

Novartis Pharmaceuticals



# Novartis Pharmaceuticals: Driving Growth

Paul Hudson, CEO Novartis Pharmaceuticals  
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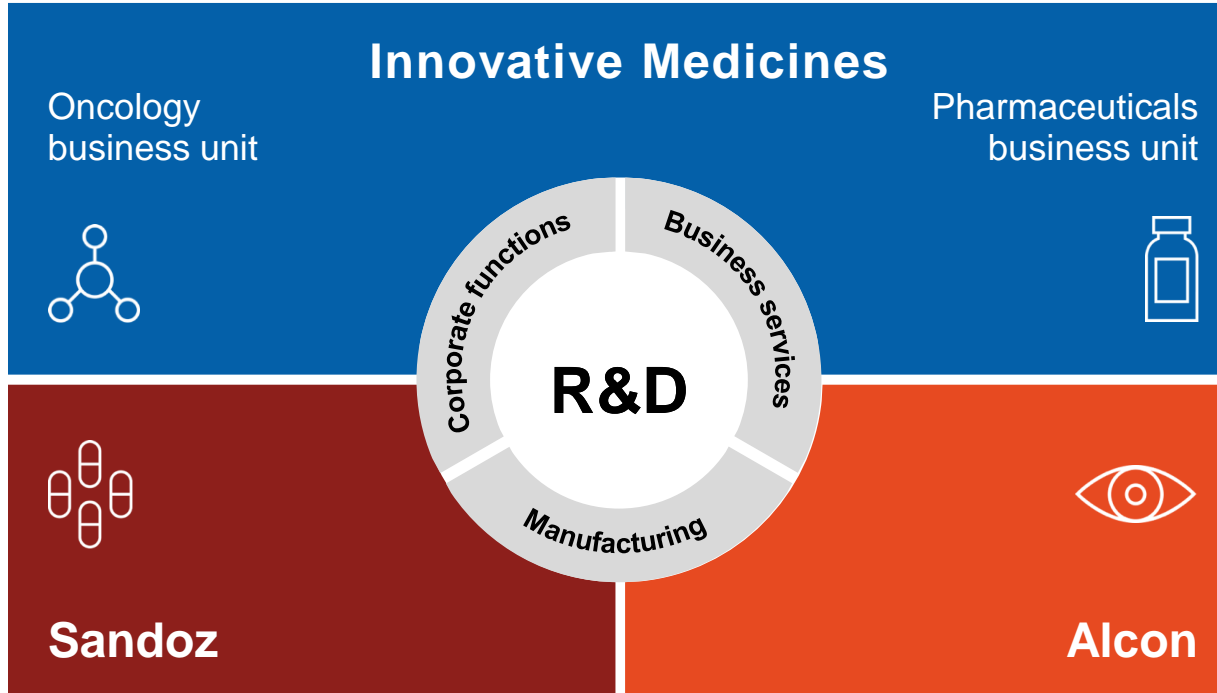
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Neither can there be any guarantee that Novartis will be able to realize any of the potential strategic benefits, synergies or opportunities as a result of the significant reorganizations of recent years, including the creation of the Pharmaceuticals 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. 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# Agenda

1. **Novartis Pharmaceuticals: Driving growth**
2. Entresto<sup>®</sup> and Cosentyx<sup>®</sup>
3. New Launches

# Novartis Group: Focused businesses fueled by innovation and functional excellence



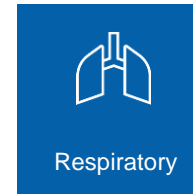
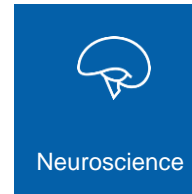
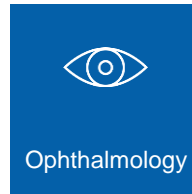
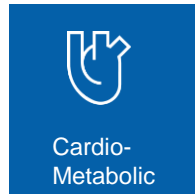
# Novartis Pharmaceuticals: A key growth driver for the Group

## Pharmaceuticals BU

USD billion	Q3 2017	% change USD	% change cc
<b>Net Sales</b>	<b>5.2</b>	<b>5</b>	<b>6</b>













**31 000** associates work across **5** core therapeutic areas








Growth rates in constant currencies (cc) vs. prior year (PY). Constant currencies, core results and free cash flow are non-IFRS measures. An explanation of these measures can be found on page 44 of the Q3 Condensed Interim Financial Report.

