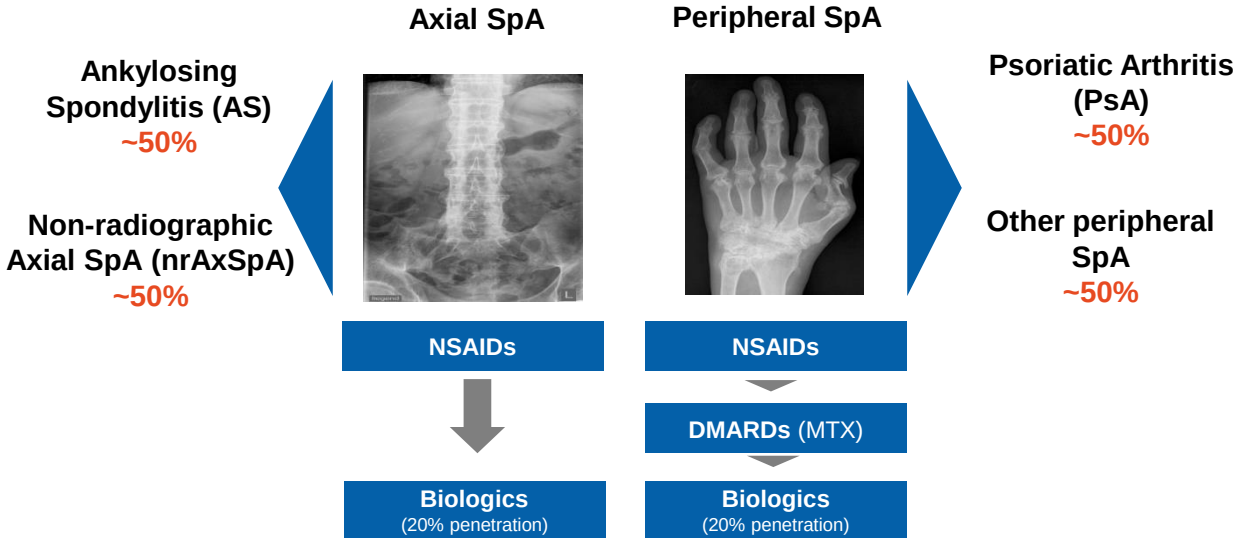
1. Langley R, et al. NEJM 2014;371:326; 2. Blauvelt A, et al. JAAD 2016 [ePub ahead of print] 3. Thaci D, et al. JAAD, 2015; 73, 3, 400–409; 4. Seminars in Cutaneous Medicine and Surgery (Supplement 7), Vol. 35, December 2016; 5. Bisonette et al. Late Breaker Poster presentation, EADV 2016; 6. van de Kerkhof P, et al. JAAD 2016;75:83; 7. Mease P, et al. Arthritis Rheumatol. 2016;68(Suppl.10). Abstract 1704; 8. Kavanaugh A, et al. Arthritis Care Res. 2016 [ePub ahead of print]; 9. Mease P, et al. Arthritis Rheumatol. 2016;68(Suppl.10). Abstract 961; 10. Baeten D, et al. Arthritis Rheumatol 2015;67(Suppl10) Abstract 2896; 11. Marzo-Ortega H, Ann Rheum Dis. 2016;75(Suppl2): Abstract 812; 12. Reich, K., et al. Br J Dermatol. 2016 doi:10.1111/bjd.14965; 13. Reich K, et al. PIN 2016. P224; 14. Blauvelt et al. Late Breaker Poster presentation, AAD 2015; 15. McInnes IB, et al. Arthritis Rheumatol. 2016;68 (suppl 10): abstract 2757; 16. Strand V, et al. Ann Rheum Dis. 2016 [ePub ahead of print]; 17. Mease P, et al. ACR 2015. Oral presentation; 18. Kavanaugh A, et al. Arthritis Care Res. 2016 [ePub ahead of print]; 19. Mease P, McInnes IB. Rheumatol Ther. 2016;3:5–29; 20. Novartis Data on File 2016. FUTURE 1 Data Tables; 14.2-1.9a, 14.2-7.9a. 14/2-12.8a; 21. Marzo-Ortega H, et al. Ann Rheum Dis. 016;75(Suppl2): abstract 812; 22. Novartis Data on File. 2015. MEASURE 2 Clinical Study Report; 23. Baeten D, et al. Arthritis Rheumatol 2015;67(Suppl10) Abstract 2896; 24. Novartis Data on File 2015. Week 104 Data Tables 14.2-1.5 and 14.2-2.5;

NOVARTIS

Cosentyx® (secukinumab)

Spondyloarthritis (SpA) – Cosentyx® addresses area of significant unmet need

SpA epidemiology: ~5.4m patients for PsA, AS and nrAxSpA (US & EU5)[1]



Unmet needs

- Preventing disease progression on X-ray
- No US and limited EU approved treatments for early disease (nrAxSpA)

1. Decision Resources Epidemiology Database 2016; Novartis analysis

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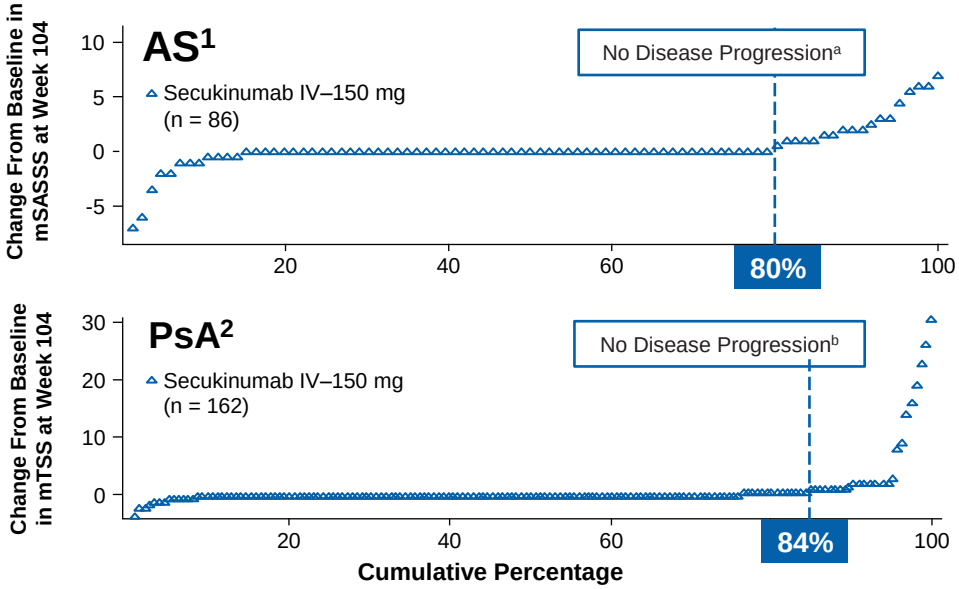
Cosentyx® (secukinumab)

Cosentyx® impacts disease progression in SpA - two H2H studies vs. adalimumab initiating



Strong profile[1-6] supports head-to-head superiority trials vs. adalimumab

- EXCEED 1 PsA study planned to start H1 2017[7]
- AS study planned to start H2 2017

a) Non-progression defined as a change in mSASS from baseline ≤0; overall population, data from the MEASURE 1 study, in which patients received intravenous loading doses of secukinumab; b) Non-progression defined as a change in mTSS from baseline ≤0.5; overall population (observed data), data from the FUTURE1 study, in which patients received intravenous loading doses of secukinumab

1. Braun J, et al. Ann Rheum Dis 2016 [IN PRESS]; 2. Kavanaugh A, et al. Arthritis Care Res. 2016 [ePub ahead of print]; 3. Nash P, et al. *Ann Rheum Dis* 2016;75(Suppl2) 353; 4. McInnes I.B., et al. Clin Exp Rheumatol 2016;34(4):782. 5. Maksymowych W, et al. Ann Rheum Dis 2016;75(Suppl2) 98; 6. Maksymowych W., et al. Clin Exp Rheumatol 2016;34(4):782; 7. ClinicalTrials.gov: NCT02745080

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Cosentyx® (secukinumab)

Ongoing Phase III trial in nrAxSpA, an underserved indication

Estimated prevalence of non-radiographic SpA

Country	Prevalent cases for nrAxSpA	% prevalence[1]
US	~570k	0.18%
France	~114k	
Germany	~142k	
Italy	~106k	
Spain	~81k	
UK	~115k	
Total US + EU5	**~1.1 mn**	

1. Decision Resources Epidemiology Database 2016 & IMS defined health 2015

Cosentyx® PREVENT trial

- Single Phase III trial for registration
  - Currently no US approved drugs for nrAxSpA
- Primary objective of ASAS40 at week 16 and week 52 versus placebo
- Trial enrolling, filing expected in 2018

NOVARTIS

Respiratory

Onco | CM | NS | I&D | Resp | Oph | Bios

Therapeutic area	Molecule	Indication	MoA	Exp. pivotal trial readout	Exp. order of entry	Potential target population
Oncology	**LEE011** (ribociclib)	HR+ HER2- advanced breast cancer	CDK4/6 inhibitor	✓	2	~0.2m (US, EU)[4]
	CTL019 (CART-T)	r/r B-Cell ALL, DLBCL	CART-T	Q2 2017[6]	1	~0.05m (US, EU)
	SEG101 (crizanlizumab)	Sickle cell pain crises	Anti-P-selectin	2020	1	~0.3m (US, EU, BRA)
Cardio-metabolic	**RLX030** (serelaxin)	Acute heart failure	Relaxin receptor agonist	Q2 2017	1	~1.2m (US, EU5)
	LCZ696 (Entresto®)	Heart failure with preserved EF	ARNI	2019	1	~4.2m (US, EU5)
	ACZ885 (canakinumab)	CV risk reduction	Anti-IL1β	H2 2017	1	~4m (G7)
Neuroscience	**OMB157** (ofatumumab)	Relapsing multiple sclerosis	Anti-CD20	2019	2	~0.6m (US, EU5)
	BAF312 (siponimod)[2]	Secondary progressive multiple sclerosis	S1P receptor modulator	✓	1	~0.3m (US, EU5)
	AMG 334 (erenumab)[3]	Prophylaxis of migraine	CGRP receptor antagonist	✓	1	~2.3m (EU5)
Immunology& Dermatology	**AIN457** (Cosentyx®)	Non-radiographic axial SpA	Anti-IL17A	2018	1	~1.1m (US, EU5)
Respiratory	**QVM149** (indacaterol, glycopyrronium, mometasone)	Asthma	LABA + LAMA + ICS	2018	1	~7.0m (EU5+JP)
	QAW039 (fevipiprant)	Asthma	CRTh2 antagonist	2019	1	~4.0m (G7)
Ophthalmology	**RTH258** (brolucizumab)	Neovascular AMD	Anti-VEGF (scFv)	H1 2017	3	~0.9m (US, EU, JP)[5]
Biosimilars	**Multiple**	Multiple	Multiple	Ongoing	Varying	Varying

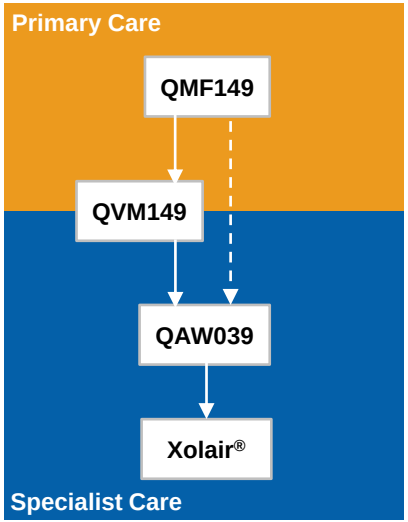
1. Blockbuster potential refers to specified indication 2. Next steps to be evaluated in consultations with health authorities 3. In collaboration with Amgen; Novartis has AMG 334 rights outside of US, Canada and Japan 4. Kantar Health; Novartis analyses 5. Rudnicka et al. Am. J. Ophthalmol. 2015 Jul; 160(1):85-93.e3; Brown et al. Can J Ophthalmol. 2005 Jun;40(3):277-87; – Yasuda M et al. Ophthalmology. 2009 Nov;116(11):2135-40. doi: 10.1016/j.ophtha.2009.04.017. Epub 2009 Sep 10; Novartis analyses 6. Ped. r/r B-cell ALL positive trial readout achieved in 2016; Note: sources for epidemiology information can be found in the respective sections

NOVARTIS

Developing leading portfolio in moderate to severe asthma

Moderate/severe asthma portfolio

Pot. eligible patients



QVM149[1]: inhaled combination therapy **7.0m (EU5+JP)**

- Once-daily triple combination for Ex-US
- Pivotal Phase III trials ongoing; planned filing 2019

QAW039: potential first-in-class oral treatment for severe asthma

- CRTh2 antagonist; add-on to ICS/LABA or ICS/LABA/LAMA[2] **4.0m (G7)**
- Pivotal Phase III trials ongoing; planned filing 2019

Xolair: first choice biologic for allergic asthma **2.2m (G7)**

- Xolair with US[3] approval for pediatric moderate to severe persistent allergic asthma

1. Fixed-dose combination of indacaterol, glycopyrronium and mometasone 2. LABA = long-acting β2-agonist; ICS = inhaled corticosteroid; LAMA = long-acting muscarinic antagonist 3. We co-promote Xolair with Genentech in the US and share a portion of operating income, but we do not record any US sales. Novartis records all sales of Xolair outside the US
Source: Novartis; Decision Resources, Epidemiology Database

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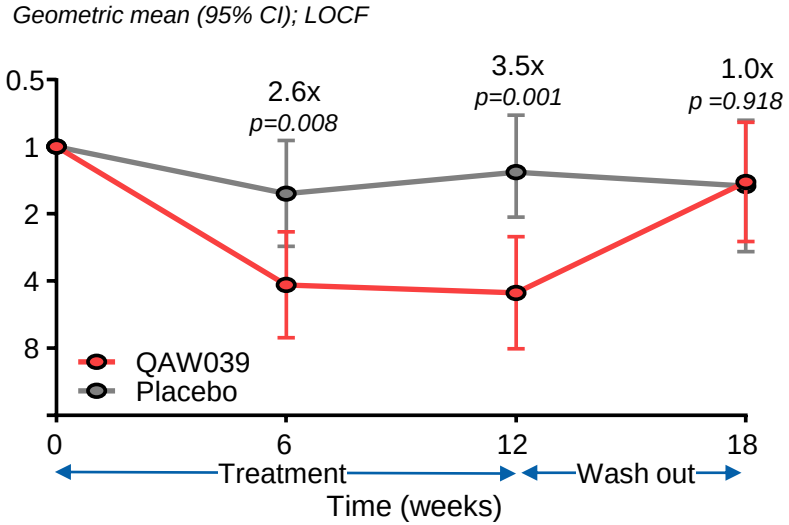
QAW039 - Phase III ongoing based on supportive Phase II data; readout expected in 2019

Fold reduction from baseline in eosinophil count



- Pre-clinical data demonstrate potential for high potency
- QAW039 (225 mg BID) induced significant suppression of sputum eosinophilia at week 12 and significant improved QoL
- Phase III pivotal trials ongoing; expected readout 2019

Source: S Gonem, R Berair et al, Phase 2a randomized placebo-controlled trial of the oral prostaglandin D2 receptor (PD2/CRTH2) antagonist QAW039 in eosinophilic asthma, ERS congress 2014
Abbreviations: BID=twice daily; LOCF=last observation carried forward; QoL=quality of life

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Ophthalmology

Onco | CM | NS | I&D | Resp | Oph | Bios

Therapeutic area	Molecule	Indication	MoA	Exp. pivotal trial readout	Exp. order of entry	Potential target population
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Biosimilars	Multiple	Multiple	Multiple	Ongoing	Varying	Varying

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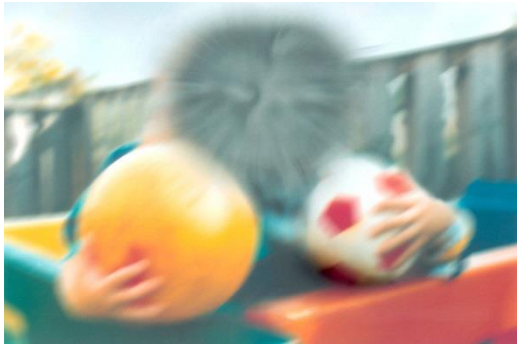
Neovascular AMD: Important unmet needs remain

Neovascular AMD Epidemiology

- 44 million people suffer from age-related macular degeneration (AMD)[1], which can lead to blindness
- AMD is a leading cause of vision loss in people aged over 50 [2]

Unmet need

- Reduced treatment burden for patients
- Patients experience long term visual decline



