

## **DAMIAN announces dexfadrostat phosphate demonstrated efficacy and tolerability in patients with primary aldosteronism in Phase 2 trial**

- *Dexfadrostat phosphate, a novel aldosterone synthase inhibitor, met its co-primary endpoints demonstrating statistically significant reduction of the aldosterone-to-renin ratio (ARR) and ambulatory systolic blood pressure (aSBP) in patients diagnosed with primary aldosteronism*
- *Dexfadrostat phosphate achieved both rapid and sustained reductions in ARR and aSBP by day 14 along with statistically significant reductions in office systolic blood pressure*
- *Dexfadrostat phosphate demonstrated a favorable safety profile, with no patients discontinuing the trial after randomization*

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DAMIAN today announced new data from the Phase 2 trial in patients with primary aldosteronism (PA), that showed the investigational compound dexfadrostat phosphate significantly reduced both aldosterone-to-renin ratio (ARR) and ambulatory systolic blood pressure (aSBP). The trial met both primary endpoints with high significance. The data were presented at the Progress in Primary Aldosteronism (PiPA-7) scientific meeting and will be endorsed at the International Society of Hypertension (ISH).

The Phase 2 study (NCT04007406) enrolled Endocrine Society Guideline diagnosed patients with primary aldosteronism. The 12-week trial consisted of a 2-week placebo run-in period during which patients maintained their background hypertension control therapy, followed by 8 weeks of treatment with dexfadrostat phosphate at one of 3 doses taken orally, daily. The final 2-weeks consisted of a placebo-controlled withdrawal period. Patients were monitored at biweekly clinic visits. The coprimary endpoints were change-from-baseline in ARR and aSBP.

Primary aldosteronism, first identified in 1955 by Jerome Conn, is an endocrine disease caused by the uncontrolled, excessive production of aldosterone by the adrenal glands and is characterized by hypertension and hypokalemia.<sup>1</sup> Aldosterone is the hormone that regulates sodium, potassium, and water balance in humans. Primary aldosteronism has been shown to increase the risk for cardiovascular events such as heart failure and stroke, independent of blood pressure.<sup>2,3</sup> Patients with PA have limited treatment options, undergoing adrenalectomy (removal of one adrenal gland) for unilateral disease or taking a mineralocorticoid receptor antagonist (spironolactone, eplerenone) if both adrenals are affected or if surgery is not indicated or wanted.<sup>4</sup> Dexfadrostat phosphate represents a new class of compounds to treat PA, aldosterone synthase inhibitors, and is the first to demonstrate both biochemical and clinical correction of PA with no significant off-target effects in a phase 2 trial.

About DAMIAN

DAMIAN is a small, privately owned, Swiss pharmaceutical company whose mission is to find first-of-a-kind solutions for aldosterone-dependent conditions.

#### Disclaimer

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#### References

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