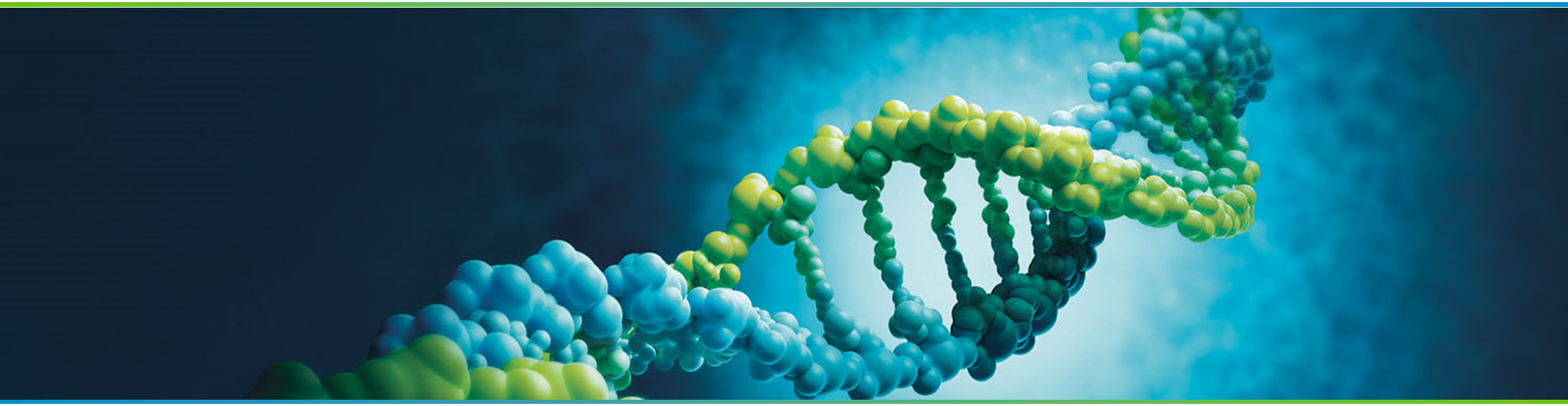
Science For A Better Life



Investor Conference Call

Data from the Phase III COMPASS trial, A Randomized Controlled Trial of Rivaroxaban for the Prevention of Major Cardiovascular Events in Patients With Coronary or Peripheral Artery Disease

August 28, 2017

Cautionary Statements Regarding Forward-Looking Information

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

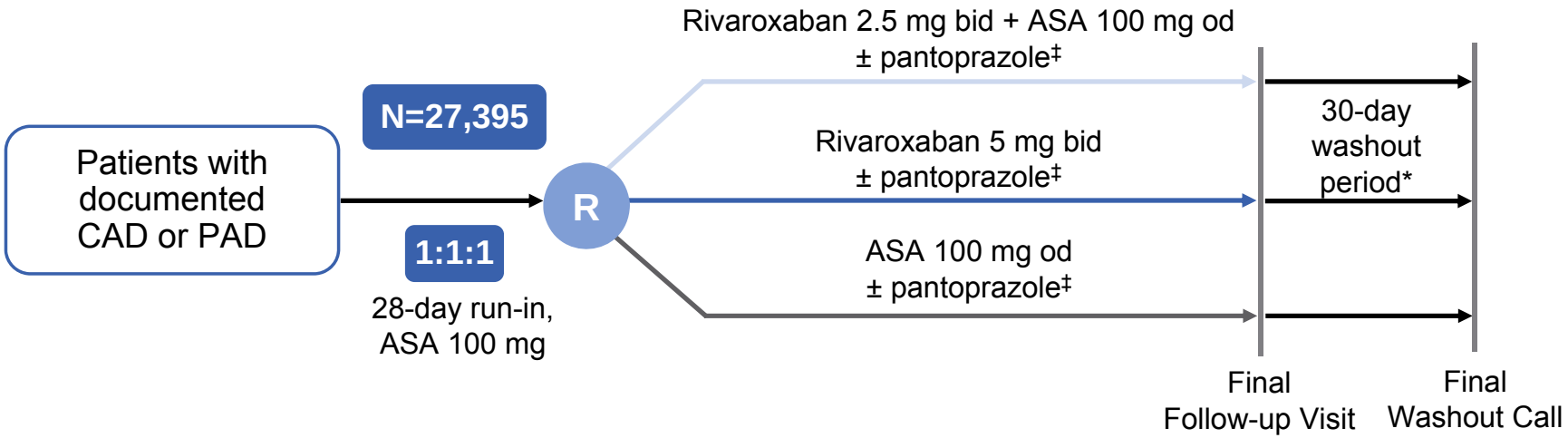
COMPASS - Key Findings

The combination of rivaroxaban 2.5 mg bid + aspirin 100 mg od compared to aspirin 100 mg od alone

- showed a 24% relative risk reduction in major adverse cardiovascular events
- showed an unprecedented 42% relative risk reduction in stroke and an 22% relative risk reduction in cardiovascular death
- demonstrated a 20% improvement in net clinical benefit, defined as the composite of stroke, cardiovascular death, myocardial infarction, fatal bleeding or symptomatic bleeding in a critical organ
- showed low overall bleeding incidence rates, although major bleeding was increased. There was no significant increase in fatal or intracranial bleeding.
- reduced major adverse limb events significantly in the PAD patient population

COMPASS - Objective and Study Design

Objective:
To determine the efficacy and safety of rivaroxaban, rivaroxaban plus ASA or ASA alone for reducing the risk of MI, stroke and cardiovascular death in CAD or PAD patients