1. Blue Mountains Eye Study 1992–2004 – 1.9% prevalence of AMD in age 50+ , Population 50+ from UN population database 2015 2. National Eye Institute. Facts About Age-Related Macular Degeneration. Available at https://nei.nih.gov/health/maculardegen/armd_facts
Image source: https://commons.wikimedia.org/wiki/File:Eye_disease_simulation,_age-related_macular_degeneration.jpg

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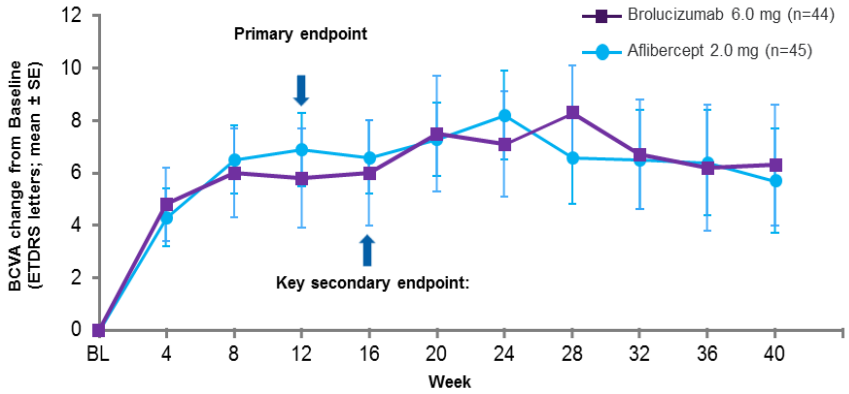
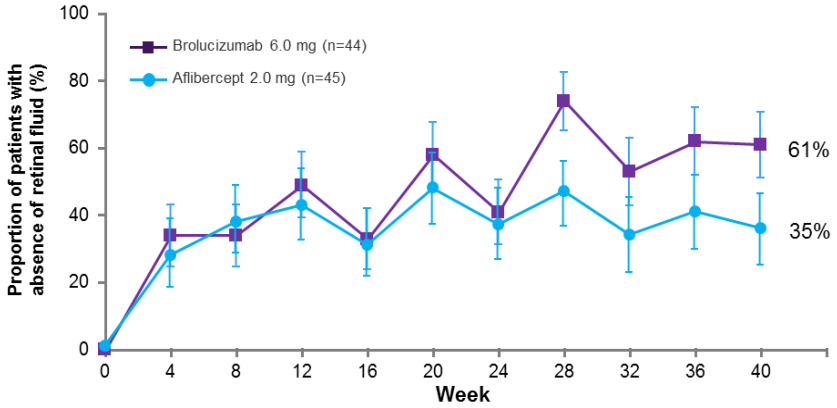
RTH258 - potential to offer better dosing than aflibercept; Ph III trial readouts expected H1 2017

RTH258 (brolucizumab)

Non-inferior BCVA[1] outcomes to aflibercept ...



... and greater resolution of retinal fluid



In the Phase II study, after 3 monthly loading doses, all subjects were dosed at 8-weekly interval up to week 40. Thereafter, the brolucizumab patients underwent 2 x cycles of 12-weekly treatment. ~50% maintained BCVA without requiring additional injections

1. BCVA = best corrected visual acuity

Sources: Holz F, EURetina 2015 oral presentation; Dugel R, Macular Society 2015 oral presentation

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RTH258 - comparable safety observed in Phase II to approved anti-VEGF therapies for nAMD

Study eye treatment emergent AEs (≥4 in any treatment arm)

C12-006: Phase II repeat-dose study vs. aflibercept

	RTH258 6 mg (n=44)	Aflibercept 2 mg (n=45)
Any event	21 (47.7)	23 (51.1)
Conjunctival haemorrhage	5 (11.4)	7 (15.6)
Vitreous floaters	5 (11.4)	4 (8.9)
Visual acuity reduced	4 (9.1)	4 (8.9)

Source: Holz F, EURetina 2015 oral presentation; Dugel R, Macular Society 2015 oral presentation

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Biosimilars

Onco
CM
NS
I&D
Resp
Oph
Bios

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Biosimilars filing milestones

Molecule	Indication[1]	Originator[2]	Agency	Filing	
Etanercept	Rheumatoid Arthritis	Enbrel etanercept	FDA	2015 (approved)	✓
Etanercept	Rheumatoid Arthritis	Enbrel etanercept	EMA	2015	✓
Pegfilgrastim	Neutropenia	Neulasta (pegfilgrastim)	FDA	2015[3]	✓
Pegfilgrastim	Neutropenia	Neulasta (pegfilgrastim)	EMA	2015	✓
Epoetin subcutaneous	Anemia	EPOGEN EPOETIN ALFA PROCRIT EPOETIN ALFA	EMA	2015 (approved)	✓
Rituximab	Non-Hodgkin's Lymphoma	Rituxan Rituximab	EMA	2016	✓
Epoetin	Anemia	EPOGEN EPOETIN ALFA PROCRIT EPOETIN ALFA	FDA	2017	
Adalimumab	Rheumatoid Arthritis	HUMIRA adalimumab	FDA	2017	
Adalimumab	Rheumatoid Arthritis	HUMIRA adalimumab	EMA	2017	
Rituximab	Non-Hodgkin's Lymphoma	Rituxan Rituximab	FDA	2017	
Infliximab	Inflammatory Bowel Disease	Remicade INFLIXIMAB	EMA	2017	

1. Main indication only 2. All trademarks are the property of the respective originator companies 3. Complete Response Letter received in June 2016

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Biosimilars: all programs progressing; Rituximab filing accepted by EMA

Etanercept	Pegfilgrastim	Infliximab	Rituximab
Erelzi® approved in US[1] Review in EU ongoing	Similar review issues raised by FDA and EMA • US: planned data submission in 2018 • EU: planned resubmission in 2017	Confirmatory study for Europe[2] demonstrated equivalent efficacy[3]/ safety to Remicade®[4]	Confirmatory study demonstrated equivalent efficacy[5]/safety to MabThera®[6] Application for biosimilar rituximab accepted by EMA

1. launch delay due to litigation 2. Rights to biosimilar infliximab (PF-06438179) in the European Economic Area were acquired from Pfizer 3. As measured by ACR20 (American College of Rheumatology)
4. Remicade® is a registered trademark of Janssen Biotech, Inc. 5. As measured by ORR (Overall Response Rate) 6 MabThera® is a registered trademark of Roche, Ltd.

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Development priorities

Creating an efficient and agile Development organization

Delivering late stage pipeline: 13 potential blockbusters

Advancing high value, mid stage opportunities

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Seamless integration to rapidly advance internal early stage assets from NIBR to Development

- Integrated governance
- Integrated teams
- Aligned priorities
- Focused on speed

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Executing bolt-on strategy in key therapeutic areas

Acquisitions

ZIARCO

ZPL389

ENCORE VISION™
Restoring Near Focus

UNR844 (EV06)

SELEXYS PHARMACEUTICALS

SEG101 (SelG1)

Licensing

Conatus Pharmaceuticals[1]

Emricasan

Pfizer

Infliximab biosimilar

Xencor

CD3 bi-specific antibodies

IONIS PHARMACEUTICALS[2]

APOCIII-L_{Rx} / APO(a)-L_{RX}

AKCEA THERAPEUTICS
A subsidiary of Ionis Pharmaceuticals, Inc.

LUBRIS BIOPHARMA

Lubricin[3]

Note: All trademarks are the property of their respective owners. 1. Regulatory approval is required to exercise the option 2. Subject to customary closing conditions 3. Option to in-license

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Steady flow of future potential significant innovations - Pipeline Watch List

Therapeutic area	Molecule	Indication	Phase	Mechanism of Action
Oncology	**15 IO assets incl. combos**	**Multiple**	**Phase Ib/II**	**Anti-PD1 + multiple others**
	ABL001	**CML**	**Phase II**	**Allosteric BCR-ABL inhibitor**
	BYL719	Breast Cancer	Phase III	PI3k inhibitor
	INC280	NSCLC	Phase Ib/II	cMET inhibitor
	Jakavi®	steroid refractory acute GVHD	Phase III	JAK1/2 inhibitor
Cardio-metabolic	**APO(a)-LRx[1]**	**High risk CVRR**	**Phase II**	**Lipoprotein(a) inhibitor**
	APOCIII-LRx[1]	**High risk CVRR**	**Phase II**	**Apolipoprotein-CIII inhibitor**
	LHW090	Resistant hypertension	Phase II	NEP inhibitor
	LIK066	**Weight loss**	**Phase II**	**SGLT1/2 inhibitor**
	MAA868	Stroke prevention	Phase I/II	Anti-thrombotic
Neuroscience	**BYM338**	Sarcopenia hip fracture	Phase II	Activin type-2 receptor
	CNP520	**Alzheimer's**	**Phase III**	**BACE inhibitor**
	EMA401	Neuropathic Pain	Phase II	Angiotensin II Type-2 Receptor antagonist
Immunology-Dermatology	**CJM112**	Multiple immune disorders	Phase II	High-affinity anti-IL17A
	Emricasan[1]	**NASH/Cirrhosis**	**Phase II**	**Oral pan-caspase inhibitor**
	LJN452	**Non-Alcoholic Steatohepatitis**	**Phase II**	**FxR agonist**
	VAY736	Sjoegren's syndrome	Phase II	Anti-BAFF-R
	ZPL389	**Atopic dermatitis**	**Phase II**	**H4 receptor antagonist**
Respiratory	**ACZ885**	Sarcoidosis	Phase II	Anti-IL1
	CJM112	Asthma	Phase II	High-affinity anti-IL17A
	QBW251	Cystic fibrosis/COPD	Phase II	CFTR potentiator
Ophthalmology	**UNR844**	**Presbyopia**	**Phase II**	**Prodrug to metabolize DHLA**

Onco
CM
NS
I&D
Resp
Oph

1 Option to license in

NOVARTIS

Ensuring readiness for emerging Immuno-Oncology pipeline

Onco
CM
NS
I&D
Resp
Oph

	Target	FIH trial initiated
IO / IO	LAG3 (LAG525) + PD-1	✓
	TIM3 (MBG453) + PD-1	✓
	GITR (GWN323) + PD-1	✓
	CSF-1 (MCS110) + PD-1	✓
	Adenosine R (NIR178) NSCLC + PD-1	✓
	Het IL-15 (NIZ985) + PD-1	2017
	IL-17 (CJM112) + PD-1	✓
	IL-1 (Ilaris®) + PD-1	✓
	TGFβ (NIS793) + PD-1	2017
	PD-L1 (FAZ053) + PD-1	✓
	STING (MIW815) + PD-1	2017
IO with chemo	CSF-1 (MCS110) + carbo/gem in TNBC	✓

	Target	FIH trial initiated
IO with targeted agent	cMET (INC280) + PD-1	✓
	Porcupine (WNT974) + PD-1	2017
	HDAC (Farydak®) + PD-1	✓
	mTOR (Afinitor®) + PD-1	✓
	IAP inh (LCL161) + PD-1	✓
	MEK (Trametinib) + PD-1	✓
	TEC (EGF816) + PD-1	✓
	B/CRAF (LXH254) + PD-1	✓

Excludes partner studies

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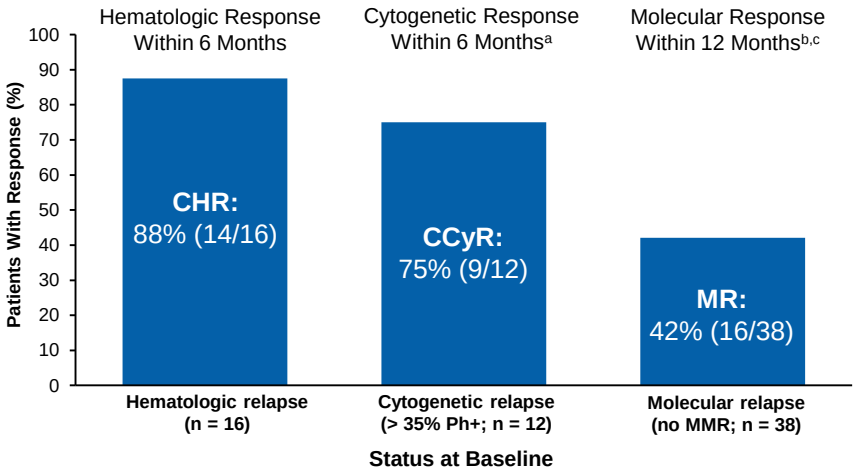
Advancing ABL001, a potent, allosteric inhibitor of BCR-ABL in 1st and 3rd line[1] in CML

Responses in CML-CP patients treated with ABL001 with ≥3 months exposure on study



- ABL001 was effective and overall well tolerated in a Phase I study in patients resistant to or intolerant of prior TKIs
- Pivotal study in ≥3rd line CML-CP patients planned to start in 2017
- Phase I study ongoing to test other regiments and TKI combination treatments[2]

a. Patients had ≥ 6 months of treatment exposure or achieved response within 6 months b. BCR-ABL1IS reduction achieved c. Patients had ≥ 12 months of treatment exposure or achieved response within 12 months
1. B. Sellers: AACR 2016 2. T. Hughes and D. White et al; ASH 2016; Abstract 1121 Abbreviations: CCyR = complete cytogenetic response; CHR = complete hematologic response; CML-CP = chronic myeloid leukemia - chronic phase; MR = molecular response; Ph+ CML = Philadelphia chromosome positive chronic myeloid leukemia; TKI = tyrosine kinase inhibitor

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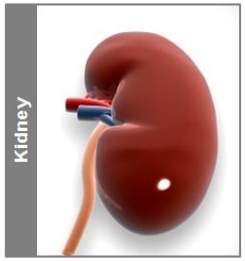
LIK066, an SGLT1/2 inhibitor, with potential for best-in-class weight loss

SGLT1/2 dual mode of action



- Inhibition of both SGLT1[1] and SGLT2[1]
  - Blocks reabsorption of filtered glucose in the kidney
  - Reduces intestinal glucose absorption
- Aim to achieve weight loss through dual mechanism of action

LIK066 development

- Proof-of-concept data projected more than 10% placebo-adjusted weight loss at 52 weeks
- Additional expected benefits include improved glycemic control, lipid profile, blood pressure
- Phase IIb trial planned to start in Q1 2017

1. SGLT = sodium-glucose co-transporter

NOVARTIS

Ionis/Akcea Option Deal: Targeting two highly validated CV targets in Phase IIb studies

Patients on optimized LDL-C therapy at high risk

Routine or Post Event Testing of Residual Risk Factors

Lp(a)-L_{RX}

- Genetically validated
- Established biomarker
- Ph IIb ongoing
- End of Ph II ~2018

Lp(a)	**ApoCIII**
>50mg/dl	>20mg/dl and/or TGs >200mg/dl

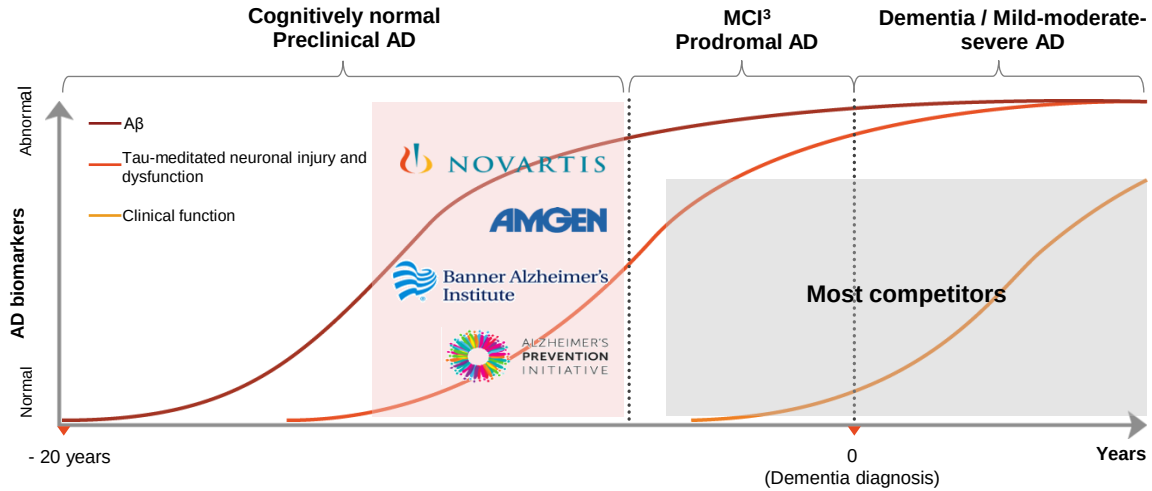
APOCIII-L_{Rx}

- Genetically validated
- Established biomarker
- Phase II planned
- End of Phase II 2019

Source: Novartis Qualitative Research
Note: option deal subject to customary closing conditions and regulatory approval