# Five core therapeutic areas with strong momentum and therapeutic depth

	 Immunology Dermatology (I&D)	 Cardio-Metabolic (CM)	 Ophthalmology	 Neuroscience	 Respiratory
<b>Key assets</b> Net sales 9 months to Sept 30, 2017 (USD m) and growth vs. PY (in cc)	 1,456 (+98%)	 322 (+215%)	 1,403 (+4%)	 2,360 (+3%)	 673 <sup>1</sup> 291 (+12%)      (+8%)
<b>Late stage pipeline assets</b>	Cosentyx® (NrAxSpA)	Entresto® (pEF) ACZ885 (canakinumab)	RTH258 (brolocizumab)	AMG 334 (erenumab) BAF312 (siponimod) OMB157 (ofatumumab)	QAW039 (fevipirant) QVM149

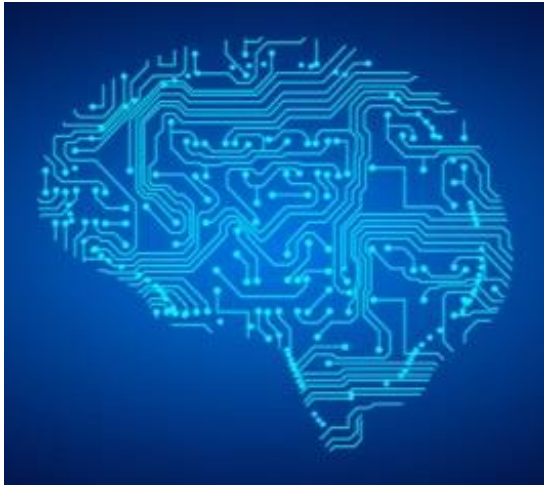
1. Net sales reflect Xolair® sales for all indications (e.g. including Xolair® SAA and Xolair® CSU, which is managed by the Immunology and Dermatology franchise).

# We are strengthening our portfolio through targeted business development

Expanding current TA with new MOAs	 <b>ZPL389</b>	 <b>UNR844 (EV06)</b>	 <b>ECF843 (rh-Lubricin)<sup>1</sup></b>	  <b>APO(a)-L<sub>RX</sub> / APOCIII-L<sub>RX</sub><sup>2</sup></b>
Expanding into new Therapeutic Areas	 <b>Emricasan<sup>3</sup></b>	 <b>Cenicriviroc collaboration</b>		
Expanding geographic scope	 <b>AMG 334 US co-commercialization<sup>4</sup></b>			

Note: All trademarks are the property of their respective owners. 1. Option exercised April 2017 for exclusive ex-EU rights 2. Option to in-license 3. Option exercised May 2017 4. Novartis and Amgen to co-commercialize AMG 334 (erenumab) in the US; Novartis to gain exclusive rights in Canada. Novartis retains commercial rights in rest of world; Amgen retains commercial rights in Japan

# Driving operational excellence through data and advanced analytics



## Commercial data – a strategic asset

- Advanced analytics and data science leveraged to get the real insights
- Adaptive and evidence-based commercial model, with continuous learning
- Connected framework for how we go to customers



