George Medicines files New Drug Application with FDA for novel low dose triple combination for treatment of hypertension following successful international Phase III development program

- ***Multi-mechanism, triple combination of existing best-in-class medicines in novel low dose single pill, GMRx2 has potential to be the only triple combination product for management of hypertension, including initial treatment***
- ***Two international Phase III clinical trials for the treatment of hypertension, vs dual therapy and placebo, met all primary efficacy and safety endpoints***
- ***Study results from both trials planned for publication by the end of the year***

London, UK 6 August 2024 – George Medicines, a late-stage, biopharmaceutical company addressing significant unmet need in the treatment of cardiometabolic disease, today announces its submission to the US Food and Drug Administration (FDA) of a New Drug Application (NDA) for GMRx2, George Medicines' lead pipeline candidate for the treatment for hypertension, including initiation of treatment.

The application was based on the achievement of all primary efficacy and safety endpoints in the Company's two Phase III studies evaluating its multi-mechanism, triple combination single pill of existing best-in-class medicines, telmisartan, amlodipine and indapamide, in novel low doses, versus dual therapy and placebo.

Mark Mallon, Chief Executive Officer of George Medicines, said: *"It is time for a new approach to tackle what remains one of the leading causes of death and disability, and a major risk factor for heart attacks, heart failure, stroke, kidney failure and dementia[1,2]. Hypertension affects nearly one in two adults in the US and only a quarter of those are controlled[3]. This leaves more than 70 million patients without their blood pressure controlled, often because of suboptimal treatment.*

"GMRx2's potential to deliver rapid and effective blood pressure control and a favourable tolerability profile, provides an opportunity to transform the management of hypertension. We look forward to the outcome of the regulatory process, alongside our ongoing activities to secure commercialization partners for GMRx2, so that we can bring the value of this important medicine to patients."

Designed for optimal efficacy, safety and adherence, GMRx2's multi-mechanism approach, at lower dosing than today's therapies, delivers the synergistic efficacy benefits of a triple therapy while maintaining tolerability. GMRx2 is expected to be an important new option for physicians and patients, initially in the $12 billion US hypertension market[4], and then globally, including in low- and middle-income countries whose populations carry a significant hypertension burden[1].

George Medicines conducted two randomized, controlled Phase III studies to support its FDA regulatory submission. Study 1 was 4 weeks in duration with 295 subjects receiving GMRx2 or placebo. Study 2 involved a 4-week active run-in period, during which 2,244 subjects received GMRx2 followed by a 12-week randomized period in which 1385 subjects received GMRx2 or one of the three component two-drug combinations.

The primary efficacy endpoint in both studies was change in home systolic blood pressure (SBP) from baseline and the primary safety endpoint was difference in withdrawals for adverse events.

The two studies are expected to be published by the end of the year.

George Medicines is a spin-out company from The George Institute for Global Health, one of the world's leading medical research institutes with a focus on addressing global health inequity. The Company's GMRx2 development program built on earlier research by The George Institute, including the 700-patient TRIUMPH trial, undertaken in Sri Lanka in 2016/17 which found that among patients with mild to moderate hypertension, treatment with a low dose, single-pill, triple combination led to an increased proportion of patients achieving their target blood pressure goal versus usual care[5].

Hypertension treatment today

The US Surgeon General's Call to Action to Control Hypertension, published in 2020[3], outlined the limitations in, and the complexity of, the current hypertension treatment pathway, leading to poor patient outcomes. In the US nearly half of adults have hypertension (120 million) and only around 1 in 4 of those have their hypertension under control (27.0 million)[1], either because they are not being treated or their treatment is suboptimal.

Too many diagnosed patients aren't achieving sufficient blood pressure control because they are on inadequate therapy, aren't receiving the right combination of medicines at the right doses or aren't taking their treatment as prescribed or continuing their treatment in the long term.

The major, globally recognized treatment guidelines[6] recommend the use of fixed dose combination therapy for most patients with hypertension, including for first-line treatment and yet, in practice, newly diagnosed patients will often still be prescribed monotherapy treatment. This is despite a broad evidence base indicating that, individually, blood pressure medicines are only modestly effective at reducing blood pressure, even at high doses, and most patients will require two or more medicines to achieve control.

As dosage of hypertension drugs is increased, so too are side effects, which can preclude the use of high doses for many patients. These side effect challenges, alongside the management of multiple hypertension medicines being taken together with treatments for other conditions, can significantly impact treatment compliance and adherence, including failure to take medications as prescribed and to persist on long-term therapy.

Ends

References

1. World Health Organization Hypertension factsheet https://www.who.int/news-room/fact-sheets/detail/hypertension
2. Lennon MJ, Lam BCP, Lipnicki DM, et al. *Use of Antihypertensives, Blood Pressure, and Estimated Risk of Dementia in Late Life: An Individual Participant Data Meta-Analysis*. *JAMA Netw Open.* 2023;6(9):e2333353. doi:10.1001/jamanetworkopen.2023.33353 https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2809194
3. The Surgeon General's Call to Action to Control Hypertension https://www.hhs.gov/sites/default/files/call-to-action-to-control-hypertension.pdf

4. Statista Market Insights: Anti-Hypertensive Drugs – United States https://www.statista.com/outlook/hmo/pharmaceuticals/anti-hypertensive-drugs/united-states
5. Fixed Low-Dose Triple Combination Antihypertensive Medication vs Usual Care for Blood Pressure Control in Patients With Mild to Moderate Hypertension in Sri Lanka. A Randomized Clinical Trial JAMA. 2018;320(6):566-579. doi:10.1001/jama.2018.10359 https://jamanetwork.com/journals/jama/fullarticle/2697010
6. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines https://www.ahajournals.org/doi/10.1161/HYP.0000000000000065; WHO Guideline for the pharmacological treatment of hypertension in adults https://iris.who.int/bitstream/handle/10665/344424/9789240033986-eng.pdf;; 2018 ESC/ESH Clinical Practice Guidelines for the Management of Arterial Hypertension https://www.escardio.org/Guidelines/Clinical-Practice-Guidelines/Arterial-Hypertension-Management-of

About George Medicines

George Medicines is a late-stage biopharmaceutical company addressing significant unmet need in the treatment of cardiometabolic diseases with innovative combinations of best-in-class existing treatments, designed for optimal efficacy and safety.

Combining best-in-class molecules from existing medicines in novel low-dose formulations, George Medicines is developing innovative and proprietary treatments to be more efficacious, safer and accessible than currently available treatment options. These multi-mechanism, single-pill combinations offer the potential to bring significant improvements in clinical outcomes and therapy adherence in patients with cardiometabolic disorders, including hypertension and diabetes, each of which remain the leading causes of premature death and disability worldwide.

The Company's lead candidate, GMRx2, has completed a Phase III development program for the treatment of hypertension, including first-line therapy, and a global trial focused on the prevention of recurrent intracerebral hemorrhage (the most severe type of stroke) is underway.

George Medicines is a spin-out company from The George Institute for Global Health, one of the world's leading medical research institutes with a focus on addressing global health inequity. The Company is backed by George Health, the commercial arm of The George Institute, and Brandon Capital, Australia's leading life sciences venture capital firm. For more information, please visit www.george-medicines.com.

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