NOVARTIS

CNP520[1] program focused on genetically identified pre-Alzheimer's population



CNP520

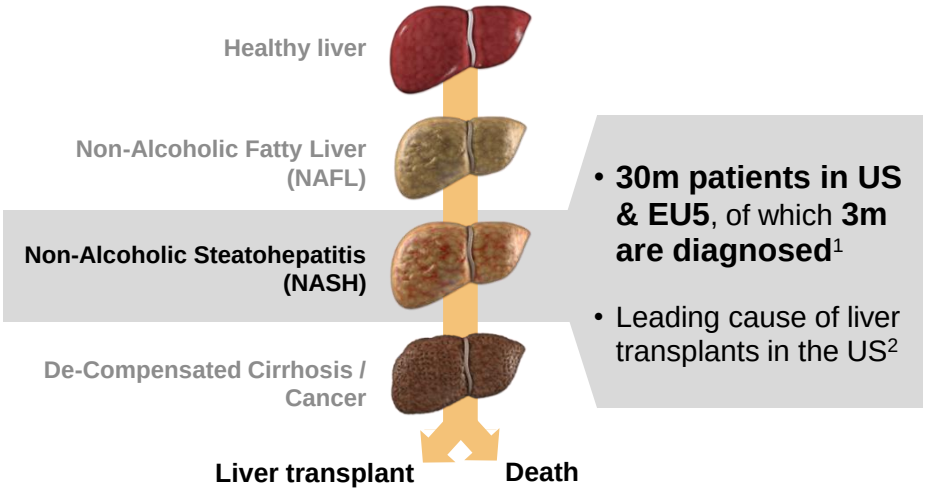
- BACE inhibitor
- Trial ongoing with subjects with strong genetic pre-disposition to develop sporadic AD[2]
- Completion expected >2022
- FDA Fast Track designation received

1. CNP520: co-developed with Amgen 2. In collaboration with Banner Alzheimer's Institute; includes Novartis investigational immunotherapy CAD106 3. MCI = Mild Cognitive Impairment

NOVARTIS

Targeting NASH and cirrhosis with 6 assets in Phase II

Pathophysiology of NASH



- **30m patients in US & EU5**, of which **3m are diagnosed**[1]
- Leading cause of liver transplants in the US[2]

Novartis assets

Project	Mode of Action	Exp. readout
LJN452	FXR agonist	2018
LMB763	FXR agonist	2018
LIK066	SGLT 1/2 inhibitor	2018
RLX030	Relaxin receptor	2019
Emricasan[3]	Pan-caspase inhibitor	2018
To be determined	Anti-inflammatory / anti-fibrotic	--

1. Decision Resources; 2. Banini BA, et al. ACG 2016. Abstract 46; 3. Exclusive option, collaboration and license agreement with Conatus

NOVARTIS

NASH: LJN452 with potential to be best-in-class FXR agonist; Phase IIb studies on-going

FLIGHT-FXR trial

- 12-week, Phase II study ongoing to assess safety, tolerability, and efficacy in NASH patients[1]
- 4 LJN452 doses vs. placebo (study part A)

LJN452: Novartis lead FXR agonist

- Potential for **~250-300x higher potency** than bile-derived FXR agonists
- **No elevation of LDL/Triglycerides** and **no notable pruritus** related adverse events to date
- FDA Fast Track designation received

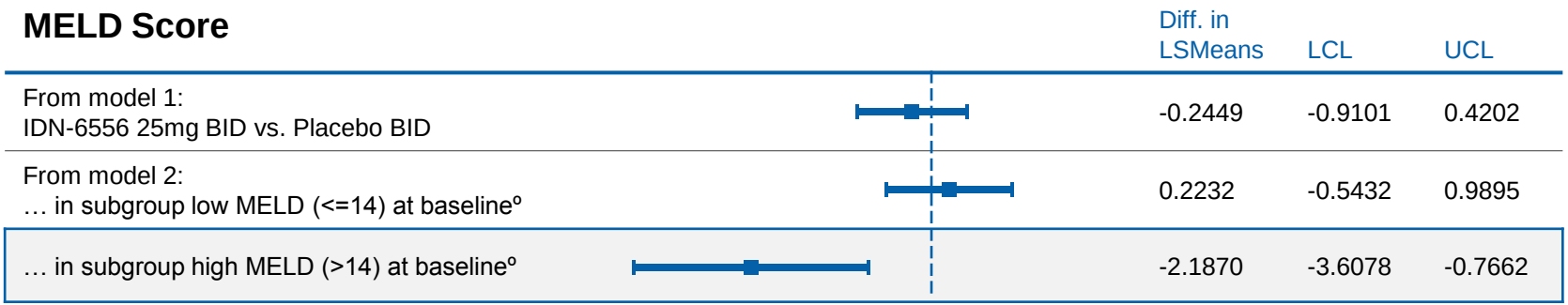
1. NCT02855164, EUDRACT 2015-005215-33

NOVARTIS

NASH: Emricasan advancing in Phase IIb studies in NASH and Cirrhosis

Improving key liver function parameters

MELD Score



	Diff. in LSMeans	LCL	UCL
From model 1: IDN-6556 25mg BID vs. Placebo BID	-0.2449	-0.9101	0.4202
From model 2: … in subgroup low MELD (<=14) at baseline[o]	0.2232	-0.5432	0.9895
… in subgroup high MELD (>14) at baseline[o]	-2.1870	-3.6078	-0.7662

- Conatus' Emricasan demonstrated significant reductions in key biomarkers of inflammation and cell death
- Potential to develop Emricasan as a single agent or in combination with our FXR agonists
- FDA granted Fast Track designation for Emricasan development, Phase IIb readouts expected in 2018

Source: Frenette C et al. Late breaking abstract LB-O5, EASL Barcelona Spain, April 2016
Note: Exclusive option, collaboration and license agreement signed with Conatus Pharmaceuticals Inc in December 2016 is subject to anti-trust approvals

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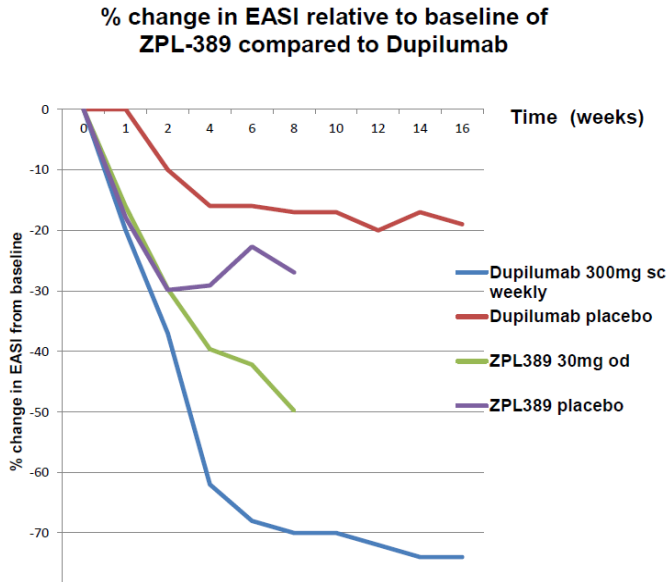
ZPL389 once daily oral for atopic dermatitis with strong Phase II data



- First in class H_4 receptor antagonist
- ~80% of dupilumab max. efficacy achieved by week 4[1-2]
- ZPL389 efficacy at week 8 appears not to have plateaued

Please note that figure above does not show intervals equidistantly

1. Werfel T. et al, Late breaking oral abstract (1346), EAACI 2016; 2. Beck LA et al, NEJM, 2014; 371; 130-139

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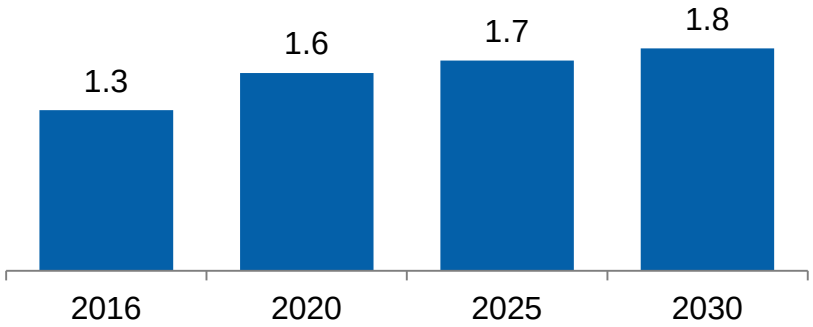
Presbyopia: progressive, age related inability to focus on near distance objects

Presbyopia prevalence[1] (in billions)



Unmet need

- One of leading causes of near vision impairment, affecting approximately 80% of people over the age of 45[2]
- Recent research suggests loss of lens elasticity is primary mechanism[3]
- No available therapies except reading glasses

1. Global Vision Impairment Due to Uncorrected Presbyopia, Arch Ophthalmol. 2008;126(12):1731-1739 2. Arch Ophthalmol. 2008;126(12):1731-1739 3. Vision Res. 1999; 39: 1991–2015

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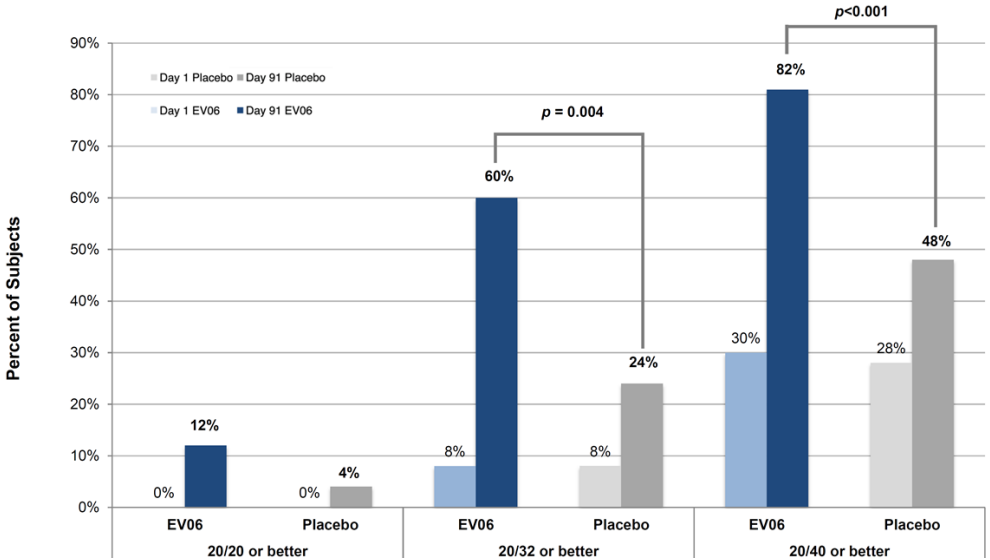
UNR844 (EV06) for potential treatment of presbyopia

82% of patients achieved DCNVA* of 20/40 with EV06



* DCNVA= distance corrected near visual acuity Encore Vision, Inc. press release, May 2016

- UNR844 improves lens flexibility through twice daily drops for 3 months
- Effects sustained over 6 months
- UNR844 was well tolerated, no sight-related AEs or other safety concerns
- Phase II dose finding now in planning
- Acquisition closing expected in Q1 2017

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Over 60 projects planned for filing 2017 to ≥2021

2017		2018	2019	2020	≥ 2021	
AMG 334[a] Migraine	Promacta®/Revolade® SAA[5] 1st line	INC280 NSCLC[7]	BAF312[d] SPMS[14]	ABL001 CML[6] 3rd line	BYM338 Hip fracture	QBW251 Cystic fibrosis
CTL019 Pediatric acute lymphoblastic leukemia	Tasigna®[c] CML[6] treatment free remission	LCI699 Cushing's disease	BYL719 + fulv HR+, HER2 (-) postmenopausal adv. BC[12] 2nd line	QGE031 CSU/CIU[18]	CAD106 Alzheimer's disease	UNR844[e] Presbyopia
RLX030 Acute heart failure	Adalimumab (US/EU) GP2017	RTH258 nAMD[8]	QAW039 Asthma	SEG101 Sickle cell disease	CJM112 Immune disorders	VAY736 Primary Sjoegren's syndrome
ACZ885 Sec. prev. CV events[1]	Epoetin-alfa (US) HX575	Arzerra® NHL[9] (refractory)	Entresto® Heart failure (PEF)[15]	Entresto® Post-acute myocardial infarction	CNP520 Alzheimer's disease	ZPL389[f] Atopic dermatitis
Afinitor®/Votubia®[b] TSC[2] seizures	Infliximab (EU) GP1111	Cosentyx® nrAxSpA[10]	Jakavi® GVHD[16]	Cosentyx® PsA H2H[19]	EMA401 Neuropathic pain	BYM338 Sarcopenia
CTL019 DLBCL[3]	Pegfilgrastim (EU) LA-EP2006	LAM320 MDR[11] tuberculosis	OMB157 RMS[17]	Jakavi® Early myelofibrosis	KAE609 Malaria	Cosentyx® AS H2H[22]
FTY720 Pediatric MS[4]	Rituximab (US) GP2013	LEE011+ fulv HR+, HER2 (-) postmenopausal adv. BC[12] 1st/2nd line	QMF149 Asthma	RTH258 DME[20]	KAF156 Malaria	INC280 NSCLC[7] (EGFRm)
		LEE011+ tmx + gsn/or NSAI + gsn HR+, HER2 (-) premenopausal adv. BC[12] 1st line	QVM149 Asthma	Tafinlar® + Mekinist® BRAF V600+ Colorectal cancer	LIK066 Weight loss	LEE011 HR+, HER2 (-) BC[12] (adjuvant)
		Lucentis® ROP[13]	Zykadia® ALK+ adv. NSCLC[7] (Brain metastases)		LJN452 NASH[21]	PKC412 AML[23] (FLT3 wild type)
		Tafinlar® + Mekinist® BRAF V600+ Melanoma (adjuvant)	Infliximab (US) GP2018		PIM447 Hematologic tumors	QAW039 Atopic dermatitis
		Pegfilgrastim (US) LA-EP2006				

New molecule
New indication
New formulation
Biosimilars

a) In collaboration with Amgen; Novartis has AMG 334 rights outside of US, Canada and Japan.
b) Submitted in EU (positive CHMP opinion).
c) Submitted in EU.
d) Ongoing health authority consultations to agree on path forward.
e) Encore Vision transaction closed in January 2017.
f) Ziarco Group transaction closed in January 2017.