# Pharmaceuticals: Our priorities

1

Ensure Entresto<sup>®</sup> and Cosentyx<sup>®</sup> success

2

Prepare for data read-outs and new launches

3

Excellence in Execution

4

Culture

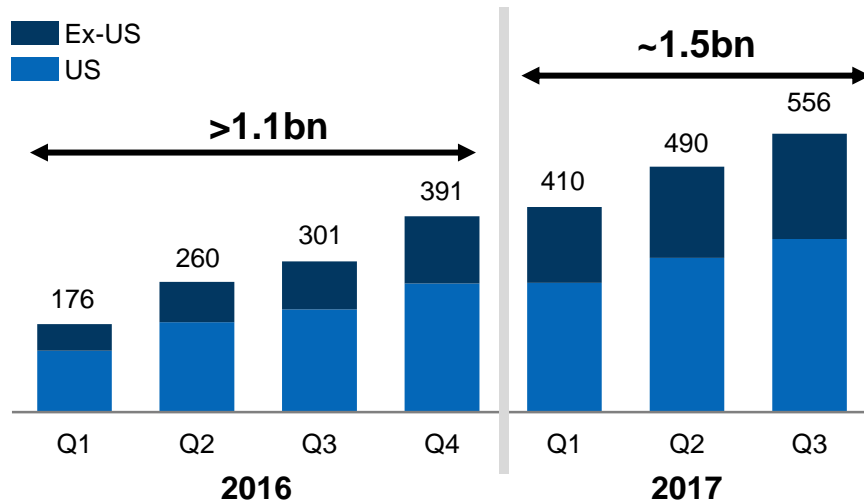
# Agenda

1. Novartis Pharmaceuticals: Driving growth
2. **Entresto<sup>®</sup> and Cosentyx<sup>®</sup>**
3. New Launches

# Cosentyx<sup>®</sup>: Strong growth momentum across indications and geographies

## Quarterly sales evolution

USD million



- Worldwide Q3 sales of USD 556m
- Strong growth driven by US and Europe, across all indications
- Established US NBRx leadership in PsA / AS, leading anti-IL17 in PsO<sup>1</sup>

1. Source: IMS weekly NBRx data (restated as of week ending August 11, 2017 to include Cosentyx<sup>®</sup> free drug access program), week ending September 29, 2017

# Cosentyx<sup>®</sup>: Strong differentiation based on unique biology

Inhibition of IL-17A, a key inflammatory cytokine, is fundamental

## Psoriasis<sup>1-9</sup>

- Superiority to anti-TNF (Enbrel<sup>®</sup>) and Stelara<sup>®</sup>
- Sustained control of signs and symptoms (5-year landmark data)
- Strong data in joints (in psoriatic arthritis, ~ 1/3 of psoriasis population) and hard-to-treat manifestations
- Potential for disease modification

## Spondyloarthritis (PsA and AS)<sup>10-19</sup>

- Sustained control of signs and symptoms
- High level of enthesitis resolution
- No radiographic progression in psoriatic arthritis and ankylosing spondylitis
- Further building the evidence with ongoing studies, incl. nrAxSpA

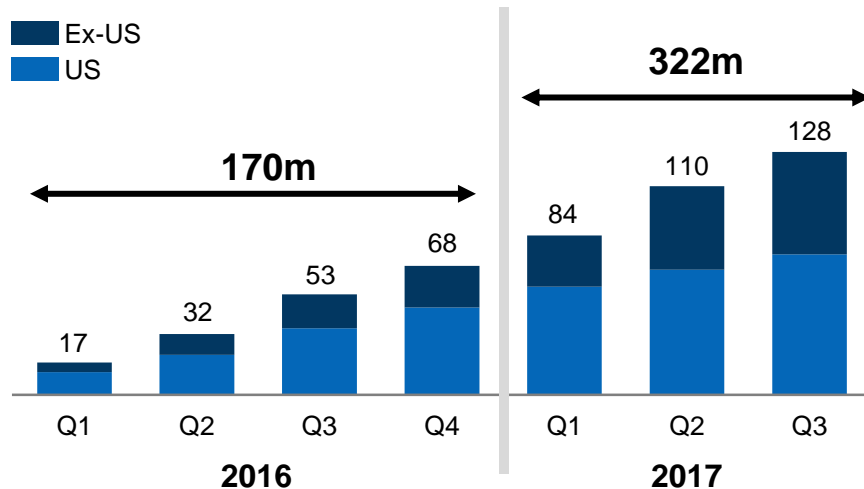
**Fully human molecule with very low immunogenicity<sup>20,21</sup>, very low injection site reactions<sup>1</sup>**