Short design: Randomized, double-blind controlled trial

First patient first visit: Q1/2013; Last patient last visit for primary analysis: Q2/2017
*patients treated according to local standard of care;
‡patients without continuous need for a proton pump inhibitor were randomized to pantoprazole or pantoprazole placebo; patients not randomized to PPI/Placebo continue with their PPI prescribed prior to randomization

COMPASS - Key Inclusion and Exclusion Criteria

Key inclusion criteria#

- PAD
- CAD with ≥1 of:
  - Age ≥65 years
  - Age <65 years plus atherosclerosis in ≥2 vascular beds or ≥2 additional risk factors
    - Current smoker
    - Diabetes mellitus
    - Renal dysfunction (eGFR <60 ml/min)
    - Heart failure
    - Non-lacunar ischemic stroke ≥1 month ago

Key exclusion criteria‡

- Stroke ≤1 month or any haemorrhagic or lacunar stroke
- Severe HF with known ejection fraction <30% or NYHA class III or IV symptoms
- **Need for dual antiplatelet therapy, other non-aspirin antiplatelet therapy, or oral anticoagulant therapy**
- eGFR <15 ml/min

including but not limited to;
‡ any other exclusion criteria in conjunction with the local product information and any other contraindication listed in the local labeling for rivaroxaban or the comparator have to be considered;

COMPASS - Main Study Outcomes

Primary efficacy outcome

- Composite of MI, stroke or cardiovascular death

Secondary efficacy outcomes

- Composite of major thrombotic events
  - coronary heart disease death, MI, ischemic stroke, acute limb ischemia
  - cardiovascular death, MI, ischemic stroke, acute limb ischemia
- Mortality (all-cause)

Primary safety outcome

- Modified ISTH major bleeding
  - fatal bleeding, and/or
  - symptomatic bleeding in a critical area or organ, such as intracranial, intraspinal, intraocular, retroperitoneal, intraarticular or pericardial, or intramuscular with compartment syndrome, or
  - bleeding into the surgical site requiring re-operation, and/or
  - bleeding leading to hospitalization

COMPASS - Primary Efficacy Outcome and Components

	2.5 mg rivaroxaban bid + 100 mg aspirin od vs. 100 mg aspirin od	
	p-value*	HR** (95% CI)
MI, stroke, or CV death	<0.001	0.76 (0.66-0.86)
MI	0.14	0.86 (0.70-1.05)
Stroke	<0.001	0.58 (0.44-0.76)
CV death	0.02	0.78 (0.64-0.96)

MI myocardial infarction; CV cardiovascular; CI confidence interval;
*stratified log-rank test; **stratified Cox proportional hazard model

5 mg rivaroxaban bid + 100 mg aspirin od vs. aspirin 100 mg od
see NEJM August 27, 2017, DOI: 10.1056/NEJMoa1709118

COMPASS - Secondary Efficacy Outcomes and Components

	2.5 mg rivaroxaban bid + 100 mg aspirin od vs. 100 mg aspirin od	
	p-value*	HR** (95% CI)
MI, ALI, ischemic stroke, CHD death	<0.001	0.72 (0.63-0.83)
MI, ALI, ischemic stroke, CV death	<0.001	0.74 (0.65-0.85)
Mortality (all-cause)	0.01	0.82 (0.71-0.96)
Net clinical benefit[#]	<0.001	0.80 (0.70-0.91)
Components* **		
Ischemic stroke	<0.001	0.51 (0.38-0.69)
ALI	0.02	0.55 (0.32-0.92)
CHD death[##]	0.03	0.73 (0.55-0.96)
Non-CV death	0.20	0.87 (0.70-1.08)

MI myocardial infarction; CV cardiovascular; ALI acute limb ischemia; CI confidence interval; *stratified log-rank test; **stratified Cox proportional hazard model; ***components not part of primary efficacy outcome; [#]primary efficay outcome and fatal and critical organ bleeding; [##]CHD coronary heart disease death: death due to acute MI, sudden death, or CV procedure

5 mg rivaroxaban bid + 100 mg aspirin od vs. aspirin 100 mg od see NEJM August 27, 2017, DOI: 10.1056/NEJMoa1709118

COMPASS - Primary Safety Outcome

	2.5 mg rivaroxaban bid + 100 mg aspirin od vs. 100 mg aspirin od	
	p-value*	HR** (95% CI)
Modified major ISTH bleeding	<0.001	1.70 (1.40-2.05)
Fatal	0.32	1.49 (0.67-3.33)
Non-fatal symptomatic intracranial	0.77	1.10 (0.59-2.04)
Non-fatal, non-intracranial, symptomatic bleeding into critical organ	0.14	1.43 (0.89-2.29)
Site of major bleeding		
Gastrointestinal	<0.001	2.15 (1.60-2.89)
Intracranial	0.60	1.16 (0.67-2.00)

*stratified log-rank test; **stratified Cox proportional hazard model

5 mg rivaroxaban bid + 100 mg aspirin od vs. aspirin 100 mg od see NEJM August 27, 2017, DOI: 10.1056/NEJMoa1709118

COMPASS - Overall Summary and Conclusion

The combination of rivaroxaban 2.5 mg bid + aspirin 100 mg od compared to aspirin 100 mg od alone

- significantly reduced the relative risk for the primary composite of stroke, myocardial infarction and cardiovascular death
- increased the risk of ISTH modified major bleeding without significant increase in intracranial or fatal bleeds
- reduced the risk for the pre-specified net clinical benefit, a composite of stroke, cardiovascular death, myocardial infarction, fatal bleeding or symptomatic bleeding in a critical organ

The dual pathway inhibition with rivaroxaban vascular dose, 2.5 mg twice-daily, combined with aspirin provides a larger relative risk reduction than dual anti-platelet strategies

Once approved, this treatment regimen could have the potential to change the standard of care for the secondary prevention of chronic stable CAD and PAD for the benefit of the patient