Combination abbreviations:

fulv	fulvestrant
tmx	tamoxifen
gsn	goserelin
NSAI	Non-steroidal aromatase inhibitor

1. Secondary prevention of cardiovascular events
2. Tuberous sclerosis complex
3. Diffuse large B-cell lymphoma
4. Multiple sclerosis
5. Severe aplastic anemia
6. Chronic myeloid leukemia
7. Non-small cell lung cancer
8. Neovascular age-related macular degeneration
9. Non-Hodgkin's lymphoma
10. Non-radiographic axial spondyloarthritis
11. Multi-drug resistant
12. Breast cancer
13. Retinopathy of prematurity
14. Secondary progressive multiple sclerosis
15. Preserved ejection fraction
16. Graft-versus-host disease
17. Relapsing multiple sclerosis
18. Chronic spontaneous urticaria / chronic idiopathic urticaria
19. Psoriatic arthritis head-to-head study versus adalimumab
20. Diabetic macular edema
21. Non-alcoholic steatohepatitis
22. Ankylosing spondylitis head-to-head study versus adalimumab
23. Acute myeloid leukemia

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Expected key 2017 milestones

	H1 2017		H2 2017	
Regulatory decisions	**LEE011**	HR+/HER2- adv. BC (US)	**LEE011**	HR+/HER2- adv. BC (EU)
	PKC412	AML and ASM (US)	**PKC412**	AML and ASM (EU)
	Tafinlar®+Mekinist®	BRAF+ NSCLC	**GP2013**	Rituximab BS[3] (EU)
	GP2015	Etanercept BS[3] (EU)	**Zykadia®**	ALK+ NSCLC (EU)
	Zykadia®	ALK+ NSCLC (US)		
Submissions	**AMG 334**	Migraine	**GP2013**	Non-Hodgkin's Lymphoma (US)
	CTL019	Ped. ALL (US)	**RLX030**	Acute heart failure[2]
	GP2017	Adalimumab BS[3] (EU)	**ACZ885**	CV risk reduction[2]
	GP1111	Infliximab BS[3] (EU)	**CTL019**	DLBCL[2] (US)
	BAF312	*Secondary progressive MS[1]*	**GP2017**	Adalimumab BS[3] (US)
			LA-EP2006	Pegfilgrastim BS[3] (EU)
Major trial readouts	**RLX030**	RELAX-AHF-2 (AHF)	**CTL019**	JULIET (DLBCL)
	ACZ885	CANTOS (CVRR)	**RTH258**	HARRIER, HAWK (nAMD)

1. Depending on outcome of consultations with health authorities 2. If results from Phase III trials are supportive 3. BS=Biosimilar

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Summary

- Focus on operational excellence and productivity with goal to achieve R&D spend of 20% of Innovative Medicines sales in the near term
- Broad, high value late stage pipeline with 13 potential blockbusters and depth and quality assets in each therapeutic area
- Strong and diverse set of emerging Phase II assets from internal research and 10 recent external deals

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Appendix

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Novartis Oncology with a leading portfolio at all stages

Onco
CM
NS
I&D
Resp
Oph

Marketed

Afinitor®
Arzerra®
Exjade® /Jadenu™
Farydak®
Femara®
Gleevec®
Jakavi®
Promacta/ Revolade®
Sandostatin® LAR
Signifor®
Tafinlar® + Mekinist®
Tasigna®
Tykerb®
Votrient®
Votubia®
Zykadia®
Zometa®

Late stage development

Afinitor®
Arzerra®
BYL719+fulv.
CTL019
INC280
Jakavi®
LEE011
PKC412
Promacta®
SEG101
Signifor® LAR
Tafinlar® + Mekinist®
Tasigna®
Zykadia®

Early stage development

PD-1 (PDR001)
PD-L1 (FAZ053)
LAG3 (LAG525)
TIM3 (MBG453)
CSF-1 (MCS110)
CSF-1R (BLZ945)
CART-19 (CTL019)
CART-BCMA (MCM998)
Het IL-15 (NIZ985)
Adenosine receptor (NIR178)
TGFβ (NIS793)
STING (MIW815)
GITR (GWN323)
CD123 x CD3 (SQZ622)
CD20 x CD3 (THG338)
ABL001
EGF816
SERD
BGJ398
FGF401
LXH254
LTT462
EGF816
HDM201
BCL201
MAK683
WNT974
ABL001
PIM447
IDH305
LSZ102
LXS196
PCA062
HKT288

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Watch List: Emerging assets

Oncology

ABL001
CML
(Ph II)

- Allosteric BCR-ABL inhibitor
- ≥3rd line Ph II trial ongoing; Ph III expected to begin 2017
- 1st line combination Ph I trial with 1st generation TKIs ongoing

INC280
cMET inhibitor
(Ph Ib/II)

- Ph Ib/II combination trial with EGFR inhibitor in NSCLC
- Expected readout: H2 2017

BYL719
PI3k inhibitor
(Ph III)

- PI3k inhibitor for HR+, HER2- postmenopausal advanced breast cancer
- Phase III in combination with fulvestrant ongoing

Jakavi®
GVHD
(Ph III)

- Potential 1st therapy for GVHD
- Ph III trial in treatment of steroid refractory acute GVHD open for enrollment
- Expected readout and filing in 2019

Abbreviations: IO=immuno-oncology; cMET=tyrosine-protein kinase Met; EGFR=epidermal growth factor receptor; GVHD=graft vs. host disease; NSCLC=non-small cell lung cancer; PD1=programmed cell death protein 1; TKI=tyrosine kinase inhibitor

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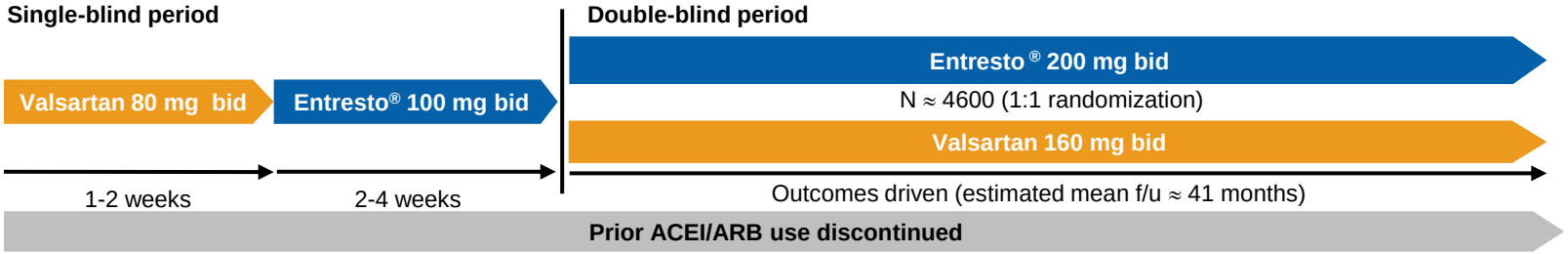
Entresto® - PARAGON trial designed to establish Entresto® in HFpEF; trial fully enrolled

PARAGON trial design

PARAGONHF



Patient population	• ≥50 years with CHF NYHA Class II–IV treated with diuretics for at least 30 days, LVEF ≥ 45%, and elevated NT-proBNP* • Structural heart disease (left atrial enlargement or left ventricular hypertrophy)
Primary Objective	CV death **and total** (first and recurrent) HF hospitalizations
Secondary objectives	(1) Change in KCCQ clinical summary score; (2) Change in NYHA class; (3) Renal progression; and (4) all-cause mortality
Sample size considerations	• N=4600 provides 95% and 85% power to detect 22% and 19% reduction in primary endpoint, respectively • Target number of primary composite events ≥1847 with minimum follow-up of 26 months • One interim efficacy analysis at 2/3 of primary events; reassessment of minimum follow-up time will be done at interim analysis

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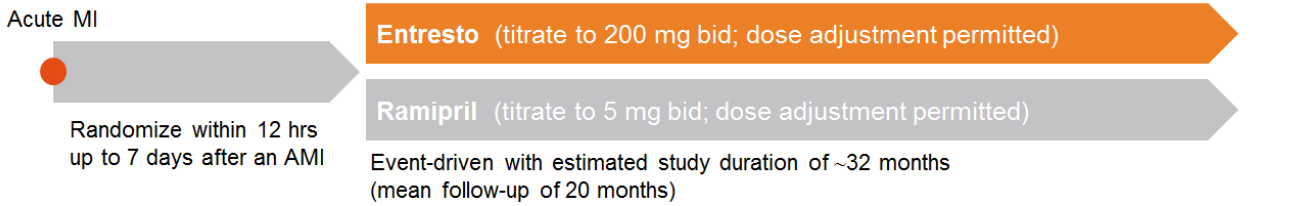
PARADISE trial designed to demonstrate potential benefit of Entresto® in post-AMI patients

PARADISE trial design



Patient population	LV systolic dysfunction (LVEF ≤40%) or pulmonary congestion following an acute MI, without prior history of chronic HF
Primary endpoint	Composite of CV death, HF hospitalization or outpatient HF
Key secondary endpoints	• Composite of CV death or HF hospitalization • Composite of HF hospitalization or outpatient HF (new onset HF) • Composite of CV death, MI or stroke
Sample size	• N=4,700 patients provides 80% power to detect 18% RRR *vs.* Ramipril • 800 primary events • 633 secondary events of CV death + HF hospitalization

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Watch List: Additional emerging assets

Cardio-Metabolic

LIK066
Weight loss
(Ph IIb)

- SGLT 1/2 inhibitor
- Projected 10+% weight loss at 52 weeks from Ph IIa data
- Phase IIb starting in H1 2017
- Expected readout in 2018

LHW090
Resistant hypertension
(Ph I)

- Target not disclosed
- Phase IIb dose ranging study in resistant hyper-tension planned in 2018

MAA868
Stroke prevention
(Ph IIb in 2017)

- Target not disclosed
- Phase IIb activities planned to start in 2017
- Expected readout ~2020

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Watch List: Emerging assets

Neuroscience

EMA401
Neuropathic pain
(Ph II)

- Angiotensin II Type-2 Receptor antagonist
- Showed significant improvement in post-herpetic neuralgia
- Ph IIb program to start in 2017

BYM338
Sarcopenia, hip fracture
(Ph II)

- Activin type-2 receptor mAb
- Ph IIb studies recruiting and expected to complete in 2018

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Cosentyx® has demonstrated strong and sustained efficacy across three indications

	Psoriasis	Psoriatic Arthritis (PsA)	Ankylosing spondylitis (AS)
Strong response	• Superiority to Enbrel® & Stelara® [1,2] • 79% PASI 90[3] • 44% PASI 100[3]	• ACR 20 – 84% at week 52[13] • Joint pain relief from week 1[14,15] • Dactylitis & enthesitis resolution at weeks 24 & 104[16,17]	• ASAS 20 – 82% at week 52[19] • Spinal pain relief from week 1[20]
Sustained response	4 years: almost 100% sustained response[4]	3 years: >80% ACR 20 response in anti–TNF-naïve patients [8,18]	2 years: >80% ASAS 20 response in anti–TNF-naïve patients [21,22]
Differentiating safety profile	Favorable safety profile similar to etanercept and ustekinumab[1,2,5]		
	No new or unexpected long-term safety signals across indications[4,6-10]		
	Very low immunogenicity[11,12]		
	Almost zero injection site reactions[1]		

1 Langley R, et al. NEJM 2014;371:326; 2. Blauvelt A, et al. JAAD 2016 [ePub ahead of print] 3. Thaci D, et al. JAAD, 2015; 73, 3, 400–409; 4. Seminars in Cutaneous Medicine and Surgery (Supplement 7), Vol. 35, December 2016; 5. van de Kerkhof P, et al. JAAD 2016;75:83; 6. Mease P, et al. Arthritis Rheumatol. 2016;68(Suppl.10). Abstract 1704; 7. Kavanaugh A, et al. Arthritis Care Res. 2016 [ePub ahead of print]; 8. Mease P, et al. Arthritis Rheumatol. 2016;68(Suppl.10). Abstract 961; 9. Baeten D, et al. Arthritis Rheumatol 2015;67(Suppl10) Abstract 2896; 10. Marzo-Ortega H, Ann Rheum Dis. 2016;75(Suppl2): Abstract 812;11. Reich, K., et al. Br J Dermatol. 2016 doi:10.1111/bjd.14965; 12. Reich K, et al. PIN 2016. P224; 13. McInnes IB, et al. Arthritis Rheumatol. 2016;68 (suppl 10): abstract 2757; 14. Strand V, et al. Ann Rheum Dis. 2016 [ePub ahead of print]; 15. Mease P, et al. ACR 2015. Oral presentation; 16. Kavanaugh A, et al. Arthritis Care Res. 2016 [ePub ahead of print]; 17. Mease P, McInnes IB. Rheumatol Ther. 2016;3:5–29; 18. Novartis Data on File 2016. FUTURE 1 Data Tables; 14.2-1.9a, 14.2-7.9a. 14/2-12.8a; 19. Marzo-Ortega H, et al. Ann Rheum Dis. 2016;75(Suppl2): abstract 812; 20. Novartis Data on File. 2015. MEASURE 2 Clinical Study Report; 21. Baeten D, et al. Arthritis Rheumatol 2015;67(Suppl10) Abstract 2896; 22. Novartis Data on File 2015. Week 104 Data Tables 14.2-1.5 and 14.2-2.5 Note: Enbrel® is a registered trademark of Amgen Inc. Stelara® is a registered trademark of Janssen Biotech, Inc.

NOVARTIS

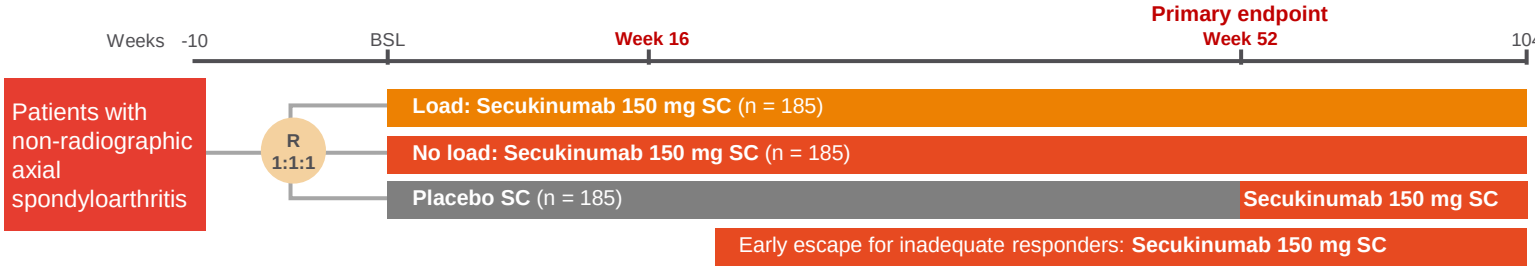
Cosentyx® PREVENT trial evaluates benefit of earlier treatment of spondyloarthritis

Cosentyx (secukinumab)

Onco
CM
NS
I&D
Resp
Oph

PREVENT trial design

PREVENT



Patient population	• Diagnosis of axial spondyloarthritis according to ASAS criteria with objective signs of inflammation on MRI and / or abnormal CRP • Active disease as assessed with a total BASDAI ≥ 4 cm and total back pain score ≥ 40 mm • No radiographic evidence for sacroiliitis according to mNY criteria
Primary Objective	ASAS40 response (Assessment of SpondyloArthritis International Society criteria) at Week 16 and at Week 52
Secondary objectives	Week 16: ASAS20, ASAS5/6, and ASAS partial remission response rates; change in BASFI, SF-36 PCF, hsCRP levels Week 16 and 52: Change in sacroiliac joint edema on MRI, ASQoL scores and BASDAI 50 response rates Week 52: rate of patients achieving ASDAS-CRP inactive disease

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Watch List: Additional Emerging assets

Immunology & Dermatology

VAY736
Sjoegren's Syndrome
(Ph IIb to start)

- Anti-BAFF-R
- Showed symptom relief in patients with primary Sjoegren's Syndrome
- Phase IIb dose ranging study planned to start in Q1 2017
- Expected readout: 2019

CJM112
Multiple
(Ph IIb to start)

- High affinity anti-IL17A mAb
- Demonstrated increased potency vs. secukinumab in psoriasis
- Multiple exploratory studies in dermatology ongoing
- Phase IIb trials expected to start in 2017

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Emerging assets: QBW251, a CFTR potentiator with potential for Cystic Fibrosis and COPD

Cystic Fibrosis

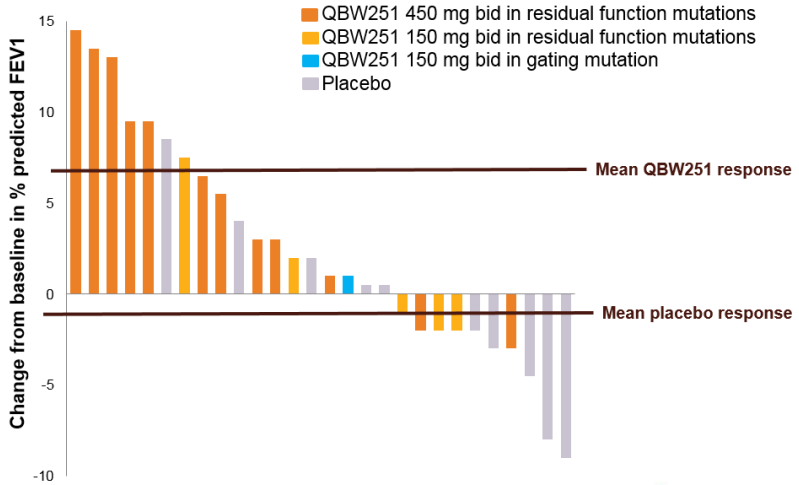
- Demonstrated promising safety and efficacy profile in proof-of-concept (PoC) study in cystic fibrosis (CF)
- Potential best-in-class CFTR modulator therapy for broad CF patient base
- Ongoing evaluation of potential pairing compound(s) for QBW251

COPD

- PoC study in COPD is ongoing

Change from baseline on FEV1 % predicted

Individual patient responses in Cohorts 1 & 2 and pooled placebo; PoC study (QBW251X2101)



Source: Presentation/poster at EU CF Congress and NACFC (2016)

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Watch List: Emerging assets

Respiratory

QBW251
Cystic Fibrosis/COPD
(Ph II)

- CFTR potentiator
- Demonstrated clear benefit in exploratory study in CF patients
- Development strategy incl. combos under evaluation

CJM112
Asthma
(Ph II)

- High affinity anti-IL17A
- Early study in severe uncontrolled asthma suggests higher response in IgE low patients
- Evaluation in neutrophilic asthma ongoing

ACZ885
Sarcoidosis
(Ph II)

- Anti-IL1β mAb
- Exploratory study ongoing in pulmonary sarcoidosis

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Pipeline of key projects in confirmatory development