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. Bissonnette R., et al. late breaking abstract at EADV; September 13, 2017 7. Bagel J et al. JAAD 2017;77:667-674 8. Gottlieb A et al. JAAD 2017;76:70-80 9. Reich K et al. Ann Rheum Dis 2016;75;suppl2 9 Lebwohl M et al. Long-term psoriasis control following secukinumab discontinuation indicated disease modification of moderate to severe psoriasis. Presented as a poster presentation at the 13th Annual Maui Derm for Dermatologists 2017. 20-24th March 2017 10. Mease PJ, et al. NEJM 2015;373:1329–39 11. McInnes IB, et al. Lancet 2015;386:1137–46 12. Mease PJ, et al. Ann Rheum Dis 2017;76 (suppl 2):952 13. McInnes IB, et al. Rheumatology 2017;56:1993–2003 14. Mease PJ, et al. Arthritis Rheumatol. 2017;69 (suppl 10):abstract 17L 15. Baeten D, et al. 2015;373:2534–48 16. Braun J, et al. Arthritis Rheumatol. 2017;69 (suppl 10):abstract 3L 17. Marzo-Ortega H, et al. Arthritis Care Res (Hoboken). 2017;69:1020–9 18. <https://clinicaltrials.gov/ct2/show/NCT02745080> 19. <https://clinicaltrials.gov/ct2/show/NCT03259074> 20. Reich, K., et al. Br J Dermatol. 2017;176:752 21. Reich K, et al. PIN 2016. P224; Enbrel<sup>®</sup> is a registered trademark of Immunex Corporation. Stelara<sup>®</sup> is a registered trademark of Johnson & Johnson.

# Entresto®: Progressing steadily, fueled by improved access and field force expansion

## Quarterly sales evolution

USD million



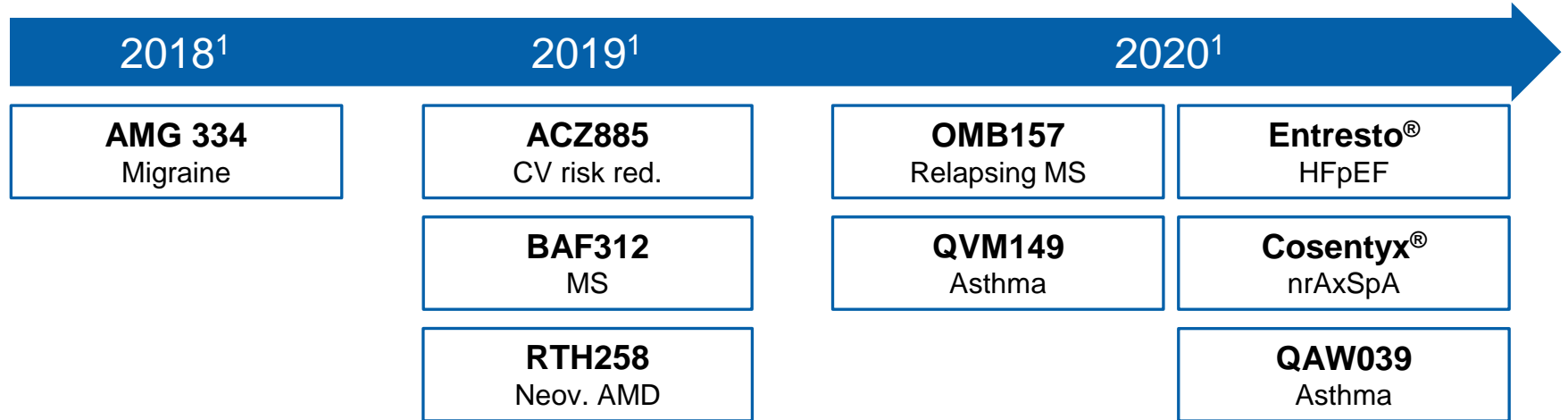
- Worldwide Q3 sales of USD 128m
- US benefitting from improved access<sup>1</sup> and expanded field force
- Continued progress on access ex-US with Entresto® launched in >45 countries
- HF-pEF<sup>2</sup> expansion studies on track for filing in 2019

