Global Aspirin™ Backgrounder

Aspirin™ has been an important medicine for more than 115 years because of its remarkable pain relief, as well as cardiovascular (CV) event prevention, properties. It has withstood the test of time, and is an excellent case study in both science and branding. As a brand, Aspirin™ has been trusted over time by more consumers worldwide longer than any other over-the-counter (OTC) pain reliever.

As has been the case since the introduction of Aspirin™, acetylsalicylic acid (ASA), its active ingredient, continues to be used as the benchmark in pain relief and CV event prevention. At over-the-counter (OTC) doses, acetylsalicylic acid offers the same pain-relieving properties as many molecules discovered decades later. It has been the most utilized pain reliever in history. As such, its efficacy and safety profile is well documented, which has certainly contributed to its remarkable longevity. Its anti-platelet and blood thinning properties separate it from all other category ingredients, and it is the only one to offer both pain relief and remarkable CV benefits. In fact, acetylsalicylic acid is included in the World Health Organization’s list of essential medications based on its pain relief and anti-platelet effects.¹

For more than 115 years, the world has relied on Aspirin™ for fast and potent relief of pain. With more than a century of clinical experience, acetylsalicylic acid continues to be recognized today as a proven, trusted and cost-effective pain reliever and is well tolerated at OTC doses. Recent meta-analyses²,³ included individual patient data or study-level

population data from 145 clinical trials representing more than 32,000 patients and 20 years of research on such use. Collectively, results reaffirmed the overall GI safety profile of acetylsalicylic acid in short-term treatment of mild to moderate pain, aches and fever due to cold or flu when used as directed, demonstrating a low incidence of minor GI side effects and no drug-related serious adverse events.

For CV event prevention, low-dose (81 mg–325 mg) Aspirin™ Cardio products are recognized for use – as directed by a physician – during suspected heart attack to help reduce damage to the heart, and as cornerstone therapy for reducing risk of recurrent CV events, specifically, heart attack and ischemic stroke. Furthermore, the drug is approved in more than 50 countries for the prevention of a first heart attack or stroke (primary prevention) in appropriate patients. In terms of safety, when used as directed for its approved cardiovascular indications, acetylsalicylic acid is well-tolerated and effective, and, for the vast majority of patients, is infrequently associated with clinically relevant side effects. For prevention of CV events, more than 200,000 patients have been studied in more than 200 randomized clinical trials evaluating the safety and efficacy of acetylsalicylic acid. Serious bleeding rarely occurs. GI bleeding has been shown to occur in less than 1% (41 of 6,300 patients) of those taking Aspirin™ to prevent a recurrent CVD event, such as a heart attack.4 A landmark meta-analysis showed that for patients taking low-dose acetylsalicylic acid to prevent a first CV event, there was a positive benefit/risk ratio greater than 2:1.5 As with all drugs, the potentially life-saving benefits of longer-term, low-dose acetylsalicylic acid therapy to prevent CV events such as heart attack and ischemic stroke must be weighed against its risks. Patients should work with their doctors to best determine if they are appropriate candidates for acetylsalicylic acid therapy.

Bayer supports the use of Aspirin™ for primary prevention of CV events in patients at appropriate risk only where there are approved indications. The cornerstone role of low-dose acetylsalicylic acid in CV event reduction is based upon clinical studies and extensive, real-world experience; most importantly, it continues to be supported and reinforced by the global scientific community through multiple international and national medical guidelines recommending its use in appropriate at-risk patients for prevention of CV events in both

---

the primary and secondary settings. Aspirin™ is universally available and offers excellent value for its cost.

The proven role of Aspirin™ in OTC pain management and low-dose Aspirin™ Cardio for cardiovascular disease prevention continues to make it a truly globally versatile, trusted brand, now more than ever. The ever-increasing global focus on cost-effective treatments further underlines the relevance of Aspirin™ across the globe, both in developed as well as emerging or under-served markets.

Contact:
Anne Coiley, phone +862 404-6314
E-mail: anne.coiley@bayer.com

October, 2016

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup 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.