

# Bristol Myers Squibb to Present Data Supporting its Cardiovascular Portfolio at the American College of Cardiology Annual Scientific Session Together With World Congress of Cardiology

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CATEGORY: [Corporate/Financial News](#)

***Data across EXPLORER-HCM, MAVA-LTE and PIONEER-OLE add to the growing body of evidence from the CAMZYOS® (mavacamten) development program, reinforcing the therapeutic value and benefit to patients***

PRINCETON, N.J.--(BUSINESS WIRE)-- [Bristol Myers Squibb](#) (NYSE: BMY) today announced the presentation of research supporting the company's cardiovascular franchise at the American College of Cardiology (ACC) Annual Scientific Session & Expo together with the World Congress of Cardiology (WCC), taking place in-person and virtually March 4-6, 2023. Findings from clinical studies will be featured, including several moderated poster presentations from the CAMZYOS® (mavacamten) development program showcasing data across various subgroups of patients with obstructive hypertrophic cardiomyopathy (HCM). During the meeting, the Bristol Myers Squibb-Pfizer Alliance will also present results characterizing the healthcare provider perspective on consumer wearables for atrial fibrillation detection.

"At this year's ACC, we are proud to showcase both short and long-term data that continues to exemplify our mission of developing and delivering medicines that make a real difference in the lives of cardiovascular patients," said Roland Chen, MD, senior vice president and head of cardiovascular development, Global Drug Development at Bristol Myers Squibb. "We look forward to presenting CAMZYOS 156-week data, the longest study of any myosin inhibitor, and additional analyses across a variety of patient subgroups, reinforcing its therapeutic value and benefit to patients."

## Key presentations include:

- Updated results from PIONEER-OLE evaluating 13 mavacamten patients through 156 weeks (three years) of follow-up — the longest study of mavacamten treatment to-date in patients with obstructive HCM.
- An exploratory analysis of longitudinal cardiac magnetic resonance data from the EXPLORER cohort of the ongoing MAVA-LTE study that evaluated the effects of long-term treatment (96 weeks) with mavacamten on cardiac remodeling and its impact on left ventricular hypertrophy, which is a key attribute and complication related to HCM.
- Multiple subgroup analyses of the Phase 3 EXPLORER-HCM trial measuring mavacamten's impact across disease severity, patient age and sex, and duration of diagnosis.
- Results from a Bristol Myers Squibb-Pfizer Alliance sponsored survey characterizing healthcare provider experiences and perceptions of consumer wearable devices for atrial fibrillation detection.

## Summary of Presentations

Select Bristol Myers Squibb and Bristol Myers Squibb-Pfizer Alliance studies at ACC.23/WCC include:

| Abstract Title   | Primary Author | Type/#                     | Session Title  | Time (CT)           |
|--|----------------|----------------------------|--|---------------------|
| <b>Sunday, March 5, 2023</b>   |                |                            |  |                     |
| Consumer wearables for atrial fibrillation detection: Results of a survey to characterize the healthcare provider perspective*   | Simonson, J    | Poster – 1464-036          | 1464 - Spotlight on Special Topics: Innovation, Digital Health, and Technology 8 | 9:45 AM – 10:30 AM  |
| The effect of mavacamten treatment for symptomatic, obstructive hypertrophic cardiomyopathy in patients with or without hypertension: Analysis of the EXPLORER-HCM trial | Wang, A        | Moderated Poster – 1042-09 | 1042 - Bulking Up: New Research in Hypertrophic Cardiomyopathy                   | 10:00 AM – 10:10 AM |