1. No Prior Authorization: 60% Medicare and 48% of Commercial segment 2. HF-pEF- heart failure with preserved ejection fraction

# Agenda

1. Pharmaceuticals: Driving growth
2. Entresto<sup>®</sup> and Cosentyx<sup>®</sup>
3. **New Launches**

# Full pipeline of late stage assets: Key expected launches in Pharmaceuticals



1. Exact launches and timing depends on filing date, HAs decisions and timelines.

# AMG 334 (erenumab): Potentially life-changing medication for a debilitating disease



## Unique approach

- First and only mAb to target and block the CGRP-receptor
- Only fully human anti-CGRP mAb



## Sustained and consistent prevention

- Chronic migraine patients on average gained one additional migraine-free week each month<sup>1</sup>
- At 1 year<sup>2</sup>, 2/3 of episodic migraine patients had at least a 50% reduction in their migraine days with 1 out of 4 being completely migraine free



## Unique & robust data package, even in the difficult to treat patients

- >2,600 patients; 5 year on-going extensions
- Strong efficacy in prior treatment failures, medication overuse patients



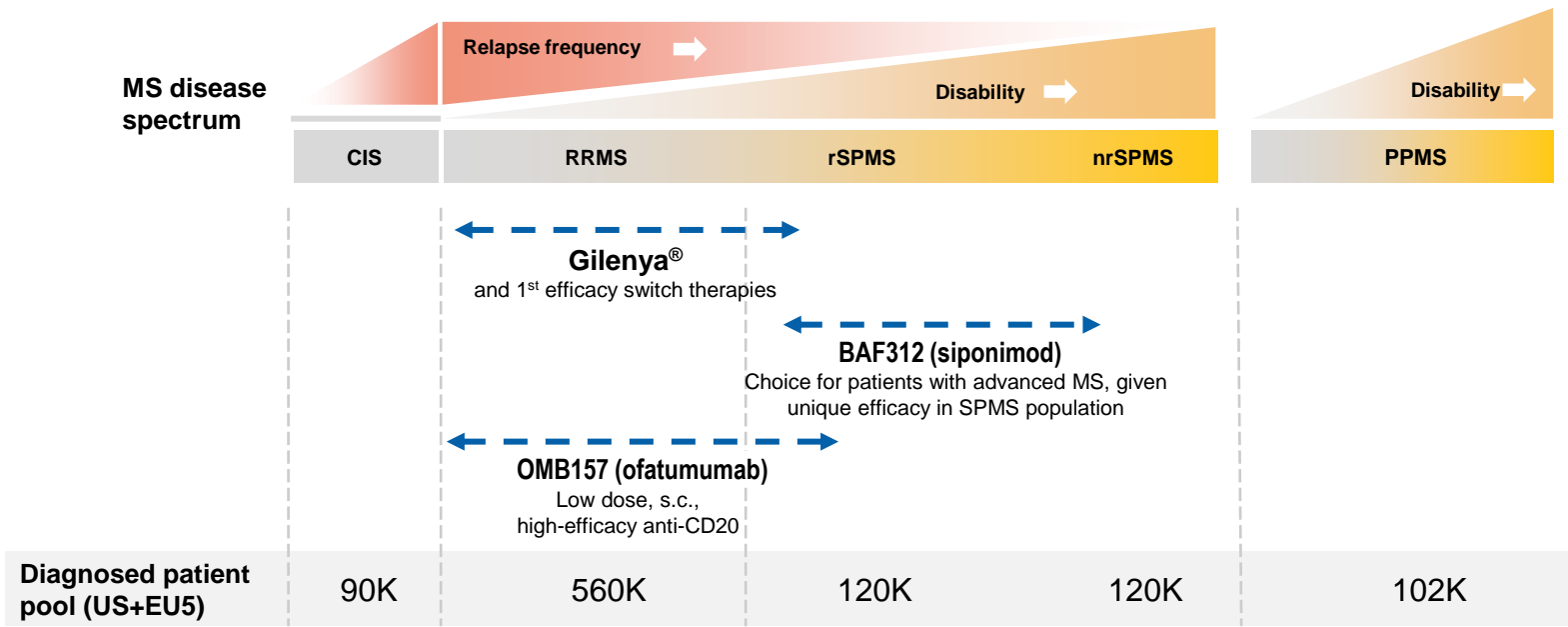
## Placebo-like safety and tolerability

- Only anti-CGRP mAb to demonstrate it did not aggravate myocardial ischemia in a dedicated clinical study<sup>3</sup>
- Very low incidence of injection site reactions in AMG 334 and placebo groups