Post-PoC			Phase III / Pivotal			In Registration
ABL001 CML[1] 3rd line	KAE609 Malaria	UNR844[a] Presbyopia	AMG 334[c] Migraine	Cosentyx® AS H2H[12]	PKC412 AML[20] (FLT3 wild type)	LEE011 + ltz HR+, HER2(-) postmenopausal adv. BC[6] 1st line
BYM338 Hip fracture	KAF156 Malaria	VAY736 Primary Sjoegren's syndrome	BAF312 SPMS[5]	CTL019 DLBCL[13]	Promacta®/Revolade® SAA[21] 1st line	PKC412 AML[20]
CAD106 Alzheimer's disease	LIK066 Weight loss	ZPL389[b] Atopic dermatitis	BYL719 + fulv HR+, HER2 (-) postmenopausal adv. BC[6] 2nd line	Entresto® Heart failure (PEF)[14]	QMF149 Asthma	Afinitor®/Votubia®[d] TSC[23] seizures
CJM112 Immune disorders	LJN452 NASH[3]	BYM338 Sarcopenia	CTL019 Pediatric acute lymphoblastic leukemia	Entresto® Post-acute myocardial infarction	QVM149 Asthma	Ilaris®[e] Periodic fever syndromes
CNP520 Alzheimer's disease	PIM447 Hematologic tumors	INC280 NSCLC[2] (EGFRm)	LCI699 Cushing's disease	FTY720 Pediatric MS[15]	RTH258 DME[22]	PKC412 ASM[24]
EMA401 Neuropathic pain	QBW251 Cystic fibrosis	QAW039 Atopic dermatitis	QAW039 Asthma	Jakavi® Early myelofibrosis	Tafinlar® + Mekinist® BRAF V600+ Melanoma (adjuvant)	Tafinlar® + Mekinist® BRAF V600+ NSCLC[2]
INC280 NSCLC[2]	QGE031 CSU/CIU[4]	Tafinlar® + Mekinist® BRAF V600+ Colorectal cancer	RLX030 Acute heart failure	Jakavi® GVHD[16]	Zykadia® ALK+ adv. NSCLC[2] (Brain metastases)	Tasigna®[f] CML[1] treatment free remission
		Infliximab (US) GP2018	RTH258 nAMD[7]	LAM320 MDR[17] tuberculosis	Adalimumab (US/EU) GP2017	Zykadia® ALK+ adv. NSCLC[2] (1st line, treatment naive)
			SEG101 Sickle cell disease	LEE011+ fulv HR+, HER2(-) postmenopausal adv. BC[6] 1st/2nd line	Epoetin-alfa (US) HX575	Signifor® LAR[25] Cushing's disease
			ACZ885 Sec. prev. CV events[8]	LEE011+ tmx + gsn/or NSAI + gsn HR+, HER2(-) premenopausal adv. BC[6] 1st line	Infliximab (EU) GP1111	Etanercept (EU) GP2015
			Arzerra® NHL[9] (refractory)	LEE011 HR+, HER2(-) BC[5] (adjuvant)	Pegfilgrastim (US/EU) LA-EP2006	Rituximab (EU) GP2013
			Cosentyx® nrAxSpA[10]	Lucentis® ROP[18]	Rituximab (US) GP2013	
			Cosentyx® PsA H2H[11]	OMB157 RMS[19]		

1. Chronic myeloid leukemia
2. Non-small cell lung cancer
3. Non-alcoholic steatohepatitis
4. Chronic spontaneous urticaria / chronic idiopathic urticaria
5. Secondary progressive multiple sclerosis
6. Breast cancer
7. Neovascular age-related macular degeneration
8. Secondary prevention of cardiovascular events
9. Non-Hodgkin's lymphoma
10. Non-radiographic axial spondyloarthritis
11. Psoriatic arthritis head-to-head study versus adalimumab
12. Ankylosing spondylitis head-to-head study versus adalimumab
13. Diffuse large B-cell lymphoma
14. Preserved ejection fraction
15. Multiple sclerosis
16. Graft-versus-host disease
17. Multi-drug resistant
18. Retinopathy of prematurity
19. Relapsing multiple sclerosis
20. Acute myeloid leukemia
21. Severe aplastic anemia
22. Diabetic macular edema
23. Tuberous sclerosis complex
24. Advanced systemic mastocytosis
25. Long-acting release

a) Encore Vision transaction closed in Jan 2017.
b) Ziarco Group transaction closed in Jan 2017.
c) In collaboration with Amgen; Novartis has AMG 334 rights outside of US, Canada and Japan.
d) Submitted in EU (positive CHMP opinion).
e) Approved in US, submitted in EU (positive CHMP opinion).
f) Submitted in EU.

New molecule
New indication
New formulation
Biosimilars

Combination abbreviations:
fulv fulvestrant
ltz letrozole
tmx tamoxifen
gsn goserelin
NSAI Non-steroidal aromatase inhibitor

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Key definitions and trademarks

This presentation contains several important words or phrases that we define as below:

ADHF: Acute decompensated heart failure
ALK: Anaplastic lymphoma kinase
ALL: Acute lymphatic leukemia
AMD: Age-Related Macular Degeneration
AMI: Acute myocardial infection
AML: Acute myeloid leukemia
Approval: In Pharmaceuticals and Alcon in US and EU; each indication and regulator combination counts as approval; excludes label updates, CHMP opinions alone and minor approvals
aRCC: advanced renal cell cancer
ARNI: Antiogensin receptor neprilysin inhibitor
AS: Ankylosing Spondylitis
ASM: Aggressive systemic mastocytosis
BTD: Breakthrough therapy designation
CGRP: Calcitonin gene-related peptide
cITP: Chronic immune thrombocytopenia
CM: Chronic migraine
CML: Chronic myeloid leukemia
COPD: Chronic Obstructive Pulmonary Disease
CSU / CIU: Chronic spontaneous urticaria / Chronic idiopathic urticaria
CVRR: Cardiovascular risk reduction
DLBCL: Diffuse large B-cell lymphoma
AML: Acute myeloid leukemia
EF: ejection fraction
EM: Episodic migraine
GvHD: graft vs. host disease**HF**: Heart failure
HF-pEF: Heart failure with preserved ejection fraction
HFrEF: Heart failure with reduced ejection fraction
HR+/HER2- mBC: Hormone Receptor positive / Human Epidermal growth factor receptor 2 negative metastatic breast cancer
LoE: Loss of exclusivity
MF: Myelofibrosis
MI: Myocardial infarction
MS: Multiple sclerosis
NASH: Non-Alcoholic Steatohepatitis
NET: Neuroendocrine tumor
New assets: Assets acquired in the GSK transaction which closed on March 2, 2015
NSAI: Nonsteroidal aromatase inhibitor
NSCLC: Non-small cell lung cancer
NTD: New Therapeutic Drug
ORR: Overall response rate
OS: Overall survival
PA: Prior authorization
PASI 90: 90% reduction in Psoriasis Area Severity Index from baseline
PFS: Progression free survival
PsA: Psoriatic arthritis
PsO: Psoriasis
PV: Polycythemia vera
PY: Prior year
QoL: Quality of Life
RCC: Renal cell cancer
ROP: Retinopathy of prematurity
RRMS: relapsing-remitting multiple sclerosis
SAA: Severe aplastic anemia
scFv: Single chain variable fragment
SCPC: Sickle cell pain crisis
SpA: Spondyloarthritis
SPMS: Secondary progressive multiple sclerosis

NOVARTIS

Appendix
Development

Includes selected ongoing or recently concluded global trials of Novartis development programs/products which are in confirmatory development or marketed (typically Phase II or later).
For further information on all Novartis clinical trials, please visit: www.novartisclinicaltrials.com

NOVARTIS

Ilaris® - Anti IL-1β

Study	NCT01327846 CANTOS (CACZ885M2301)	NCT02059291 CLUSTER (CACZ885N2301)
Indication	Cardiovascular risk reduction	Hereditary periodic fevers
Phase	Phase III	Phase III
Patients	10,064	203
Primary Outcome Measures	Time to first occurrence of major adverse cardiovascular event, which is a composite of CV death, non-fatal MI, and stroke	To demonstrate significant reduction of disease activity with canakinumab vs. placebo
Arms/Intervention	• Canakinumab 50 mg + standard care therapy • Canakinumab 150 mg + standard care therapy • Canakinumab 300 mg + standard care therapy • Placebo + standard care therapy	• Canakinumab • Placebo
Target Patients	Post-myocardial infarction patients on standard of care with elevated hsCRP	Patients with, 3 separate disease cohorts TRAPS, HIDS, and colchicine resistant FMF (Hereditary periodic fevers)
Expected Completion	H2-2017	Q3-2017
Publication	Press release planned Q2-2017; Primary endpoint results ESC 2017; publication in Q3-2017	N2301-Epoch 2-Efficacy and Safety publication in Q4-2017

NOVARTIS

Ilaris® - Anti IL-1β

Study	NCT02296424 ß-SPECIFIC 4 Patients (CACZ885G2306)
Indication	SJIA - Systemic Juvenile Idiopathic Arthritis
Phase	Phase IIIB/IV
Patients	182
Primary Outcome Measures	Proportion of patients in clinical remission on canakinumab who are able to remain at an initial reduced canakinumab dose or prolonged canakinumab dose interval
Arms/Intervention	• Canakinumab dose reduction • Canakinumab dose interval prolongation
Target Patients	Patients with Systemic Juvenile Idiopathic Arthritis (SJIA) (Pediatric)
Expected Completion	Q4-2017
Publication	TBD

NOVARTIS

Cosentyx® - Anti IL-17

Study	NCT01636687 JUNCTURE (CAIN457A2309)	NCT02404350 FUTURE 5 (CAIN457F2342)
Indication	Psoriasis	Psoriatic arthritis
Phase	Phase III	Phase III
Patients	171	990
Primary Outcome Measures	Psoriasis Area and Severity Index (PASI) 75 score and Investigators' Global Assessment (IGA) with 0 or 1 response	American College of Rheumatology 20 (ACR20) response at Week 16
Arms/Intervention	- Secukinumab 150 mg - Secukinumab 300 mg - Placebo	- Secukinumab 150 mg load - Secukinumab 150 mg no load - Secukinumab 300 mg load - Placebo
Target Patients	Patients with chronic plaque-type psoriasis	Patients with active psoriatic arthritis
Expected Completion	Q1-2017	2019
Publication	TBD	TBD

NOVARTIS

Cosentyx® - Anti IL-17

Study	NCT01863732 (CAIN457F2305E1 – extension study)	NCT02896127 (CAIN457F2308)
Indication	Ankylosing spondylitis	Ankylosing spondylitis
Phase	Phase III	Phase III
Patients	300	450
Primary Outcome Measures	Assessment of spondyloarthritis international society criteria / ASAS 20 response	The proportion of participants who achieve an ASAS 20 response
Arms/Intervention	- Secukinumab 75 mg in PFS - Secukinumab 150 mg in PFS	- Secukinumab 150 mg s.c. - Placebo s.c.
Target Patients	Patients with active ankylosing spondylitis	Patients with active ankylosing spondylitis
Expected Completion	2018	2019
Publication	TBD	TBD

NOVARTIS

Cosentyx® - Anti IL-17

Study	NCT01649375 (CAIN457F2310)	NCT02008916 (CAIN457F2314)
Indication	Ankylosing spondylitis	Ankylosing spondylitis
Phase	Phase III	Phase III
Patients	222	222
Primary Outcome Measures	Assessment of SpondyloArthritis International Society / ASAS 20 response	Assessment of Spondyloarthritis International Society criteria / ASAS 20 response
Arms/Intervention	- Secukinumab 75 mg - Secukinumab 150 mg - Placebo	- Secukinumab 10 mg/kg / 300 mg - Secukinumab 10 mg/kg / 150 mg - Placebo
Target Patients	Patients with active ankylosing spondylitis	Patients with active ankylosing spondylitis
Expected Completion	2019	Q4-2017
Publication	TBD	TBD

NOVARTIS

Cosentyx® - Anti IL-17

Study	NCT02159053 (CAIN457F2320)	NCT01989468 (CAIN457F2318)
Indication	Ankylosing spondylitis	Psoriatic arthritis
Phase	Phase III	Phase III
Patients	350	405
Primary Outcome Measures	Assessment of Spondyloarthritis International Society criteria / ASAS 20	American College of Rheumatology 20 (ACR20) response in subjects treated with secukinumab vs. placebo
Arms/Intervention	- Secukinumab 150 mg s.c. with loading - Secukinumab 150 mg s.c. without loading - Placebo	- Secukinumab (AIN457) 150 mg s.c. - Secukinumab (AIN457) 300 mg s.c. - Placebo
Target Patients	Patients with active ankylosing spondylitis	Patients with active psoriatic arthritis
Expected Completion	2018	2018
Publication	TBD	TBD

NOVARTIS

Cosentyx® - Anti IL-17

Study	NCT01752634 (CAIN457F2312)	NCT01892436 FUTURE 1 extension (CAIN457F2306E1)
Indication	Psoriatic arthritis	Psoriatic arthritis
Phase	Phase III	Phase III
Patients	400	500
Primary Outcome Measures	Proportion of subjects achieving American College of Rheumatology 20 (ACR20) response criteria	Proportion of subjects that have a positive clinical response to treatment (individual improvement) in disease activity according to ACR20 (or ACR50 or ACR 70)
Arms/Intervention	- Secukinumab (AIN457) 150 mg s.c. - Secukinumab (AIN457) 75 mg s.c. - Secukinumab (AIN457) 300 mg s.c. - Placebo s.c.	- Secukinumab 75 mg - Secukinumab 150 mg
Target Patients	Patients with active psoriatic arthritis	Patients with active psoriatic arthritis
Expected Completion	2019	2018
Publication	TBD	TBD

NOVARTIS

Cosentyx® - Anti IL-17

Study	NCT02294227 FUTURE 4 (CAIN457F2336)	NCT02471144 (CAIN457A2310)
Indication	Psoriatic arthritis	Psoriasis
Phase	Phase III	Phase III
Patients	318	160
Primary Outcome Measures	Assessment of American College of Rheumatology 20 (ACR20)	The percentage of Participants achieving a 75% Improvement from Baseline in PASI Score at week 12
Arms/Intervention	- Secukinumab 150 mg with loading - Secukinumab 150 mg without loading - Placebo	- Secukinumab low dose - Secukinumab high dose - Placebo - Etanercept (comparator)
Target Patients	Patients with active psoriatic arthritis	Patients from 6 to less than 18 years of age with severe chronic plaque
Expected Completion	2018	2023
Publication	TBD	TBD

NOVARTIS

Cosentyx® - Anti IL-17

Study	NCT01555125 FEATURE (CAIN457A2308)	NCT01640951 (CAIN457A2304E1 – extension study)
Indication	Psoriasis	Psoriasis
Phase	Phase III	Phase III
Patients	171	740
Primary Outcome Measures	Psoriasis Area and Severity Index (PASI) 75 score and Investigators' Global Assessment (IGA) with 0 or 1 response	The number and percentage of subjects having any AE
Arms/Intervention	- Secukinumab 150 mg - Secukinumab 300 mg - Placebo	- Fixed-time interval regimen secukinumab 150 mg - Retreatment at start of relapse secukinumab 150 mg - Fixed-time interval regimen secukinumab 300 mg - Retreatment at start of relapse secukinumab 300 mg - Open label secukinumab 300 mg
Target Patients	Patients with chronic plaque-type psoriasis	Patients with moderate to severe chronic plaque-type psoriasis treated with either a fixed dose regimen or on a retreatment at start of relapse regimen
Expected Completion	Q1-2017	Q3-2017
Publication	TBD	TBD

NOVARTIS

Cosentyx® - Anti IL-17

Study	NCT02748863 ALLURE (CAIN457A2323)	NCT01544595 (CAIN457A2302E1 – extension study)
Indication	Psoriasis	Psoriasis
Phase	Phase III	Phase III
Patients	210	1,144
Primary Outcome Measures	Percentage of patients who achieve ≥ 75% reduction in PASI and achieve IGA mod 2011 0 or 1 and improved by at least 2 points on the IGA scale compared to baseline	Cumulative rate of subjects with loss of psoriasis area and severity index (PASI) 75 response; demonstrate long-term efficacy, safety, and tolerability
Arms/Intervention	- Secukinumab 2 mL form - Secukinumab 1 mL form - Placebo	- Secukinumab 150 mg or 300 mg - Placebo
Target Patients	Adult subjects with moderate to severe plaque psoriasis	Patients with moderate to severe chronic plaque-type psoriasis completing preceding psoriasis phase III studies with secukinumab
Expected Completion	2018	2017
Publication	TBD	TBD

