

## **Bristol Myers Squibb Announces New PDUFA Date for Mavacamten**

(PRINCETON, N.J., November 19, 2021) -- [Bristol Myers Squibb](#) (NYSE: BMY) today announced that the U.S. Food and Drug Administration (FDA) has extended the review of the New Drug Application (NDA) for mavacamten for the treatment of patients with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to April 28, 2022.

The FDA notified Bristol Myers Squibb on November 18, 2021 of the extension of the PDUFA date to allow sufficient time to review information pertaining to updates to the proposed Risk Evaluation Mitigation Strategy (REMS). A REMS program was included in the initial application for mavacamten. No additional data or studies have been requested.

“We are confident in the profile of mavacamten. This first-in-class cardiac myosin inhibitor demonstrated clinically meaningful improvements in symptoms, functional status, and quality of life in symptomatic oHCM patients in the pivotal EXPLORER-HCM trial,” said [Samit Hirawat, M.D.](#), executive vice president, chief medical officer, global drug development, Bristol Myers Squibb. “We look forward to continuing to work closely with the FDA to bring this important medicine to patients.”

### **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](#).

### **Bristol Myers Squibb Cautionary Statement Regarding Forward-Looking Statements**

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 pharmaceutical products. 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 mavacamten may not receive regulatory approval for the indication described in this release in the currently anticipated timeline or at all, any marketing approvals, if granted, may

have significant limitations on their use, and, if approved, whether such product candidate for such indication described in this release will be commercially successful. 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, 2020, 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.

## **Bristol Myers Squibb**

### **Media Inquiries:**

[media@bms.com](mailto:media@bms.com)

Susan Francis

[susan.francis@bms.com](mailto:susan.francis@bms.com)

### **Investors:**

Nina Goworek

650-243-8550

[nina.goworek@bms.com](mailto:nina.goworek@bms.com)