1. Tepper S, Lancet Neurology 16(6), June 2017, 425-434    2. Ashina M et al. Neurology 89 (12), 1237-1243, 2017    3. Depre C et al. Presented at IHC 2017, Vancouver Canada [PO-01-198]



# BAF312: Efficacy in SPMS creates opportunity to address an unmet need in more advanced patients



Diagnosed Patient pool derived from Decision Resources epi data; Atlas of MS, IMS actual volume sales, Quant SPMS MR 2016, Annette L, Sonu M. et. al. The incidence of clinically isolated syndrome in a multi-ethnic cohort. J Neurol (2014) 261:1349-1355. Roberto D'Alessandro, Risk of multiple sclerosis following clinically isolated syndrome: a 4-year prospective study, J Neurol (2013) 260:1583-1593

# ACZ885: Strong value proposition a pre-requisite for a biologic treatment in a post-MI/CV risk reduction setting

## Targeting narrow, well defined population

- ACZ885 population is well defined as post-MI and elevated inflammation (hsCRP $\geq$ 2 mg/L)
- ACZ885 responder population is targeted to the patients who benefit the most (1 injection and who achieve hsCRP < 2mg/L in 3 months)

## Straightforward patient selection

- hsCRP test is low cost and easy to perform; 1<sup>st</sup> test to identify eligible patients and 2<sup>nd</sup> test to identify responders

## Very significant magnitude of benefit in responders<sup>1</sup>

While CANTOS met its primary endpoint in reducing risk of MACE by 15% in the overall study population<sup>2</sup>, the benefits were markedly greater in the responder population:

