

DURECT CORPORATION

Corporate Factsheet, January 2024

DURECT is pioneering the development of epigenetic therapies that target dysregulated DNA methylation to transform the treatment of serious and life-threatening conditions, including acute organ injury and cancer.

PIPELINE OVERVIEW

	Indication	Pre-clinical	Ph 1	Ph 2	Ph 3	Marketed	Status	FAST FACTS
Larsucosterol	Alcohol-Associated Hepatitis (AH)						Completed Phase 2b AHFIRM trial; FDA meeting planned for Q1 2024	NASDAQ: DRRX (Common Stock)
New Chemical Entities (NCE)	Hematology/Oncology						Preclinical studies ongoing	Cash & investments ¹ : \$39.1 M
POSIMIR® (bupivacaine solution)							Sold by Innocoll in the U.S.; DURECT maintains ex-U.S. rights	Debt ¹ : \$18.7 M
								Market Cap ² : \$16.6 M
								Shares outstanding ³ : 29.8 M
								¹ As of September 30, 2023
								² As of January 2, 2024
								³ As of November 13, 2023

LARSUCOSTEROL

Larsucosterol is an endogenous sulfated oxysterol and an epigenetic modulator. It binds to and inhibits the activity of DNA methyltransferases (DNMTs), epigenetic enzymes associated with aberrant DNA methylation, found to be elevated in severe alcohol-associated hepatitis (AH) patients. By modulating DNA hypermethylation, larsucosterol regulates the expression of genes important in maintaining cellular functions, thereby reducing cell death, lipotoxicity, inflammation and oxidative stress and improving hepatic regeneration in AH.

Larsucosterol is investigational and has not been approved by the FDA for marketing in the U.S. for any indication.

PROGRAM HIGHLIGHTS

LARSUCOSTEROL FOR AH: Compelling Opportunity in Underserved Market



AH: life-threatening acute liver disease caused by chronic misuse of alcohol, frequently after increased consumption, with no approved therapies and a 90-day overall mortality rate of ~30% following hospital admission; ~158K U.S. hospitalizations/year



Phase 2b AHFIRM data showed compelling mortality reduction at 90 days compared to standard of care (SOC); there is strong rationale for advancing larsucosterol to a registrational Phase 3 trial with 90-day mortality as the primary endpoint.



Discussion of AHFIRM data with FDA planned for Q1 2024

ANTI-CANCER CANDIDATES: Novel Approach via Epigenetic Modulation



DURECT has internally developed multiple novel small molecule DNMT inhibitors that exhibit broad spectrum activity against multiple hematologic and solid tumor types, with unique pharmacokinetic profiles and favorable tolerability.

POSIMIR® (bupivacaine solution)



POSIMIR is FDA-approved – It is indicated for post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression.



Exclusively licensed to Innocoll Pharmaceuticals for commercialization in the U.S.; DURECT is eligible to receive up to \$122 million in future milestone payments and low double-digit to mid-teens royalties on net product sales. DURECT maintains ex-U.S. rights.

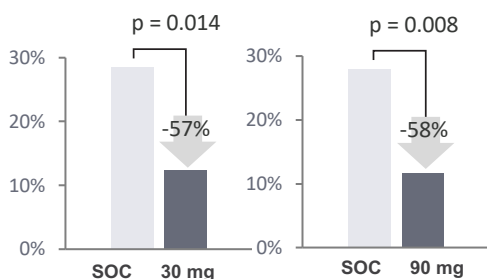


LARSUCOSTEROL FOR AH – TOPLINE PHASE 2b AHFIRM RESULTS

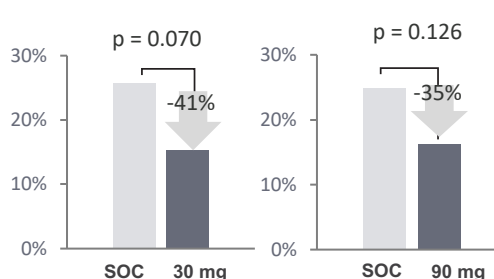
- **Pronounced reduction in mortality at 90 days in U.S. population**
 - 57% reduction with 30 mg dose
 - 58% reduction with 90 mg dose
- **Compelling trend in key secondary endpoint of mortality reduction at 90 days**
 - 41% reduction with 30 mg dose
 - 35% reduction with 90 mg dose
- Numerical improvement in primary endpoint of mortality or transplant at 90 days did not achieve statistical significance
- **Both doses of larsucosterol were well-tolerated**

Strong rationale for advancing larsucosterol to a registrational Phase 3 trial with 90-day mortality as the primary endpoint

Mortality at 90 Days (U.S. Patients)



Mortality at 90 Days



About AHFIRM

AHFIRM was a randomized, double-blind, placebo-controlled, international study, comprised of three arms with 307 total patients (approximately 100 patients per arm): (1) SOC, which consists of placebo plus supportive care, (2) larsucosterol (30 mg), and (3) larsucosterol (90 mg).

ADDITIONAL EVIDENCE OF LARSUCOSTEROL POTENTIAL

The potential of larsucosterol has been demonstrated in human studies beyond AH. In a Phase 1b clinical trial in patients with nonalcoholic steatohepatitis (NASH) with stage 1 to 3 fibrosis, larsucosterol showed potential efficacy signals with no drug related serious adverse events; more than 500 patients have been dosed in multiple Phase 1 & 2 trials.

DURECT Forward-Looking Statements. This factsheet contains forward-looking statements of DURECT Corporation ("DURECT," the "Company," "we," "our" or "us") and its collaborative partners within the meaning of applicable securities laws and regulations, which are subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements with respect to DURECT's plans for a Phase 3 trial for larsucosterol and to meet with the FDA to review the results of AHFIRM trial, the potential for a Phase 3 trial of larsucosterol to show a statistically significant improvement in the treatment of alcohol-associated hepatitis ("AH") over standard of care, the potential FDA regulatory approval of larsucosterol for the treatment of AH, anticipated product benefits and other potential uses of larsucosterol, anticipated product markets and potential sales, clinical trial results and plans, including the target date of selection of anti-cancer molecule candidates, DURECT's future business plans and projected financial results. These forward-looking statements involve risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, the risk that future clinical trials of larsucosterol do not confirm the results from subset analyses of the AHFIRM trial, including geographic or other segmentation, or of earlier clinical or pre-clinical trials, or do not demonstrate the safety or efficacy of larsucosterol in a statistically significant manner, the risk that the FDA or other government agencies may require additional clinical trials for larsucosterol before approving it for the treatment of AH, and risks related to the sufficiency of our cash resources, our anticipated capital requirements and capital expenditures, our need or desire for additional financing, our ability to obtain capital to fund our operations and expenses and our ability to continue to operate as a going concern. Further information regarding these and other risks is included in DURECT's most recent U.S. Securities and Exchange Commission ("SEC") filings, including its Annual and Quarterly Report on Form 10-K or 10-Q, respectively, filed with the SEC under the heading "Risk Factors." DURECT is under no duty to update any of these forward-looking statements after the date hereof to conform these statements to actual results or revised expectations, except as required by law. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Subsequent events and developments may cause DURECT's expectations and beliefs to change.

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