NOVARTIS

Cosentyx® - Anti IL-17

Study	NCT02696031 (CAIN457H2315)	NCT02826603 CLARITY (CAIN457A2326)
Indication	Non-radiographic Axial Spondyloarthritis	Psoriasis
Phase	Phase III	Phase IIIB
Patients	555	1,100
Primary Outcome Measures	The proportion of participants who achieved an ASAS 40 response (Assessment of SpondyloArthritis International Society criteria); Evaluate the safety, tolerability and efficacy up to 2 years	Psoriasis Area and Severity Index (PASI) will be assessed/calculated as per usual standard
Arms/Intervention	- Secukinumab 150 mg - Secukinumab 150 mg no load - Placebo	- Secukinumab 300 mg - Ustekinumab 45 mg/ 90 mg
Target Patients	Patients with non-radiographic axial spondyloarthritis	Patients with moderate to severe plaque psoriasis
Expected Completion	2018	2018
Publication	TBD	TBD

NOVARTIS

Tasigna® - Bcr-Abl, c-Kit and PDGF-R tyrosine kinase inhibitor

Study	NCT00471497 ENESTnd (CAMN107A2303)	NCT01698905 ENESTop (CAMN107A2408)
Indication	CML res/intol to imatinib	CML res/intol to imatinib
Phase	Phase III	Phase II
Patients	771	117
Primary Outcome Measures	Molecular Response Rate (MMR) at 12 months	No documented confirmed loss of MR4, no documented loss of MMR and no re-starting of nilotinib therapy
Arms/Intervention	- Nilotinib 300mg - Nilotinb 400 mg - Imatinib 400mg	- Single-arm study of nilotinib
Target Patients	Adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia in chronic phase (CML-CP)	Adult CML-CP patients who received a minimum of 3 years of TKI therapy, started off with imatinib treatment for > 4 weeks, then switched to nilotinib for at least 2 years prior to study entry and achieved MR4.5 on nilotinib, but did not have documented MR4.5 at the time of switch from imatinib to nilotinib
Expected Completion	2018	2019
Publication	Saglio G, et al. N Engl J Med. 2010;362(24):2251-2259	Hughes TP, et al. J Clin Oncol. 2016;34 [abstract 7054]

NOVARTIS

Tasigna® - Bcr-Abl, c-Kit and PDGF-R tyrosine kinase inhibitor

Study	NCT01784068 ENEST Freedom (CAMN107I2201)	NCT01844765 DIALOG (CAMN107A2203)
Indication	CML res/intol to imatinib	Newly diag. CML and CML res/intol to imatinib/dasatinib
Phase	Phase II	Phase II
Patients	175	70
Primary Outcome Measures	Percentage of patients who are in MMR (major molecular response) at 48 weeks after starting the treatment-free remission (TFR) phase	Rate of Major Molecular Responder (MMR) by BCR-ABL RQ-PCR analysis from peripheral blood by 12 cycles
Arms/Intervention	- Single-arm study of nilotinib followed by treatment-free	- Newly diagnosed and untreated Ph+ CML in first chronic phase - Resistant/intolerant Ph+ CML in chronic phase - Resistant/intolerant Ph+ CML in accelerated phase
Target Patients	Patients with BCR-ABL1 positive Chronic Myelogenous Leukemia in chronic phase who have achieved durable minimal residual disease (MRD) status on first line nilotinib treatment	Pediatric patients with newly diagnosed Ph+ chronic myelogenous leukemia (CML) in chronic phase (CP) or with Ph+ CML in CP or accelerated phase (AP) resistant or intolerant to either imatinib or dasatinib
Expected Completion	2020	2020
Publication	Hochhaus A, et al. J Clin Oncol. 2016;34 [abstract 7001]	Congress/journal TBD in Q3-2017

NOVARTIS

API015 - CAD106 active Beta-amyloid immunotherapy; CNP520 BACE Inhibitor

Study	NCT02565511 GENERATION (CAPI015A2201J)
Indication	Alzheimer’s disease
Phase	Phase IIB/III
Patients	1,340
Primary Outcome Measures	Time to diagnosis of MCI due to Alzheimer's disease or dementia due to Alzheimer's disease; evaluate the efficacy of CAD106 and CNP520
Arms/Intervention	- CAD106 450 µg + Alum 450 µg i.m. - Placebo to CAD106 + Alum 450 µg i.m. - CNP520 50 mg oral - Placebo to CNP520 oral
Target Patients	Asymptomatic ApoE4 homozygotes at risk for developing Alzheimer’s disease dementia.
Expected Completion	>2022
Publication	TBD

NOVARTIS

BAF312 - S1P-R modulator

Study	NCT01185821 BOLD (CBAF312A2201E1)	NCT01665144 -EXPAND (CBAF312A2304)
Indication	Secondary Progressive Multiple Sclerosis	Secondary Progressive Multiple Sclerosis
Phase	Phase II	Phase III
Patients	297	1,530
Primary Outcome Measures	Long-term safety and tolerability (emphasis on cardiovascular events, viral infections, macular edema and dermatologic alterations)	The delay in time to confirmed disability progression as measured by EDSS
Arms/Intervention	- BAF312 10 mg - BAF312 2 mg - BAF312 0.5 mg - BAF312 dose between 0.1- 8 mg blinded	- BAF312 0.25 to 2 mg - Placebo
Target Patients	Patients (with relapsing-remitting Multiple Sclerosis) completed the core study BAF312A2201	Patients with secondary progressive multiple sclerosis
Expected Completion	Q1-2017	2023
Publication	TBD	TBD

NOVARTIS

BYL719 - Alpha-specific PI3K inhibitor

Study	NCT02437318 SOLAR-1 (CBYL719C2301)
Indication	HR+ mBC
Phase	Phase III
Patients	560
Primary Outcome Measures	Progression-free survival (PFS) for patients with PIK3CA mutant status
Arms/Intervention	- Fulvestrant 500 mg + alpelisib 300 mg - Fulvestrant 500 mg + placebo
Target Patients	Men and postmenopausal women with hormone receptor positive, HER2-negative advanced breast cancer which progressed on or after aromatase inhibitor treatment
Expected Completion	2018
Publication	TBD

NOVARTIS

BYM338 - Activin receptor II B

Study	NCT02333331 InvestiGAIT (CBYM338E2202)	NCT02152761 (CBYM338D2201)
Indication	Sarcopenia	Hip fracture recovery
Phase	Phase IIB	Phase IIB
Patients	280	245
Primary Outcome Measures	Dose range finding study to assess the effect of monthly doses of bimagrumab	Change from baseline in total lean body mass measured by DXA at week 24
Arms/Intervention	- Bimagrumab low dose - Bimagrumab moderate dose - Bimagrumab high dose - Placebo	- Bimagrumab low dose - Bimagrumab moderate dose - Bimagrumab high dose - Placebo
Target Patients	Older adults with sarcopenia	Patients after surgical treatment of hip fracture
Expected Completion	2018	2018
Publication	TBD	TBD

NOVARTIS

CTL019 - CART therapy

Study	NCT02445248 JULIET (CCTL019C2201)	NCT02435849 ELIANA (CCTL019B2202)
Indication	Relapsed / refractory DLBCL	Relapsed/ refractory pediatric and young adult ALL
Phase	Phase II	Phase II
Patients	105	100
Primary Outcome Measures	Overall response rate; efficacy and safety of CTL019	Overall remission rate (ORR) - overall remission rate during the 6 months after CTL019 administration, which includes CR and CR with incomplete blood count recovery (CRi) as determined by IRC assessment
Arms/Intervention	Single-arm study of CTL019	Single-arm study of single dose of CTL019
Target Patients	Adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)	Pediatric and young adult patients with relapsed and refractory B-cell acute lymphoblastic leukemia
Expected Completion	2023 (IA Q1 2017)	2022 (IA 2016)
Publication	Congress/journal TBD in Q3/Q4-2017	Congress/journal TBD in Q3-2017

NOVARTIS

Tafinlar®+Mekinist® - BRAF inhibitor and MEK inhibitor

Study	NCT01978236 GSK116521 (CDRB436B2202)	NCT01072175 Study 220 (CDRB436B2201)
Indication	Melanoma and Brain Metastases	Melanoma
Phase	Phase IIB	Phase IIB
Patients	30	430
Primary Outcome Measures	Concentrations and tissue distribution of dabrafenib and its metabolites	Safety, pharmacokinetics, pharmacodynamics and clinical activity of the BRAF inhibitor dabrafenib in combination with the MEK inhibitor trametinib
Arms/Intervention	- Dabrafenib 150 mg - Trametinib 2 mg	- Dabrafenib 75 mg - Trametinib 2 mg - Dabrafenib 75 mg + trametinib 2mg + dose escalation
Target Patients	Patients with BRAF mutation-positive metastatic melanoma to the brain	Patients with BRAF mutant metastatic melanoma
Expected Completion	Q2-2017	2018
Publication	TBD	Flaherty KT, et al. N Engl J Med. 2012 Nov;367(18):1694-703

NOVARTIS

Tafinlar®+Mekinist® - BRAF inhibitor and MEK inhibitor

Study	NCT01227889 BREAK-3 (CDRB436A2301)	NCT01336634 (CDRB436E2201)
Indication	Melanoma	NCSLC
Phase	Phase IIIA	Phase IIA
Patients	200	124
Primary Outcome Measures	Progression-free Survival (PFS) as assessed by the investigator	Overall response rate (ORR)
Arms/Intervention	- Dabrafenib150 mg - Intravenous dacarbazine (DTIC) 1000 mg/m2 - Crossover dabrafenib150 mg	- Dabrafenib 150 mg - Dabrafenib 150 mg + trametinib 2 mg
Target Patients	Previously untreated subjects with BRAF mutation positive advanced (Stage III) or metastatic (Stage IV) melanoma	Subjects with BRAF V600E mutation positive metastatic (stage IV) non-small cell lung cancer
Expected Completion	Q1-2017	2020
Publication	Hauschild A, et al. Lancet. 2012 Jul 28;380(9839):358-65	TBD

NOVARTIS

Tafinlar®+Mekinist® - BRAF inhibitor and MEK inhibitor

Study	NCT01682083 (CDRB436F2301)	NCT01584648 COMBI-d (CDRB436B2301)
Indication	Adjuvant Melanoma	Melanoma
Phase	Phase IIIA	Phase IIIA
Patients	852	340
Primary Outcome Measures	Relapse-free survival (RFS)	Progression-Free Survival (PFS) as Assessed by the Investigator
Arms/Intervention	- Dabrafenib 150 mg + trametinib 2 mg - Placebo	- Dabrafenib 150 mg + trametinib 2 mg - Placebo
Target Patients	Subjects with high-risk BRAF V600 mutation-positive melanoma after surgical resection	Patients with unresectable (Stage IIIC) or metastatic (Stage IV) BRAF V600E/K mutation-positive cutaneous melanoma
Expected Completion	2020	2018
Publication	TBD	Long GV, et al. N Engl J Med. 2014 Nov 13;371(20):1877-88

NOVARTIS

Tafinlar®+Mekinist® - BRAF inhibitor and MEK inhibitor

Study	NCT01597908 COMBI-V (CDRB436B2302)	NCT01677741 (CDRB436A2102)
Indication	Melanoma	Melanoma
Phase	Phase IIIB	Phase I
Patients	694	60
Primary Outcome Measures	Overall survival	Safety, tolerability and pharmacokinetics
Arms/Intervention	- Dabrafenib 150 mg + trametinib 2 mg - Vemurafenib 960 mg	Single-arm study of oral dabrafenib
Target Patients	Patients with unresectable (stage IIIc) or metastatic (stage IV) BRAF V600E/K mutation positive cutaneous melanoma	Pediatric Subjects Aged 1 Month to <18 Years with Advanced BRAF V600-Mutation Positive Solid Tumors
Expected Completion	2018	2018
Publication	Robert C, et al. N Engl J Med. 2015 Jan 1;372(1):30-9	TBD

NOVARTIS

Tafinlar®+Mekinist® - BRAF inhibitor and MEK inhibitor

Study	NCT01153763 BREAK-2 (CDRB436A2201)	NCT02039947 COMBI-MB (CDRB436B2204)
Indication	Melanoma	Melanoma
Phase	Phase IIA	Phase IIB
Patients	30	120
Primary Outcome Measures	Number of participants with a best overall response of confirmed Complete Response (CR) or Partial Response (PR) as assessed by the investigator	Intracranial response (IR) rate
Arms/Intervention	Single-arm study of dabrafenib150 mg	Dabrafenib 150 mg + trametinib 2 mg
Target Patients	Patients with BRAF mutant metastatic melanoma	Patients with BRAF mutation-positive melanoma that has metastasized to the brain
Expected Completion	Q2-2017	2019
Publication	Ascierto PA, et al. J Clin Oncol. 2013 Sep 10;31(26):3205-11	Congress/journal in Q1/Q2 2017

NOVARTIS

Gilenya® - S1P-R modulator

Study	NCT01892722 PARADIGMS (CFTY720D2311)	NCT01201356 LONGTERMS (CFTY720D2399)
Indication	Pediatric Multiple Sclerosis	Relapsing Multiple Sclerosis (RMS)
Phase	Phase IIIB	Phase IIIB/IV
Patients	190	4,133
Primary Outcome Measures	Frequency of relapses in patients treated for up to 24 months (using ARR)	Long-term safety and tolerability
Arms/Intervention	- Interferon beta-1a i.m. - Fingolimod 0.5 mg/ 0.25 mg	Single-arm study of Fingolimod 0.5 mg/day
Target Patients	Pediatric patients with multiple sclerosis with five-year fingolimod Extension Phase	Patients with relapsing multiple sclerosis
Expected Completion	2023	2019
Publication	TBD	TBD

NOVARTIS

Gilenya® - S1P-R modulator

Study	NCT01633112 ASSESS (CFTY720D2312)
Indication	Relapsing Remitting Multiple Sclerosis (RRMS)
Phase	Phase IIIB
Patients	1,960
Primary Outcome Measures	Comparison of 2 doses (0.25 mg and .5 mg) of fingolimod to glatiramer acetate (20 mg) in reducing the annualized relapse rate up to 12 months
Arms/Intervention	- Fingolimod 0.5 mg orally - Fingolimod 0.25mg orally - Copaxone® 20 mg s.c.
Target Patients	Patients with relapsing-remitting multiple sclerosis
Expected Completion	2022
Publication	TBD

NOVARTIS

GP2018 - Biosimilar infliximab

Study	GP18 101
Indication	Immunology
Phase	Phase I
Patients	210
Primary Outcome Measures	Pharmacokinetics and safety
Arms/Intervention	- GP2018 - EU-authorized Remicade® - US-licensed Remicade®
Target Patients	Healthy male volunteers
Expected Completion	Q3-2017
Publication	TBD

NOVARTIS

GP2013 - Biosimilar rituximab

Study	NCT02514772 (GP13 302)	NCT01419665 (GP13 301)
Indication	Immunology	Oncology
Phase	Phase III	Phase III
Patients	100	618
Primary Outcome Measures	Incidence of adverse events and serious adverse events, anaphylactic reactions, hypersensitivity; immunogenicity	Overall response rate in patients with FL
Arms/Intervention	- GP2013 10 mg/mL - Rituxan® or MabThera® 10 mg/mL	- GP2013 - Rituximab
Target Patients	Patients with active Rheumatoid Arthritis, previously treated with Rituxan or MabThera (ASSIST-RT)	Patients with previously untreated, advanced stage follicular lymphoma (ASSIST-FL)
Expected Completion	2016	2018
Publication	ASH in Q4-2016	ASH Poster 2016

NOVARTIS

GP2013 - Biosimilar rituximab

Study	NCT01274182 (GP13 201)
Indication	Immunology
Phase	Phase II
Patients	288
Primary Outcome Measures	Compare pharmacokinetics (PK) of GP2013 and rituximab following IV infusion in patients with RA
Arms/Intervention	- GP2013 1000 mg - Rituximab 1000 mg
Target Patients	Patients with rheumatoid arthritis refractory or intolerant to standard DMARDs and one or up to three anti-TNF ther
Expected Completion	Q1-2017
Publication	Journal TBD in Q4-2017; ACR Poster 2016

NOVARTIS

Erelzi® - Biosimilar etanercept

Study	NCT02638259 (GP15 301)
Indication	Immunology
Phase	Phase IIIb
Patients	366
Primary Outcome Measures	Change in DAS28-CRP score from baseline to week 24 in patients treated with GP2015 and patients treated with Enbrel
Arms/Intervention	- GP2015 50 mg - EU-authorized Enbrel® 50mg
Target Patients	Patients with moderate to severe, active rheumatoid arthritis
Expected Completion	Q4-2017
Publication	Presentation/poster at ACR Q4-2017