|   |           |                               |  |                     |
|---|-----------|-------------------------------|--|---------------------|
| 96-week cardiac magnetic resonance (CMR) results of treatment with mavacamten from the EXPLORER cohort of the MAVA-long-term extension (LTE) study in patients (pts) with obstructive hypertrophic cardiomyopathy (HCM) | Saberi, S | Moderated<br>Poster – 1042-11 | 1042 - Bulking Up: New Research in Hypertrophic Cardiomyopathy | 10:15 AM – 10:25 AM |
| The effect of mavacamten treatment for symptomatic, obstructive hypertrophic cardiomyopathy in patients of older age and longer duration of diagnosis: Analysis of the EXPLORER-HCM trial                               | Wang, A   | Moderated<br>Poster – 1042-13 | 1042 - Bulking Up: New Research in Hypertrophic Cardiomyopathy | 10:30 AM – 10:40 AM |
| Women in EXPLORER-HCM had more severe heart failure at baseline but similar, or greater, response to mavacamten   | Cresci, S | Moderated<br>Poster – 1066-03 | 1066 - The Latest Hype In Hypertrophic Cardiomyopathy          | 2:30 PM – 2:40 PM   |
| Long-term safety and efficacy of mavacamten in patients (pts) with symptomatic obstructive hypertrophic cardiomyopathy (HCM): Updated results from the PIONEER-OLE study  | Masri, A  | Moderated<br>Poster – 1066-07 | 1066 - The Latest Hype In Hypertrophic Cardiomyopathy          | 3:00 PM – 3:10 PM   |
| Obstructive HCM patients in EXPLORER-HCM with high left ventricular filling pressures had more severe heart failure but similar or greater response to mavacamten   | Cresci, S | Moderated<br>Poster – 1066-09 | 1066 - The Latest Hype In Hypertrophic Cardiomyopathy          | 3:15 PM – 3:25 PM   |

\*Sponsored by the Bristol Myers Squibb-Pfizer Alliance

#### **About CAMZYOS (mavacamten)**

CAMZYOS (mavacamten) is the first and only cardiac myosin inhibitor approved in the U.S., indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms. It has also received regulatory approvals in Australia, Canada, and Brazil. CAMZYOS is an allosteric and reversible inhibitor selective for cardiac myosin. CAMZYOS modulates the number of myosin heads that can enter “on actin” (power-generating) states, thus reducing the probability of force-producing (systolic) and residual (diastolic) cross-bridge formation. Excess myosin actin cross-bridge formation and dysregulation of the super-relaxed state are mechanistic hallmarks of HCM. CAMZYOS shifts the overall myosin population towards an energy-sparing, recruitable, super-relaxed state. In HCM patients, myosin inhibition with CAMZYOS reduces dynamic left ventricular outflow tract (LVOT) obstruction and improves cardiac filling pressures.

#### **IMPORTANT SAFETY INFORMATION**

##### **WARNING: RISK OF HEART FAILURE**

**CAMZYOS reduces left ventricular ejection fraction (LVEF) and can cause heart failure due to systolic dysfunction.**

Echocardiogram assessments of LVEF are required prior to and during treatment with CAMZYOS. Initiation of CAMZYOS in patients with LVEF <55% is not recommended. Interrupt CAMZYOS if LVEF is <50% at any visit or if the patient experiences heart failure symptoms or worsening clinical status.

Concomitant use of CAMZYOS with certain cytochrome P450 inhibitors or discontinuation of certain cytochrome P450 inducers may increase the risk of heart failure due to systolic dysfunction; therefore, the use of CAMZYOS is contraindicated with the following:

- Moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors
- Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers

Because of the risk of heart failure due to systolic dysfunction, CAMZYOS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CAMZYOS REMS PROGRAM.

##### **CONTRAINDICATIONS**

CAMZYOS is contraindicated with concomitant use of:

- Moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors
- Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers

##### **WARNINGS AND PRECAUTIONS**

## Heart Failure

CAMZYOS reduces systolic contraction and can cause heart failure or totally block ventricular function. Patients who experience a serious intercurrent illness (e.g., serious infection) or arrhythmia (e.g., atrial fibrillation or other uncontrolled tachyarrhythmia) are at greater risk of developing systolic dysfunction and heart failure.

Assess the patient's clinical status and LVEF prior to and regularly during treatment and adjust the CAMZYOS dose accordingly. New or worsening arrhythmia, dyspnea, chest pain, fatigue, palpitations, leg edema, or elevations in N-terminal pro-B-type natriuretic peptide (NT-proBNP) may be signs and symptoms of heart failure and should also prompt an evaluation of cardiac function.

Asymptomatic LVEF reduction, intercurrent illnesses, and arrhythmias require additional dosing considerations.

