Widaplik™ (telmisartan/amlodipine/indapamide) – New drug approval

- On June 5, 2025, the FDA approved George Medicines' Widaplik (telmisartan/amlodipine/indapamide), for the **treatment of hypertension in adult patients, to lower blood pressure**.
    - Widaplik may be used as initial therapy in patients likely to need multiple drugs to achieve blood pressure goals.
- Widaplik is a combination tablet containing telmisartan, an angiotensin II receptor blocker, amlodipine, a dihydropyridine calcium channel blocker and indapamide, a thiazide-like diuretic.
- The efficacy of Widaplik was established in Study 1, a 4-week, randomized, double-blind, placebo-controlled study in 295 adults with systolic hypertension who were taking 0 to 1 antihypertensive medication at screening and who were at a low risk for cardiovascular disease per local guidelines. Patients were randomized to receive Widaplik (10 mg/1.25 mg/0.625 mg), Widaplik (20 mg/2.5 mg/1.25 mg), or placebo. The primary endpoint was the change from randomization to week 4 in home systolic blood pressure.
    - The least squares mean (LSM) change in home systolic blood pressure was -2.2 mmHg with placebo, -9.6 mmHg with Widaplik 10 mg/1.25 mg/0.625 mg and -10.4 mmHg with Widaplik 20 mg/2.5 mg/1.25 mg. The difference vs. placebo was -7.3 (95% CI: -10.2, -4.5; $p < 0.0001$) with Widaplik 10 mg/1.25 mg/0.625 mg and -8.2 (95% CI: -11.3, -5.2; $p < 0.0001$) with Widaplik 20 mg/2.5 mg/1.25 mg.
- The efficacy of Widaplik was also established in Study 2, a 12-week, randomized, double-blind study comparing Widaplik up to 40 mg/5 mg/2.5 mg vs. each of its two-drug combinations at the same doses: telmisartan/indapamide, telmisartan/amlodipine, or amlodipine/indapamide. Enrolled patients were required to have a mean systolic blood pressure of 140 to 179 mmHg if on no antihypertensive medications, 130 to 170 mmHg if on one, 120 to 160 mmHg if on two, or 110 to 150 mmHg if on three. A total of 1,385 patients were included in the randomized portion of the study. The primary endpoint was the change in home seated mean systolic blood pressure from randomization to week 12.
    - The LSM change in home systolic blood pressure was -4.0 mmHg with Widaplik vs. -1.5 mmHg with telmisartan/indapamide vs. 1.4 mmHg with telmisartan/amlodipine vs. 0.5 mmHg with amlodipine/indapamide ($p < 0.0001$ vs. all dual combinations)
- Widaplik carries a boxed warning for **fetal toxicity**.
- Widaplik is contraindicated in patients with:
    - Known hypersensitivity to telmisartan, amlodipine, indapamide, or to other sulfonamide-derived drugs, or to any other component of this product
    - Anuria
    - Co-administration with aliskiren in patients with diabetes.
- Additional warnings and precautions for Widaplik include hypotension; electrolyte and glucose imbalances; impaired renal function; acute angle-closure glaucoma, acute myopia, and choroidal effusion; and hyperuricemia.

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- The most common adverse reaction with Widaplik use is symptomatic hypotension. Low sodium and potassium values were recorded more often with Widaplik compared to placebo.

- The recommended starting dosage for Widaplik (10 mg/1.25 mg/0.625 mg) is orally once daily or Widaplik (20 mg/2.5 mg/1.25 mg) orally once daily, based on anticipated need for blood pressure reduction.

    — In elderly patients, starting with Widaplik (10 mg/1.25 mg/0.625 mg) orally once daily should be considered.
    — The maximum recommended dose is Widaplik (40 mg/5 mg/2.5 mg) orally once daily.

- George Medicines' launch plans for Widaplik are pending. Widaplik will be available as 10 mg/1.25 mg/ 0.625 mg, 20 mg/2.5 mg/1.25 mg, or 40 mg/5 mg/2.5 mg tablets.

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