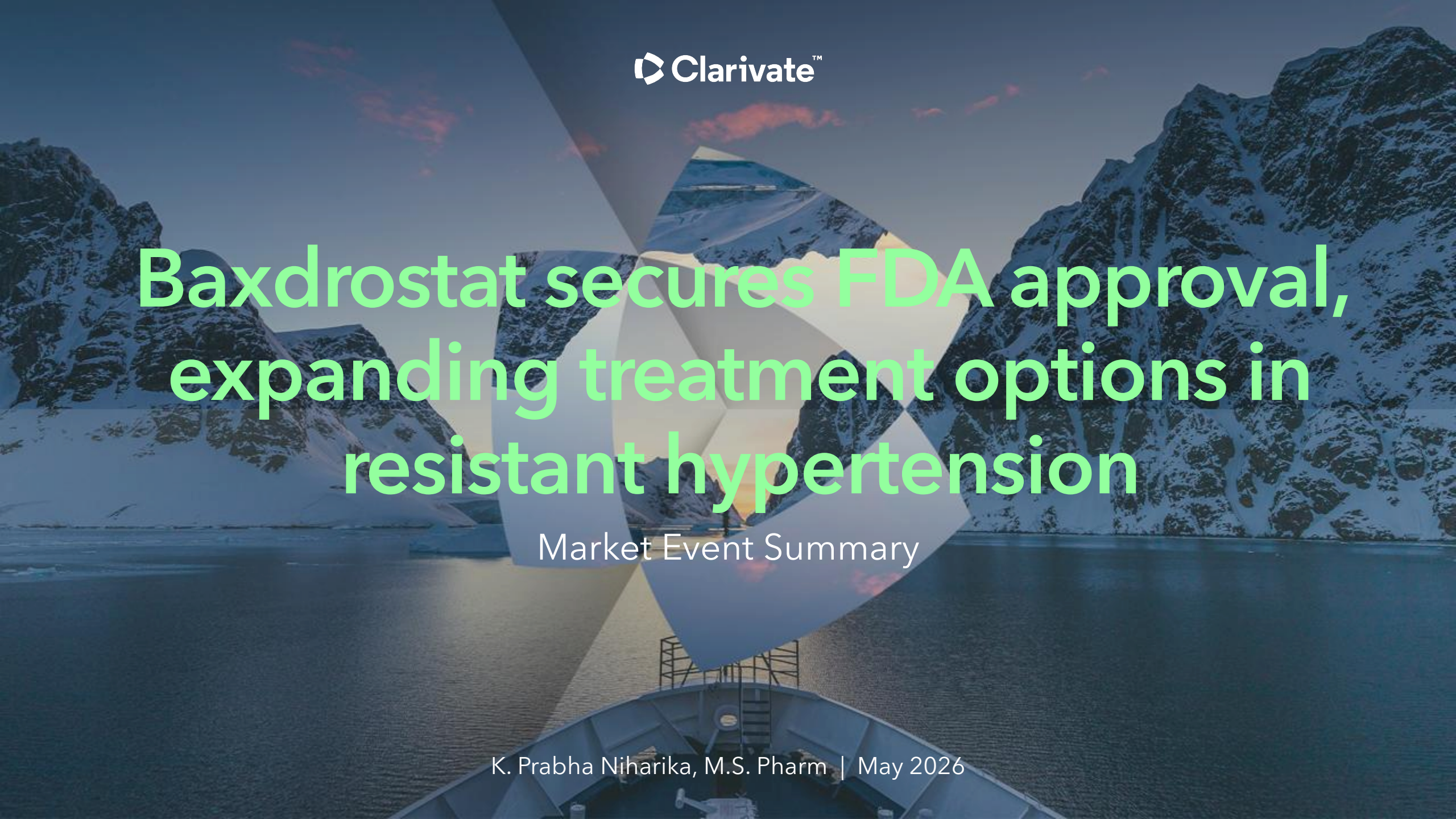

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Baxdrostat secures FDA approval, expanding treatment options in resistant hypertension

Market Event Summary

K. Prabha Niharika, M.S. Pharm | May 2026

Aldosterone targeting unlocks novel option in resistant hypertension

Background

- Hypertension is a leading, modifiable cardiovascular risk factor, yet a large proportion of patients remain uncontrolled despite combination therapy, highlighting persistent real-world blood pressure (BP) management gaps.
- Resistant hypertension (RHTN), defined as BP uncontrolled on 3 or more agents including a diuretic, reflects unresolved underlying drivers. Recent approvals such as Idorsia's aprocitentan (Tryvio /Jeraygo) reinforce renewed focus on pathway-targeted approaches.
- The treatment landscape is largely generic, with MRAs as the guideline-recommended fourth-line therapy. However, tolerability concerns and monitoring burden limit use, supporting the need for more effective and targeted approaches such as aldosterone synthesis inhibition.

Baxdrostat – first in class aldosterone synthase inhibitor

- Baxdrostat (marketed as Baxfendy in the United States) is a selective aldosterone synthase inhibitor (ASI) that lowers aldosterone to reduce sodium retention and plasma volume.
- Baxfendy received FDA approval in May 2026 based on Phase 3 BaxHTN data, demonstrating 15.7 and 14.2 mm Hg systolic BP (SBP) reductions, with placebo-adjusted reductions of 9.8 and 8.7 mm Hg for the 2 mg and 1 mg doses, respectively, at 12 weeks, with a favorable safety profile.
- Baxfendy will launch at a WAC price of $900 for 30 tablets ($7,200 annually) and is expected to be available in the United States in June 2026.

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Clarivate's takeaways

Novel therapy with limited disruption

Baxfendy demonstrated meaningful BP reductions in RHTN, but its efficacy is broadly in line with guideline-recommended fourth-line agents like spironolactone, without anti-androgen effects. We expect Baxfendy to face competition from Tryvio as well as emerging therapies offering superior efficacy, which are likely to limit differentiation and near-term impact.

Access and evidence will define uptake

Baxfendy's uptake will be gradual, constrained by step-therapy requirements favoring low-cost MRAs and ongoing monitoring needs. Early use will focus on patients with uncontrolled BP despite being on four antihypertensive agents, primarily as an add-on therapy rather than a replacement. Wider adoption will depend on outcomes data and real-world evidence.

European approval – an incremental opportunity

With regulatory submission underway in Europe, approval is expected in 2027. However, Europe's RHTN market, like the United States, is generic-driven, with Jeraygo approved but not yet launched. Baxdrostat may be the first novel entrant in decades, though uptake is likely to remain modest.

About the author

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Ms. Niharika conducts extensive secondary research on indications such as hemophilia A, kidney transplant, hyperkalemia, diabetic nephropathy, and heart failure. She holds a master's degree in pharmacoinformatics from the National Institute of Pharmaceutical Education and Research (NIPER) in Mohali and a bachelor's degree in pharmacy from Kakatiya University in Warangal, India.

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