Initiation of CAMZYOS in patients with LVEF <55% is not recommended. Avoid concomitant use of CAMZYOS in patients on disopyramide, ranolazine, verapamil with a beta blocker, or diltiazem with a beta blocker as these medications and combinations were excluded from EXPLORER-HCM. Concomitant use of CAMZYOS with disopyramide in combination with verapamil or diltiazem has been associated with left ventricular systolic dysfunction and heart failure symptoms in patients with obstructive HCM.

## CYP 450 Drug Interactions Leading to Heart Failure or Loss of Effectiveness

CAMZYOS is primarily metabolized by CYP2C19 and CYP3A4 enzymes. Concomitant use of CAMZYOS and drugs that interact with these enzymes may lead to life-threatening drug interactions such as heart failure or loss of effectiveness.

Advise patients of the potential for drug interactions, including with over the counter medications (such as omeprazole, esomeprazole, or cimetidine). Advise patients to inform their healthcare provider of all concomitant products prior to and during CAMZYOS treatment.

## CAMZYOS Risk Evaluation and Mitigation Strategy (REMS) Program

CAMZYOS is only available through a restricted program called the CAMZYOS REMS Program because of the risk of heart failure due to systolic dysfunction. Notable requirements of the CAMZYOS REMS Program include the following:

- Prescribers must be certified by enrolling in the REMS Program.
- Patients must enroll in the REMS Program and comply with ongoing monitoring requirements.
- Pharmacies must be certified by enrolling in the REMS Program and must only dispense to patients who are authorized to receive CAMZYOS.
- Wholesalers and distributors must only distribute to certified pharmacies.

Further information is available at [www.CAMZYOSREMS.com](http://www.CAMZYOSREMS.com) or by telephone at 1-833-628-7367.

## Embryo-Fetal Toxicity

CAMZYOS may cause fetal toxicity when administered to a pregnant female, based on animal studies. Confirm absence of pregnancy in females of reproductive potential prior to treatment and advise patients to use effective contraception during treatment with CAMZYOS and for 4 months after the last dose. CAMZYOS may reduce the effectiveness of combined hormonal contraceptives (CHCs). Advise patients using CHCs to use an alternative contraceptive method that is not affected by CYP 450 enzyme induction or to add nonhormonal contraception. Advise females of reproductive potential about the potential risk to the fetus with maternal exposure to CAMZYOS during pregnancy.

## ADVERSE REACTIONS

In the EXPLORER-HCM trial, adverse reactions occurring in >5% of patients and more commonly in the CAMZYOS group than in the placebo group were dizziness (27% vs 18%) and syncope (6% vs 2%).

### Effects on Systolic Function

In the EXPLORER-HCM trial, mean (SD) resting LVEF was 74% (6) at baseline in both treatment groups. Mean (SD) absolute change from baseline in LVEF was -4% (8) in the CAMZYOS group and 0% (7) in the placebo group over the 30-week treatment period. At Week 38, following an 8-week interruption of trial drug, mean LVEF was similar to baseline for both treatment groups. In the EXPLORER-HCM trial, 7 (6%) patients in the CAMZYOS group and 2 (2%) patients in the placebo group experienced reversible reductions in LVEF <50% (median 48%: range 35-49%) while on treatment. In all 7 patients treated with CAMZYOS, LVEF recovered following interruption of CAMZYOS.

## DRUG INTERACTIONS

### Potential for Other Drugs to Affect Plasma Concentrations of CAMZYOS

CAMZYOS is primarily metabolized by CYP2C19 and to a lesser extent by CYP3A4 and CYP2C9. Inducers and inhibitors of CYP2C19 and moderate to strong inhibitors or inducers of CYP3A4 may affect the exposures of CAMZYOS.