NOVARTIS

GP2017 - Biosimilar adalimumab

Study	NCT02016105 (GP17 301)	NCT02744755 (GP17 302)
Indication	Immunology	Immunology
Phase	Phase III	Phase III
Patients	448	308
Primary Outcome Measures	PASI 75 response rate	Change in DAS28-CRP score from baseline to week 12 in patients treated with GP2017 and patients treated with Humira
Arms/Intervention	- GP2017 - Humira® Adalimumab	- GP2017 - US licensed Humira® Adalimumab
Target Patients	Patients with moderate to severe chronic plaque-type psoriasis	Patients with moderate to severe active rheumatoid arthritis
Expected Completion	2016	2018
Publication	Abstract and poster at AAD 2017; Abstract and poster at ACG 2017; Manuscript of primary endpoint (16 weeks data) – journal TBD	TBD

NOVARTIS

GP2017 - Biosimilar adalimumab

Study	GP17 104
Indication	Immunology
Phase	Phase I
Patients	318
Primary Outcome Measures	Pharmacokinetics and safety
Arms/Intervention	- GP2017 - Humira® EU-authorized - Humira® US-licensed
Target Patients	Healthy male subjects
Expected Completion	2016
Publication	Abstract and poster at ACR 2017

NOVARTIS

HX575 US - Biosimilar epoetin alfa

Study	HX575 111
Indication	Oncology
Phase	Phase I
Patients	60
Primary Outcome Measures	Pharmacokinetics and pharmacodynamics
Arms/Intervention	- HX575 epoetin alfa - US-licensed epoetin alfa (Procrit®)
Target Patients	Healthy volunteers
Expected Completion	2016
Publication	TBD

NOVARTIS

Exjade® - Iron chelation of bis-hydroxy-phenyl triazole type

Study	NCT00940602 TELESTO (CICL670A2302)
Indication	Iron Overload
Phase	Phase II
Patients	225
Primary Outcome Measures	To compare deferasirox to placebo with regard to event-free survival in low and int-1 risk MDS patient with transfusional iron overload
Arms/Intervention	- Deferasirox, iron chelator - Placebo
Target Patients	Patients with myelodysplastic syndromes (low/int-1 risk) and transfusional iron overload (TELESTO)
Expected Completion	2018
Publication	TBD

NOVARTIS

INC280 - cMET Inhibitor

Study	NCT02468661 (CINC280B2201)	NCT02414139 (CINC280A2201)
Indication	EGFR mutated advanced/metastatic Non-small Cell Lung Cancer (NSCLC)	EGFR Wild-type, ALK negative advanced Non-small Cell Lung Cancer (NSCLC)
Phase	Phase IB/II	Phase II
Patients	135	318
Primary Outcome Measures	Phase Ib: Frequency and characteristics of Dose Limiting Toxicity (DLTs) to the INC280 and erlotinib combination; Phase II: Progression-free Survival (PFS	Overall Response Rate (ORR)
Arms/Intervention	- INC280 single agent - INC280 in combination with erlotinib - Platinum in combination with pemetrexed (comparator)	- Pre-treated pts. with cMET GCN ≥ 6 - Pre-treated pts. with cMET GCN ≥ 4 and < 6 - Pre-treated pts. with cMET GCN < 4 - Pre-treated pts. with cMET mutations regardless of cMET GCN - Treatment-naïve pts. with cMET dysregulation
Target Patients	Adult patients with EGFR mutation (L858R and /or ex19del), cMET-amplified, locally advanced/metastatic nonsmall cell lung cancer (NSCLC) with acquired resistance to EGFR TKI	Adult patients with EGFR wild-type (wt), ALK-negative advanced non-small cell lung cancer (NSCLC) with either cMET amplification or cMET mutations and are either pretreated with 1 or 2 prior lines of systemic therapy or are treatment-naïve for the advanced stage of disease
Expected Completion	H2 2017	2019
Publication	Congress in 2017	Congress in 2017

NOVARTIS

Jakavi® - JAK1/2 inhibitor

Study	NCT02598297 RETHINK (CINC424A2353)
Indication	Early Myelofibrosis
Phase	Phase III
Patients	320
Primary Outcome Measures	Progression free survival (PFS-1)
Arms/Intervention	- Ruxolitinib 10 mg - Placebo
Target Patients	Patients with high molecular risk mutations
Expected Completion	2021
Publication	TBD

NOVARTIS

LA-EP2006 - Biosimilar pegfilgrastim

Study	LA EP06 103
Indication	Oncology
Phase	Phase I
Patients	184
Primary Outcome Measures	Pharmacokinetics, pharmacodynamics and safety
Arms/Intervention	- LA-EP2006 - Neulasta® (EU-authorized)
Target Patients	Healthy volunteers
Expected Completion	Q2-2017
Publication	Manuscript in Q4-2017, journal TBD

NOVARTIS

Tykerb® - HER2 inhibitor

Study	NCT01160211 ALTERNATIVE (CLAP016A2307)
Indication	HER2+ breast cancer
Phase	Phase IIIA
Patients	369
Primary Outcome Measures	Progression free survival (PFS) of lapatinib/ trastuzumab/ aromatase inhibitor (AI) combination vs. trastuzumab/ AI combination
Arms/Intervention	- Lapatinib plus trastuzumab plus aromatase inhibitor - Trastuzmab plus aromatase inhibitor - Lapatinib plus aromatase inhibitor
Target Patients	Patients with hormone receptor positive, HER2-positive metastatic breast cancer (MBC) who have received prior trastuzumab and endocrine therapies
Expected Completion	2018
Publication	Congress/journal in Q1/Q2-2017

NOVARTIS

Farydak® - Histone Deacetylase (HDAC) inhibitor

Study	NCT02654990 PANORAMA-3 (CLBH589D2222)
Indication	Multiple myeloma
Phase	Phase II
Patients	240
Primary Outcome Measures	Overall response rate (ORR) up to 8 cycles
Arms/Intervention	- 20mg panobinostat three times a week - 20mg panobinostat twice a week - 10mg panobinostat three times a week
Target Patients	Patients with relapsed or relapsed/refractory multiple myeloma who have been previously exposed to immunomodulatory agents
Expected Completion	2022
Publication	TBD

NOVARTIS

LCI699 - Hydroxylase inhibitor

Study	NCT02697734 LINC-4 (CLCI699C2302)	NCT02180217 LINC-3 (CLCI699C2301)
Indication	Cushing's disease	Cushing's disease
Phase	Phase III	Phase III
Patients	69	132
Primary Outcome Measures	Demonstrate the superiority of osilodrostat compared to placebo in achieving a complete response mean urine free cortisol ≤ upper limit of normal (mUFC ≤ ULN) at Week 12	Compare the complete response rate at the end of the 8-week period
Arms/Intervention	- Osilodrostat - Placebo	Single-arm LCI699
Target Patients	Patients with Cushing's disease	Patients with Cushing's disease
Expected Completion	2020	2020
Publication	TBD	TBD

NOVARTIS

Entresto® - Dual ARB + NEP inhibitor

Study	NCT02678312 PANORAMA HF (CLCZ696B2319)	NCT02661217 TRANSITION (CLCZ696B2401)
Indication	Heart failure in pediatric patients	Heart failure
Phase	Phase II/III	Phase IV
Patients	360	1,000
Primary Outcome Measures	Pharmacodynamics and pharmacokinetics of LCZ696 analytes	Assessing the percentage of patients who achieve the target dose of 200 mg bid LCZ696 at 10 weeks after randomization
Arms/Intervention	- LCZ696 0.8 mg/kg or 3.1 mg/kg or both - Enalapril is 0.2 mg/kg - LCZ696 3.125 mg granules and adult formulation (50, 100, 200 mg)	- Pre-discharge treatment initiation - LCZ696 - Post-discharge treatment initiation - LCZ696
Target Patients	Pediatric patients from1 month to < 18 years of age with heart failure due to systemic left ventricle systolic dysfunction	Heart failure patients with reduced ejection-fraction hospitalized for an acute decompensation event
Expected Completion	2021	2018
Publication	TBD	TBD

NOVARTIS

Entresto® - Dual ARB + NEP inhibitor

Study	NCT02884206 PERSPECTIVE (CLCZ696B2320)	NCT02468232 PARALLEL-HF (CLCZ696B1301)
Indication	Heart failure	Heart failure, reduced ejection fraction
Phase	Phase III	Phase III
Patients	520	220
Primary Outcome Measures	Change from baseline in the CogState Global Cognitive Composite Score (GCCS)	Time to the first occurrence of the composite endpoint - either cardiovascular (CV) death or heart failure (HF) hospitalization
Arms/Intervention	- LCZ696 50, 100, and 200 mg with placebo of valsartan - Valsartan 40, 80, and 160 mg tablets with placebo for LCZ696	- LCZ696 50 mg, 100 mg, 200 mg/placebo of Enalapril - Enalapril 2.5 mg, 5 mg, 10 mg / placebo of LCZ696
Target Patients	Patients with chronic heart failure with preserved ejection fraction	Japanese heart failure patients (NYHA Class II-IV) with reduced ejection fraction
Expected Completion	2021	2019
Publication	TBD	TBD

NOVARTIS

Entresto® - Dual ARB + NEP inhibitor

Study	NCT01920711 PARAGON (CLCZ696D2301)	NCT02924727 PARADISE-MI (CLCZ696G2301)
Indication	Heart failure, preserved ejection fraction	Myocardial infarction, acute
Phase	Phase III	Phase III
Patients	4,600	4,650
Primary Outcome Measures	Cumulative number of primary composite events of cardiovascular (CV) death and total (first and recurrent) HF hospitalizations	Time to the first occurrence of a confirmed composite endpoint (cardiovascular (CV) death, heart failure (HF) hospitalization, or outpatient heart failure)
Arms/Intervention	- LCZ696 50 mg, 100 mg and 200 mg - Valsartan 40 mg, 80 mg and 160 mg	- LCZ696 24/26 mg, 49/51 mg and 97/103 mg/ placebo of ramipril/valsartan - Ramipril 1.25 mg, 2.5 mg, and 5 mg/ placebo of LCZ696/ placebo for valsartan
Target Patients	Heart failure patients (NYHA Class II-IV) with preserved ejection fraction	Post-AMI patients with evidence of LV systolic dysfunction and/or pulmonary congestion, with no known prior history of chronic HF
Expected Completion	2019	2019
Publication	TBD	TBD

NOVARTIS

Zykadia® - ALK inhibitor

Study	NCT02040870 ASCEND-6 (CLDK378A2109)	NCT02336451 ASCEND-7 (CLDK378A2205)
Indication	ALK activated NSCLC after crizotinib failure	ALK activated NSCLC metastatic to the brain
Phase	Phase II	Phase II
Patients	103	160
Primary Outcome Measures	Pharmacokinetics of LDK378 after daily oral dose; safety and tolerability	Overall response rate (ORR)- the proportion of patients with a best overall confirmed response of CR or PR in the whole body as assessed per RECIST 1.1 by the investigator
Arms/Intervention	Single-arm study of LDK378 750 mg	Five-arm study of LDK378 (ceritinib) 750 mg
Target Patients	Adult Chinese patients with ALK-rearranged (ALK-positive) advanced non-small cell lung cancer (NSCLC) previously treated with Crizotinib	Patients with ALK-activated non-small cell lung cancer (NSCLC) metastatic to the brain and/or to leptomeninges
Expected Completion	Q2-2017	2018
Publication	Zhang L, et al. Presented at ESMO-Asia 2016; abstract 1035 Journal TBD in Q2-2017	TBD

NOVARTIS

Zykadia® - ALK inhibitor

Study	NCT01828099 ASCEND-4 (CLDK378A2301)	NCT02465528 (CLDK378A2407)
Indication	ALK activated 1st line NSCLC	ALK activated rare tumors
Phase	Phase III	Phase II
Patients	376	106
Primary Outcome Measures	Progression Free Survival (PFS) - time from date of randomization to date of first documented disease or date of death due to any cause	Disease Control Rate (DCR) based on local assessments
Arms/Intervention	- LDK378 750 mg - Pemetrexed + cisplatin or pemetrexed + carboplatin	Multi-arm study of ceritinib (LDK378)
Target Patients	1st line adult patients with ALK rearranged (ALK-positive), stage IIIB or IV, non-squamous non-small cell lung cancer	Patients with advanced solid tumors and hematological malignancies characterized by genetic abnormalities of anaplastic lymphoma kinase
Expected Completion	2018	2019
Publication	De Castro Jr G, et al. Presented at WCLC 2016; abstract PL03.07; Journal TBD in Q1-2017	TBD

NOVARTIS

Zykadia® - ALK inhibitor

Study	NCT01685138 ASCEND-3 (CLDK378A2203)	NCT01828112 ASCEND-5 (CLDK378A2303)
Indication	ALK activated NSCLC crizotinib naive + post chemotherapy	ALK activated NSCLC after crizotinib failure
Phase	Phase II	Phase III
Patients	126	231
Primary Outcome Measures	Overall response rate (ORR) to LDK378 by investigator assessment	Progression Free Survival (PFS) - time from the date of randomization to the date of the first radiologically documented disease progression or death due to any cause
Arms/Intervention	single-arm study of oral LDK378 750 mg	- Oral LDK378 750 mg once daily - Pemetrexed/ docetaxel
Target Patients	Crizotinib naive adult patients with ALK-activated non-small cell lung cancer post chemotherapy	Adult patients with ALK-rearranged (ALK-positive) advanced non-small cell lung cancer who have been treated previously with chemotherapy (platinum doublet) and crizotinib
Expected Completion	Q4-2017	2019
Publication	Felip E, et al. Presented at ESMO 2016; abstract 1208O Journal TBD in Q2-2017	Scagliotti G, et al. Presented at ESMO 2016; abstract 3732 Journal TBD in Q1-2017

NOVARTIS

LEE011 - CDK 4/6 inhibitor

Study	NCT01958021 MONALEESA-2 (CLEE011A2301)	NCT02278120 MONALEESA-7 (CLEE011E2301)
Indication	Advanced breast cancer - 1st line (with letrozole)	Advanced breast cancer - 1st line (pre-menopausal)
Phase	Phase III	Phase III
Patients	668	672
Primary Outcome Measures	Progression Free Survival (PFS) - time from the date of randomization to the date of the first documented progression or death due to any cause	Progression Free Survival (PFS) - time from the date of randomization to the date of the first documented progression or death due to any cause and assessed according to RECIST 1.1
Arms/Intervention	- LEE011 600 mg + letrozole 2.5 mg - Placebo + letrozole 2.5 mg	- LEE011 600 mg + NSAI/tamoxifen + goserelin 3.6 mg - Placebo of LEE011 + NSAI/tamoxifen + goserelin 3.6 mg
Target Patients	Postmenopausal women with hormone receptor positive, HER2 negative, advanced breast cancer who received no prior hormonal therapy for advanced disease	Premenopausal women with hormone receptor positive, HER2-negative, advanced breast cancer
Expected Completion	2016	2018
Publication	Congress in Q4-2017	TBD

NOVARTIS

LEE011 - CDK 4/6 inhibitor

Study	NCT02422615 MONALEESA-3 (CLEE011F2301)
Indication	Advanced breast cancer – 1st / 2nd line (with fulvestrant)
Phase	Phase III
Patients	727
Primary Outcome Measures	Progression Free Survival (PFS) - time from the date of randomization to the date of the first documented progression or death due to any cause
Arms/Intervention	- Ribloclclib 600mg + fulvestrant 500mg - Placebo of Ribloclclib + fulvestrant 500mg
Target Patients	Postmenopausal women with hormone receptor positive, HER2-negative, advanced breast cancer who have received no or only one line of prior endocrine treatment
Expected Completion	H2 2017
Publication	TBD

NOVARTIS

LJN452 - FXR Agonist

Study	NCT02855164 (CLJN452A2202)
Indication	Non-alcoholic steatohepatitis
Phase	Phase II
Patients	250
Primary Outcome Measures	Adverse event profile of different doses; etermine the dose relationship of LJN42 on markers of hepatic inflammation in NASH (ALT and AST)
Arms/Intervention	Multiple LJN452 doses and placebo
Target Patients	Patients with non-alcoholic steatohepatitis (NASH)
Expected Completion	2018
Publication	TBD

NOVARTIS

Seebri® - LA muscarinic receptor antagonist

Study	NCT02371629 (CNVA237A2320)
Indication	COPD
Phase	Phase IIIB/IV
Patients	752
Primary Outcome Measures	Trough Forced Expiratory Volume in 1 Second (FEV1) at week 12
Arms/Intervention	- NVA237 once daily - NVA237 twice daily
Target Patients	Patients with moderate and severe chronic obstructive pulmonary disease
Expected Completion	2016
Publication	TBD