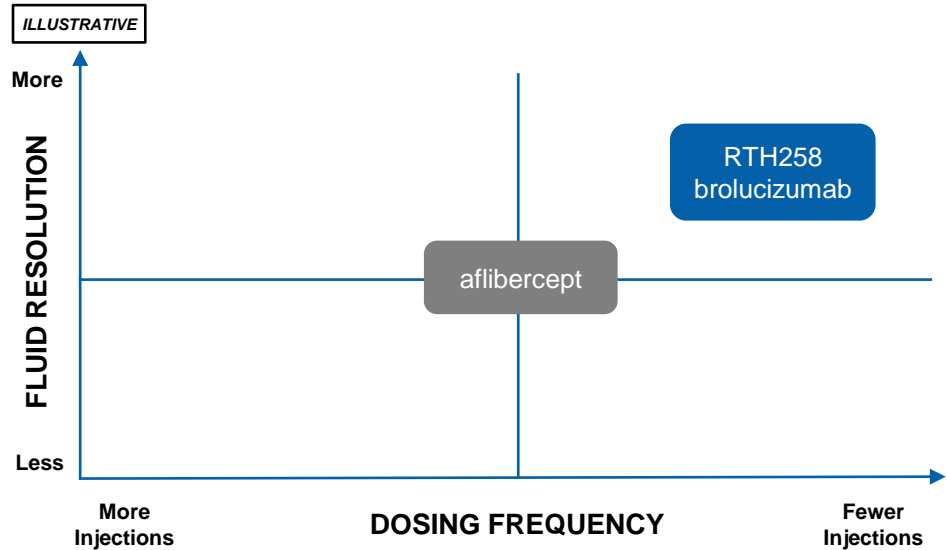
- 25% RRR in MACE (CV death, MI, stroke)
- 31% RRR in CV death alone

1. Ridker et al, Lancet 2017 [in press]: [http://dx.doi.org/10.1016/S0140-6736\(17\)32814-3](http://dx.doi.org/10.1016/S0140-6736(17)32814-3); Pooled dose analysis. 150mg arm also showed 25% RRR on MACE. 2. Ridker et al, NEJM 2017, DOI: 10.1056/NEJMoa1707914 MACE: CANTOS primary endpoint a composite of MI, Stroke and CV death MI: Myocardial Infarction, component of primary endpoint. Urgent revascularization procedures is a component of a statistically significant key secondary endpoint

ACZ885 is an investigational compound for cardiovascular risk reduction and has not been approved by any regulatory or health authority for cardiovascular risk reduction

# RTH258: Potential to address unmet needs vs. current therapies

- RTH258 (Brolucizumab) met the primary endpoint of non-inferiority vs. aflibercept in change in BCVA from baseline to Week 48<sup>1</sup>
- Significantly fewer patients treated with RTH258 showed signs of disease activity<sup>1,2</sup> as well as retinal fluids (IRF and/or SRF)<sup>1,3</sup>
- RTH258 delivered superior reductions in retinal thickness (CST) due to fluid accumulation versus aflibercept<sup>1,3</sup>
- Majority of RTH258 patients exclusively maintained on q12w dosing interval immediately following loading phase through week 48<sup>1,4</sup>



1. Dugel PU, et al. AAO 2017 [Oral presentation]. 2. Prespecified secondary endpoint in both HAWK and HARRIER with confirmatory analysis in HAWK (brolucizumab 6 mg vs aflibercept 2 mg). Week 16 disease activity assessed by: decrease in BCVA of > 5 letters compared with baseline, decrease in BCVA of > 3 letters and CST increase > 75µm compared with week 12, decrease in BCVA of > 5 letters due to neovascular AMD disease activity compared with week 12, new or worse intraretinal cysts (IRC) / intraretinal fluid (IRF) compared with week 12. 3. Prespecified secondary endpoint in both HAWK and HARRIER with confirmatory analysis in HAWK (brolucizumab 6 mg vs aflibercept 2 mg). 4. Prespecified secondary endpoint Illustration: Dosing regimen referenced according to label for aflibercept, brolucizumab based on q12w regime in HAWK & HARRIER; fluid resolution defined as presence of retinal fluids, key markers of disease activity (prespecified secondary endpoint in both HAWK and HARRIER with confirmatory analysis in HAWK; brolucizumab 6 mg vs aflibercept 2 mg).

# Pharmaceuticals: Driving Growth

- 1 Prioritizing to win in our core therapeutic areas
- 2 Demonstrating executional excellence through Cosentyx<sup>®</sup> and Entresto<sup>®</sup>
- 3 Poised for future growth, fueled by a strong late stage pipeline