## Impact of Other Drugs on CAMZYOS:

- Moderate to Strong CYP2C19 Inhibitors or Strong CYP3A4 Inhibitors: Concomitant use increases CAMZYOS exposure, which may increase the risk of heart failure due to systolic dysfunction. Concomitant use is contraindicated.
- Moderate to Strong CYP2C19 Inducers or Moderate to Strong CYP3A4 Inducers: Concomitant use decreases CAMZYOS exposure, which may reduce CAMZYOS' efficacy. The risk of heart failure due to systolic dysfunction may increase with discontinuation of these inducers as the levels of induced enzyme normalizes. Concomitant use is contraindicated.
- Weak CYP2C19 Inhibitors or Moderate CYP3A4 Inhibitors: Concomitant use with a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor increases CAMZYOS exposure, which may increase the risk of adverse drug reactions. Initiate CAMZYOS at the recommended starting dose of 5 mg orally once daily in patients who are on stable therapy with a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor. Reduce dose of CAMZYOS by one level (i.e., 15 to 10 mg, 10 to 5 mg, or 5 to 2.5 mg) in patients who are on CAMZYOS treatment and intend to initiate a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor. Schedule clinical and echocardiographic assessment 4 weeks after inhibitor initiation, and do not up-titrate CAMZYOS until 12 weeks after inhibitor initiation. Avoid initiation of concomitant weak CYP2C19 and moderate CYP3A4 inhibitors in patients who are on stable treatment with 2.5 mg of CAMZYOS because a lower dose is not available.

## Potential for CAMZYOS to Affect Plasma Concentrations of Other Drugs

CAMZYOS is an inducer of CYP3A4, CYP2C9, and CYP2C19. Concomitant use with CYP3A4, CYP2C19, or CYP2C9 substrates may reduce plasma concentration of these drugs. Closely monitor when CAMZYOS is used in combination with CYP3A4, CYP2C19, or CYP2C9 substrates where decreases in the plasma concentration of these drugs may reduce their activity.

Hormonal Contraceptives: Progestin and ethinyl estradiol are CYP3A4 substrates. Concomitant use of CAMZYOS may decrease exposures of ethinyl estradiol and progestin, which may lead to contraceptive failure or an increase in breakthrough bleeding. Advise patients to use a contraceptive method that is not affected by CYP 450 enzyme induction (e.g., intrauterine system) or add nonhormonal contraception (such as condoms) during concomitant use and for 4 months after the last dose of CAMZYOS.

## Drugs That Reduce Cardiac Contractility

Expect additive negative inotropic effects of CAMZYOS and other drugs that reduce cardiac contractility. Avoid concomitant use of CAMZYOS with disopyramide in combination with verapamil or diltiazem. If concomitant therapy with a negative inotrope is initiated, or if the dose of a negative inotrope is increased, monitor LVEF closely until stable doses and clinical response have been achieved.

## SPECIFIC POPULATIONS

### Pregnancy

CAMZYOS may cause fetal harm when administered to a pregnant female. Advise pregnant females about the potential risk to the fetus with maternal exposure to CAMZYOS during pregnancy. There is a pregnancy safety study for CAMZYOS. If CAMZYOS is administered during pregnancy, or if a patient becomes pregnant while receiving CAMZYOS or within 4 months after the last dose of CAMZYOS, healthcare providers should report CAMZYOS exposure by contacting Bristol Myers Squibb at 1-800-721-5072 or [www.bms.com](http://www.bms.com).

### Lactation

The presence of CAMZYOS in human or animal milk, the drug's effects on the breastfed infant, or the effects on milk production are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for CAMZYOS and any potential adverse effects on the breastfed child from CAMZYOS or from the underlying maternal condition.

## Females and Males of Reproductive Potential

Confirm absence of pregnancy in females of reproductive potential prior to initiation of CAMZYOS. Advise females of reproductive potential to use effective contraception during treatment with CAMZYOS and for 4 months after the last dose. Use of CAMZYOS may reduce the effectiveness of CHCs. Advise patients using CHCs to use an alternative contraceptive method or add nonhormonal contraception.

Please see US Full [Prescribing Information](#), including **Boxed WARNING** and [Medication Guide](#).

## 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](http://BMS.com) or follow us on [LinkedIn](#), [Twitter](#), [YouTube](#), [Facebook](#) and [Instagram](#).

## 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 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 future study results may not be consistent with the results to date, that CAMZYOS® (mavacamten) may not receive regulatory approval for the indication described in this release, that any marketing approvals, if granted, may have significant limitations on their use, and, if approved, that such product candidate for such indication described in this release will be commercially successful. 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, 2022, 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.

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