NOVARTIS

Arzerra® - Anti-CD20

Study	NCT01039376 PROLONG (COMB157C2301)	NCT01077518 COMPLEMENT A+B (COMB157E2301)
Indication	CLL Extended Therapy	Refractory iNHL (3rd Line)
Phase	Phase IIIA	Phase IIIA
Patients	480	346
Primary Outcome Measures	Progression-free Survival, as assessed by the investigator and Independent Review Committee (IRC)	Progression-free-survival following ofatumumab and bendamustine combination therapy
Arms/Intervention	- Ofatumumab - Observation and assessments as per arm of ofatumumab	- Ofatumumab and Bendamustine infusions - Bendamustine infusion
Target Patients	Subjects with relapsed chronic lymphocytic leukemia (CLL) who have responded to induction therapy	Patients with indolent B-cell non-Hodgkin's lymphoma unresponsive to rituximab or a rituximab-containing regimen during or within six months of treatment
Expected Completion	2022	2024
Publication	van Oers et al. Lancet Oncol Sep 2015	Congress in Q3-2017

NOVARTIS

OMB157 - Anti-CD20

Study	NCT02792218 Asclepios (COMB157G2301)	NCT02792231 Asclepios (COMB157G2302)
Indication	Multiple Sclerosis	Multiple Sclerosis
Phase	Phase III	Phase III
Patients	900	900
Primary Outcome Measures	Annualized Relapse Rate (ARR) - number of confirmed relapses in a year calculated based on cumulative number of relapses by patient adjusted for time-in-study by patient	Annualized Relapse Rate (ARR) - number of confirmed relapses in a year calculated based on cumulative number of relapses by patient adjusted for time-in-study by patient
Arms/Intervention	- Ofatumumab subcutaneous - Teriflunomide oral	- Ofatumumab subcutaneous - Teriflunomide oral
Target Patients	Patients with relapsing forms of multiple sclerosis	Patients with relapsing forms of multiple sclerosis
Expected Completion	2019	2019
Publication	TBD	TBD

NOVARTIS

PKC412 - Multi-targeted kinase inhibitor

Study	NCT00651261 RATIFY (CPKC412A2301)	NCT00782067 (CPKC412D2201)
Indication	AML	Advanced Mastocytosis
Phase	Phase III	Phase II
Patients	717	116
Primary Outcome Measures	Overall survival	Overall response rate according to established criteria by assessing clinical findings at the end of 6 cycles
Arms/Intervention	- Induction and consolidation chemotherapy plus midostaurin - Induction and consolidation chemotherapy plus placebo	Single arm study of midostaurin
Target Patients	Newly diagnosed patients < 60 years of age with FLT3 mutated acute myeloid leukemia (AML)	Patients with aggressive systemic mastocytosis or mast cell leukemia +/- an associated hematological clonal non-mast cell lineage disease
Expected Completion	2021	2017
Publication	R. Stone et al, ASH2015, Abstract No 6	J. Gotlib et al., N Engl J Med 2016; 374(26): 2530-41

NOVARTIS

Votrient® - Inhibition of VEGFR, PDGFR

Study	NCT00720941 COMPARZ (CPZP034A2301)	NCT01235962 PROTECT (CPZP034D2301)
Indication	RCC	RCC adjuvant
Phase	Phase IIIB	Phase IIIA
Patients	876	1,500
Primary Outcome Measures	Progression-free Survival (PFS) - interval between the date of randomization and the earliest date of progressive disease (PD), as defined by the Independent Review Committee (IRC) or death due to any cause	Disease-free survival
Arms/Intervention	- Pazopanib 800 mg - Sunitinib 50 mg	- Pazopanib 600 mg/800 mg - Placebo
Target Patients	Patients with locally advanced and/or metastatic renal cell carcinoma	Subjects with localized or locally advanced RCC following nephrectomy
Expected Completion	2018	2019
Publication	Motzer RJ, et al. Pazopanib vs. sunitinib in metastatic renal-cell carcinoma. N Engl J Med. 2013;369:722–731	Data to be presented in Q2-2017; Journal TBD in Q2-2017

NOVARTIS

Votrient® - Inhibition of VEGFR, PDGFR

Study	NCT01147822 COMPARZ (CPZP034A2201)	NCT02014636 (CPZP034A2101)
Indication	RCC	RCC
Phase	Phase IIB	Phase I
Patients	175	228
Primary Outcome Measures	Progression-free Survival (PFS) - interval between the date of randomization and the earliest date of progressive disease (PD), as defined by the Independent Review Committee (IRC), or death due to any cause	Incidence and severity of adverse events (AEs) and serious adverse events (SAEs); Progression-free survival (PFS)
Arms/Intervention	- Pazopanib 800 mg - Sunitinib 50 mg	- Dose escalation phase: pazopanib and MK 3475 - Randomized phase: pazopanib monotherapy pazopanib+MK-3475 MK-3475 monotherapy
Target Patients	Advanced RCC patients from Asian	Patients with advanced renal cell carcinoma
Expected Completion	2018	2021
Publication	Journal TBD in Q3-2017	Data to be presented Q2-2017

NOVARTIS

QAW039 - CRTh2 antagonist

Study	NCT02555683 (CQAW039A2307)	NCT02563067 (CQAW039A2314)
Indication	Asthma	Asthma
Phase	Phase III	Phase III
Patients	846	846
Primary Outcome Measures	Reduction in the rate of moderate-to-severe asthma exacerbations	Reduction in the rate of moderate-to-severe asthma exacerbations
Arms/Intervention	- QAW039 Dose 1 - QAW039 Dose 2 - Placebo	- QAW039 Dose 1 - QAW039 Dose 2 - Placebo
Target Patients	Patients with uncontrolled severe asthma	Patients with uncontrolled severe asthma
Expected Completion	2019	2019
Publication	TBD	TBD

NOVARTIS

QGE031 - Anti-IgE

Study	NCT02649218 (CQGE031C2201)
Indication	Chronic spontaneous urticaria
Phase	Phase IIB
Patients	360
Primary Outcome Measures	Long-term safety; number of participants with treatment-emergent adverse events (AEs)
Arms/Intervention	Multiple doses of QGE031
Target Patients	Patients with Chronic Spontaneous Urticaria (CSU)
Expected Completion	Q3-2017
Publication	TBD

NOVARTIS

QVA149 - LA beta2 agonist + LA muscarinic antagonist

Study	NCT02487446 (CQVA149A2349)	NCT02487498 (CQVA149A2350)
Indication	COPD	COPD
Phase	Phase IIIB	Phase IIIB
Patients	354	354
Primary Outcome Measures	Demonstrate non-inferiority of QVA149 compared to umeclidinium/vilanterol in terms of FEV1 AUC 0-24h	Demonstrate non-inferiority of QVA149 compared to umeclidinium/vilanterol in terms of FEV1 AUC 0-24h
Arms/Intervention	- QVA149 - Umeclidinium/vilanterol	- QVA149 - Umeclidinium/vilanterol
Target Patients	Patients with moderate to severe chronic obstructive pulmonary disease	Patients with moderate to severe chronic obstructive pulmonary disease
Expected Completion	2016	2016
Publication	TBD	TBD

NOVARTIS

QVM149 - LABA, ICS, LAMA fixed dose combination

Study	NCT02554786 (CQVM149B2301)	NCT02571777 (CQVM149B2302)
Indication	Asthma	Asthma
Phase	Phase III	Phase III
Patients	2,800	3,155
Primary Outcome Measures	Trough FEV1	Trough FEV1
Arms/Intervention	- QMF149 150/160 µg - QMF149 150/320 µg - MF 400 µg - MF 400 µg - Salmeterol 50 µg /fluticasone 500 µg	- QVM149 150/50/160 µg - QVM149 150/50/80 µg - QMF149 150/160 µg - QMF149 150/320 µg - Salmeterol 50 µg /fluticasone 500 µg
Target Patients	Adult and adolescent patients with uncontrolled asthma despite med-/high-dose ICS or low-dose ICS/LABA(GINA step 3)	Adult patients with uncontrolled asthma despite med/high-dose ICS/LABA (GINA ≥4)
Expected Completion	2018	2018
Publication	TBD	TBD

NOVARTIS

Certican® - Inhibition of mTOR

Study	NCT01888432 (CRAD001H2307)	NCT01698918 BOLERO-4 (CRAD001Y24135)
Indication	Transplantation liver	ER+ breast cancer 2nd / 3rd line
Phase	Phase IIIB	Phase II
Patients	280	200
Primary Outcome Measures	Composite efficacy failure of treated biopsy proven acute rejection, graft loss or death in everolimus with reduced tacrolimus group compared to standard tacrolimus	Percentage of patients progression-free after completion of 1st line treatment (everolimus + letrozole)
Arms/Intervention	- Everolimus (3-8 ng/mL) + reduced tacrolimus (3-5 ng/mL) ± corticosteroids - Standard tacrolimus (5-15 ng/mL) ± corticosteroids	- Everolimus + letrozole (10mg daily) - Everolimus + exemestane (2.5mg daily)
Target Patients	Recipients of living donor liver transplants	Postmenopausal women with estrogen receptor positive HER2 negative metastatic or locally advanced breast cancer
Expected Completion	Q4-2017	2018
Publication	TBD	Congress/journal TBD in Q1/Q3-2017

NOVARTIS

Afinitor® - Inhibition of mTOR

Study	NCT01524783 RADIANT-4 (CRAD001T2302)	NCT01713946 EXIST-3 (CRAD001M2304)
Indication	Non-functional carcinoid tumors	Tuberous sclerosis complex (TSC)
Phase	Phase III	Phase III
Patients	302	355
Primary Outcome Measures	PFS is defined as the time from randomization to the date of the first documented tumor progression as per modified RECIST 1.0 or death from any cause, whichever comes first. Progression is assessed by cat scan (CT) and/or magnetic resonance imaging (MRI).	Percentage reduction from baseline in partial onset seizure frequency during maintenance period of the core phase.
Arms/Intervention	- Everolimus + BSC (10mg daily) - Everolimus placebo + BSC	- Everolimus (titrated to 3-7 ng/mL) - Everolimus (titrated to 9-15 ng/mL) - Placebo
Target Patients	Patients with advanced NET of GI or lung origin	Patients with tuberous sclerosis complex (TSC) who have refractory partial-onset seizures
Expected Completion	2021	2018
Publication	Yao JC, et al. Lancet. 2016;387:968-977	French JA, et al. Lancet. 2016;388:2153-2163

NOVARTIS

Afinitor® - Inhibition of mTOR

Study	NCT01783444 BOLERO-6 (CRAD001Y2201)
Indication	ER+ breast cancer 2nd / 3rd line
Phase	Phase II
Patients	300
Primary Outcome Measures	To estimate the hazard ratio of PFS for everolimus plus exemestane versus everolimus alone. Progression Free Survival (PFS) Time Frame: 28 months after first patient randomized or once 150 PFS have occurred.
Arms/Intervention	- Capecitabine monotherapy (1250mg/m2 twice daily) - Everolimus monotherapy (10mg daily) - Everolimus (10mg daily) with exemestane (25mg daily)
Target Patients	Postmenopausal women with estrogen receptor position, locally advanced, recurrent, or metastatic breast cancer after recurrence or progression on prior letrozole or anastrozole
Expected Completion	Q4-2017
Publication	Congress in Q3-2017

NOVARTIS

Lucentis® - Anti-VEGF

Study	NCT02375971 RAINBOW (CRFB002H2301)	NCT01922102 BRILLIANCE (CRFB002F2302)
Indication	Retinopathy of Prematurity (ROP)	Choroidal neovascularization secondary to pathologic myopia
Phase	Phase III	Phase III
Patients	300	475
Primary Outcome Measures	To achieve absence of active Retinopathy of Prematurity (ROP) and unfavorable structural outcome, patients must fulfill all the following criteria, 1) survival, 2) no intervention with a second modality for ROP, 3) absence of active ROP and 4) absence of unfavorable structural outcome	change from baseline BCVA to the average level of BCVA (letters) over all monthly post-baseline assessments: BCVA change; by measuring BCVA score at 4 meters distance using Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity charts
Arms/Intervention	- Ranibizumab 0.2 mg - Ranibizumab 0.1 mg - Laser therapy	- Group I ranibizumab 0.5 mg - Group II ranibizumab 0.5 mg - Verteporfin PDT
Target Patients	Male and female preterm infants with bilateral retinopathy of prematurity (ROP) who require treatment.	Patients with CNV due to PM
Expected Completion	2018	2016
Publication	TBD	ESASO Q2-2017; EURETINA Q3-2017

NOVARTIS

RLX030 - Relaxin receptor agonist

Study	NCT02007720 (CRLX030A2302)	NCT01870778 (CRLX030A2301)
Indication	Acute heart failure	Acute heart failure
Phase	Phase III	Phase III
Patients	1,520	6,800
Primary Outcome Measures	Percentage of patients with a clinical composite endpoint of treatment success, treatment failure, or no change. Time Frame: Treatment success at Day 2, Treatment failure through Day 5, and No change through Day 5.	Time to confirmed cardiovascular (CV) death during the follow-up period of 180 days. Time Frame: From baseline to 180 days.
Arms/Intervention	- Serelaxin - Placebo	- Serelaxin - Placebo
Target Patients	Acute heart failure patients	Acute heart failure patients
Expected Completion	2019	Q2-2017
Publication	TBD	TBD

NOVARTIS

RLX030 - Relaxin receptor agonist

Study	NCT01979614 (CRLX030A2203)
Indication	Acute heart failure
Phase	Phase II
Patients	60
Primary Outcome Measures	Change from baseline in micro-vascular function assessed by regional and global determinations of myocardial perfusion. Time Frame: At pre-dose on Day 1 (baseline) and prior to the end of the 48 hour drug infusion.
Arms/Intervention	- Serelaxin (30 µg/kg/24h) - Placebo
Target Patients	Patients with coronary artery disease
Expected Completion	2016
Publication	TBD

NOVARTIS

RTH258 - Anti-VEGF

Study	NCT02434328 HARRIER (CRTH258A2302)	NCT02307682 HAWK (CRTH258A2301)
Indication	nAMD	nAMD
Phase	Phase III	Phase III
Patients	860	990
Primary Outcome Measures	Change in Best Corrected Visual Acuity (BCVA) from baseline at week 48	Change in Best Corrected Visual Acuity (BCVA) from baseline at week 48
Arms/Intervention	- RTH258 (6 mg/50 µL) - Aflibercept (2 mg/50 µL)	- RTH258 dose A - RTH258 dose B - Aflibercept
Target Patients	Subjects with exudative age-related macular degeneration	Subjects with exudative age-related macular degeneration
Expected Completion	H1-2017	H1-2017
Publication	Abstract/presentation at congress in Q4-2017	Abstract/presentation at congress in Q4-2017

NOVARTIS

SIGNIFOR® - Somatostatin Analogue

Study	NCT01915303 CAPACITY (CSOM230B2411)	NCT01137682 PAOLA (CSOM230C2402)
Indication	Cushing's disease	Acromegaly
Phase	Phase II	Phase III
Patients	64	186
Primary Outcome Measures	Proportion of patients who attain mUFC ≤1.0 ULN at week 35 with pasireotide alone or in combination with cabergoline	Proportion of patients with a reduction of mean GH levels to < 2.5 µg/L and normalization of sex- and age-adjusted IGF-1 at 24 weeks.
Arms/Intervention	- Pasireotide +/- Cabergoline - Pasireotide alone or with Cabergoline	- Pasireotide LAR (40 mg) - Pasireotide LAR (60 mg) - Octreotide or lanreotide
Target Patients	Patients with persistent or recurrent Cushing's disease or patients with de novo Cushing's disease that are not considered candidates for pituitary surgery	Patients with inadequately controlled acromegaly
Expected Completion	2018	2018
Publication	Congresses/journal in Q2/Q3-2017	Gadelha MR et al. Lancet Diabetes Endocrinol. 2014;2(11):875-84

NOVARTIS

SIGNIFOR® - Somatostatin Analogue

Study	NCT02354508 SWITCH (CSOM230C2413)
Indication	Acromegaly
Phase	Phase III
Patients	112
Primary Outcome Measures	Proportion of patients who achieve biochemical control defined as GH <1µg/L and IGF-1 <ULN at week 36.
Arms/Intervention	- Pasireotide LAR (40 mg) - Pasireotide LAR (up-titrated 60 mg)
Target Patients	Patients with inadequately controlled acromegaly
Expected Completion	2019
Publication	TBD

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Mekinist® - MEK-inhibitor

Study	NCT01245062 METRIC (CTMT212A2301)
Indication	Melanoma
Phase	Phase IIIA
Patients	297
Primary Outcome Measures	Progression-free Survival in BRAF V600E mutation-positive participants without a history of brain metastases as assessed by the investigator and independent review
Arms/Intervention	- MEK inhibitor - Chemotherapy - Crossover
Target Patients	Patients with advanced or metastatic BRAF V600E/K mutation-positive melanoma
Expected Completion	Q1-2017
Publication	Flaherty KT, et al. Improved survival with MEK inhibition in BRAF-mutated melanoma. N Engl J Med. 2012 Jul 12;367(2):107-14

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