Bristol-Myers Squibb and Pfizer Announce Randomized, Controlled Trial to Evaluate the Effect of Atrial Fibrillation Screening on Health Outcomes in Older Individuals

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PRINCETON, N.J. & The Bristol-Myers Squibb-Pfizer Alliance today announced the initiation of a new randomized, controlled study, GUARD-AF (ReducinG stroke by screening for UndiAgnosed atRial fibrillation in elderly inDividuals). The study seeks to determine if earlier detection of atrial fibrillation (AFib) through screening in previously undiagnosed men and women at least 70 years of age in the U.S. ultimately impacts the rate of stroke, compared to usual standard medical care. This study will also assess potential bleeding leading to hospitalization, and therefore provide an evaluation of net clinical benefit or harm. AFib is the most common type of significant irregular heart rhythm, and it is estimated that 8 million people in the U.S. will be affected by AFib in 2019.i,ii AFib is a significant risk factor for stroke; stroke risk is up to five times higher in people with AFib than in those without it.iii,iv AFib can often go undetected, as it can be asymptomatic,i and some studies suggest that more than 25 percent of people who have an AFib-related stroke find out they have AFib after a stroke.v

“There is a real need for a study like GUARD-AF to assess the impact of screening for AFib on the crucially important outcome of stroke,” said Daniel Singer, M.D., Professor of Medicine at Harvard Medical School and Professor in the Department of Epidemiology at Harvard T.H. Chan School of Public Health, and an academic general internist at Massachusetts General Hospital. “This study has the potential to directly affect clinical practice and could lead to more AFib patients being identified and appropriately managed

to avoid stroke."

AFib-related strokes may have more serious consequences than strokes not related to AFib, and approximately 25 percent of people may die within one month of an AFib-related stroke.vi Despite this and the increased risk of stroke associated with undiagnosed and untreated AFib, there have been no studies to date demonstrating that proactive screening for AFib in appropriate patient populations reduces stroke risk compared to usual standard medical care, which is defined as normal follow-up care without a proactive screening intervention. This lack of data has been identified as a key gap in knowledge by national screening committees and guideline-making bodies.vii

"The GUARD-AF trial is important because it seeks to answer vital outcomes questions, and because it intends to do that by including more than 50,000 adults aged 70 and over – a demographic that's at risk and has historically been underrepresented in trials," said Rod MacKenzie, Ph.D., Chief Development Officer and Executive Vice President, Pfizer. "This novel, large-scale, pragmatic study is part of the ongoing commitment by the BMS-Pfizer Alliance to help patients and their care providers find better ways to manage the significant risks that come with atrial fibrillation."

The study population (n=52,000) will include men and women at least 70 years of age visiting their primary care physician for usual follow-up care, who are willing to provide consent to participate in the study. Participants will be randomized to receive the AFib detection intervention using an electrocardiogram (ECG) patch for 14 days, or to receive usual standard medical care. The primary outcome measures will be stroke and bleeding events leading to hospitalization. A novel, pragmatic aspect of the trial is that outcome events will be ascertained from a healthcare claims database which, although subject to certain limitations, are expected to provide evidence on health outcomes associated with AFib detection intervention that may help inform future guidelines.

"Through earlier AFib detection, we're focused on helping to reduce the number of individuals who suffer an AFib-related stroke," said Roland Chen, M.D., Vice President, Head of Clinical Development, Innovative Medicines, Bristol-Myers Squibb. "With this study, the BMS-Pfizer Alliance intends to help inform clinical practice regarding screening for this common type of heart rhythm condition."

Enrollment is expected to begin in the coming weeks. More information on the study can be found on www.clinicaltrials.gov under the identifier NCT04126486.

About the Bristol-Myers Squibb and Pfizer Alliance

The Bristol-Myers Squibb and Pfizer Alliance is committed to driving education and awareness about atrial fibrillation and venous thromboembolism. With long-standing cardiovascular leadership, global scale and expertise in this field, the Alliance strives to implement global, research-driven approaches to illuminate and address the unmet needs around strokes related to non-valvular atrial fibrillation, which are often fatal or debilitating. Through collaborations with non-profit organizations, the Alliance aims to provide patients, physicians, and decision makers with the information they need to understand and take appropriate action on risk factors associated with stroke and other cardiovascular conditions.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit us at BMS.com or follow us on LinkedIn , Twitter , YouTube, Facebook and Instagram.

About Pfizer Inc.: Breakthroughs that change patients’ lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Bristol-Myers Squibb Forward-Looking Statement

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, the research, development and commercialization of medical products and the Bristol-Myers Squibb-Pfizer Alliance. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are

based on historical performance and current expectations and projections about our future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond our control and could cause our future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. These risks, assumptions, uncertainties and other factors include, among others, that the expected benefits of, and opportunities related to, the BMS-Pfizer Alliance may not be realized by Bristol-Myers Squibb or may take longer to realize than anticipated. No forward-looking statement can be guaranteed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect Bristol-Myers Squibb's business and market, particularly those identified in the cautionary statement and risk factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2018, as updated by our subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. The forward-looking statements included in this document are made only as of the date of this document and except as otherwise required by applicable law, Bristol-Myers Squibb undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise.

Pfizer Disclosure Notice

The information contained in this release is as of November 15, 2019. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a pragmatic randomized, controlled study, GUARD-AF that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including, without limitation, the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, as well as the possibility of unfavorable clinical trial results, including the possibility of unfavorable new clinical data and further analyses of existing clinical data.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-

Looking Information and Factors That May Affect Future Results”, as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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i CDC. Atrial Fibrillation Fact Sheet. https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_atrial_fibrillation.htm. Accessed March 2019. ii Colilla S, Crow A, Petkun W, et al. Estimates of Current and Future Incidence and Prevalence of Atrial Fibrillation in the U.S. Adult Population. Am J Cardiol. 2013;112:1142-1147 iii Cleveland Clinic. Know Your Risk Factors for Stroke. https://my.clevelandclinic.org/health/articles/13398-know-your-risk-factors-for-stroke. Accessed August 28, 2019 iv January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2014;64:e1–76 v Freedman B, Potpara TS, Lip GY. Stroke prevention in atrial fibrillation. Lancet. 2016;388:806–817 vi Lin HJ, Wolf PA, Kelly-Hayes M, Beiser AS. Stroke severity in AF: Framingham Heart Study. Stroke. 1996; 10:1760-4 vii US Preventive Services Task Force. Screening for Atrial Fibrillation With Electrocardiography: US Preventive Services Task Force Recommendation Statement. JAMA. 2018;320(5):478-484. doi:10.1001/jama.2018.10321

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