

DURECT CORPORATION

Corporate Factsheet, September 2023

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)	[Progress bar]				Enrollment completed in Phase 2b AHFIRM trial; Topline data expected in Q4 2023	
	Non-Alcoholic Steatohepatitis (NASH)	[Progress bar]				Positive Phase 1b topline results	
New Chemical Entities (NCE)	Hematology/Oncology	[Progress bar]				Molecule selection targeted for Q4 2023	
POSIMIR® (bupivacaine solution)	[Progress bar]					Sold by Innocoll in the U.S.; DURECT maintains ex-U.S. rights	
							NASDAQ: DRRX (Common Stock)
							Cash & investments ¹ : \$48.7 M
							Debt ² : \$20.7 M
							Market Cap ³ : \$84.5 M
							Shares outstanding ⁴ : 27.6 M

FAST FACTS

NASDAQ: DRRX (Common Stock)

Cash & investments¹: \$48.7 M

Debt²: \$20.7 M

Market Cap³: \$84.5 M

Shares outstanding⁴: 27.6 M

¹As of 6/30/23. Pro forma for receipt of \$13.8M of net proceeds from July 2023 registered direct offering

²As of 6/30/23

³As of 8/31/23

⁴As of 8/7/23.

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 hypermethylation, found to be elevated in severe alcohol-associated hepatitis (AH) patients. By decreasing DNA hypermethylation, larsucosterol modulates the expression of genes important in maintaining cellular functions, thereby reducing cell death, lipotoxicity and inflammation 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 29% following hospital admission; ~158K U.S. hospitalizations/y



Positive Phase 2a data: 100% survival rate at 28 days; showed improvement in key biomarkers and prognostic indicators



Potential pivotal data expected in Q4 2023; successful trial may support NDA filing; FDA Fast Track Designation

LARSUCOSTEROL FOR NASH: Novel Approach via Epigenetic Modulation



Non-alcoholic steatohepatitis (NASH): advanced form of non-alcoholic fatty liver disease; no approved drugs



Positive topline Phase 1b data: improvements in liver enzymes, liver stiffness, biomarkers and serum lipids

POSIMIR® (bupivacaine solution)



U.S. rights exclusively licensed to Innocoll Pharmaceuticals. DURECT is eligible to receive up to \$122 million in future milestone payments as well as low double-digit to mid-teens royalties on net product sales



Commercially available in the U.S. - Indicated for post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression



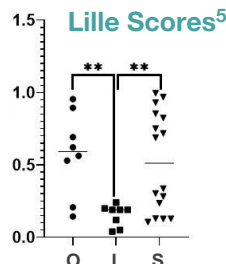
LARSUCOSTEROL FOR AH – COMPELLING PHASE 2a RESULTS¹

Survival	100% of patients treated with larsucosterol (n=19) survived the 28-day follow-up period in contrast to 26% historical 28-day mortality rate
Time to Discharge	74% of patients treated with larsucosterol discharged within 4 days of treatment after 1 dose
Bilirubin	Significant reduction compared to baseline at days 7 and 28
Prognostic Indicators of Mortality for AH	MELD (Model for End-Stage Liver Disease): significant reduction at day 28 compared to baseline
	LILLE SCORE: AH patients with Lille score <0.45 have an 85% 6-month survival rate vs. 25% survival rate when Lille score >0.45 ²
	Lille score in severe AH patients: All 8 severe AH patients in the 30 or 90 mg dose cohorts were treatment responders ³ (Lille score <0.45) and their Lille scores were statistically lower than those of well-matched patients from an Observational Arm and Study-Steroid Arm of the DASH Consortium trial in a cross-study comparison ⁴ (shown below) ⁵

¹Hassanein, T et al. 2023. Am J Gastroenterol, DOI: 10.14309/ajg.0000000000002275; ²Louvet A et al. 2007, Hepatology, 45: 1348-54; ³Lille score <0.45 is considered a "responder." ⁴Patients from both comparative arms were diagnosed with AH, screened for inclusion and exclusion criteria similar to the larsucosterol trial, and treated with standard-of-care, including corticosteroids. In addition, they were matched by MELD score to the 8 severe AH patients who received 30 or 90 mg of larsucosterol.

Arm	Median Baseline MELD
Observational (O)*	24.5
Larsucosterol (L)	24.5
Study-Steroid (S)*	24

* Patients who did not survive at 28 days were censored



LARSUCOSTEROL FOR NASH: POSITIVE PHASE 1B TOPLINE DATA

(N=65) * Indicates p-value <0.05; ** indicates p < 0.01; *** indicates p <0.001; Data at 28-days

Liver Enzymes	Significant median reduction from baseline of serum ALT (-17%***), AST (-18%**), and GGT (-8%*) in the high dose group
Liver Imaging	At day 28, 43% of patients showed ≥10% liver fat reduction from baseline. Significant reduction in liver stiffness as measured by FibroScan (-10%**), in the low dose group
Serum Lipids & Biomarkers	Median reduction in triglycerides (-24%**), in patients with elevated baseline (≥200 mg/dL; n=16) across all dose groups; Reduction in LDL-C (-11%*) in the mid dose group and CK-18s in those with reduced liver fat

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 to report topline data from the AHFIRM trial in Q4 2023, anticipated product benefits and other potential uses of larsucosterol, anticipated product markets and potential sales, clinical trial results and plans, DURECT's future business plans and projected financial results, DURECT's emergence as an innovative biopharmaceuticals company and other future events that involve risks and uncertainties. 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 risks that the AHFIRM trial takes longer to complete than anticipated, the risk that ongoing and future clinical trials of larsucosterol do not confirm the results from 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 alcohol-associated hepatitis even if the results of the AHFIRM trial are successful, 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.

MANAGEMENT TEAM

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