NAFLD/NASH Drugs in Development

While there is currently no FDA-approved treatment for NASH, there are a multitude of drugs under development. This chart helps summarize a selection of these drugs and organizes them by mechanism, target, effect seen, and clinical phase. Drugs in Phase 1 can often take up to seven years before being approved for Phase 2, and from Phase 2 or 3 to FDA-approved can take another five to eight years.

Treatment Target	Working Name	Mechanism	Treatment Outcome	Clin. Trial Phase
Lipid metabolism, regulation of bile acid production, general inflammation	ARX618/BMS-986036	Fibroblast growth factor 21 agonist	Alters metabolism, reduces body weight, blood glucose, insulin and lipid levels, reversed hepatic steatosis, enhanced fatty acid activation and mitochondrial beta-oxidation in liver	2
	EDP-305	Farnesoid X receptor agonist	Regulates bile acid levels in liver and small intestine	2
	GS-9674		Regulates bile synthesis	2
	Tropifexor			2
	LMB763			2
	Obeticholic acid		Regulates bile synthesis, decreases hepatic gluconeogenesis and lipogenesis	3
	Gemcabene	Acetyl-CoA carboxylase and HGM-CoA synthase inhibitor	Prevents triacylglyceride and cholesterol synthesis	2
	IONIS-DGAT2Rx	Diacylglycerol acyltransferase 2 reduction	Prevents synthesis of triacylglyceride	2
	SGM-1019	P2X7 receptor inhibitor	Reduces inflammation	2
	Emricasan	Caspase inhibitor Galactins inhibitor	Inhibits apoptosis; prevents inflammation	2
	GR-MD-02			2
	IMM-124E	Anti-lipopolysaccharide immunoglobin	Reduces inflammation	2
	MSDC-0602K	Mitochondrial pyruvate carrier enhancer	Increases entry of pyruvate into mitochondria, enhancing metabolic respiration and glucose metabolism	2
	NC101	Mitochondrial metabolism enhancer	Allows body to consume glucose and fatty acids more quickly	2
	NGM282	FGF19 supplement	Regulates bile acid synthesis, glucose homeostasis, and triglyceride regulation	2
	Volixibat	Sodium-dependent bile acid transporter inhibitor	Removal of free cholesterol through reducing bile circulation	2
	VK2809	Thyroid hormone receptor beta-selective agonist	Increases activity of thyroid hormone; reduces amount of liver fat	2
	MGL-3196			2



Treatment Target	Working Name	Mechanism	Treatment Outcome	Trial Phase
Blood glucose	CER209	P2Y13 receptor agonist	Promotes HDL uptake; reduces cholesterol levels and decreases risk of atherosclerosis	1
	Evogliptin	DPP-4 inhibitor	Reduces level of glucagon	1
	PF-0688291	Glucagon-like peptide 1 receptor agonist	Enhances insulin secretion	1
	NS-0200	Similar to diabetes drug	Increased hepatic fatty acid oxidation and reduced lipogenic gene expression	2
	Semaglutide	GLP1R agonist	Enhances insulin secretion, reduces obesity	2
	Remogliflozin etabonate	Sodium glucose-dependent renal transporter 2 inhibitor	Inhibits reabsorption of glucose in kidneys; increases glucose released in urine	2
	Lanibiranor	PPAR agonist	Increased fat burning, fatty acid oxidation, increase HDL	2
	Lipaglyn			2
	Seladelpar	PPAR delta agonist	Increases fatty acid oxidation, HDL concentrations, reduces blood lipid levels	2
	Elafibranor	Dual agonist of PPAR alpha and delta	Increased fat burning, fatty acid oxidation, increased HDL	3
Lipid homeostasis, reduction of fatty acid synthesis	DUR928	Nuclear receptor	Reduces lipid accumulation	1
	PF-06835919	Diacylglycerol O-acyltransferase 2	Prevents first step of triacylglyceride synthesis	2
	PF-0686557		Inhibits enzymes that assist in fatty acid formation	1
	RYI-018	Cannabinoid-1 receptor inhibitor	Less fatty acid synthesis	1
	TVB-2630	Fatty acid synthase inhibitor	Reduces production of fatty acids in liver	2
	GS-0976	Acetyl-CoA carboxylase inhibitor	Prevents first step of liver lipogenesis	2
	MK-4074		Inhibits fatty acid synthesis, increases ketones, reduces liver triglycerides	1
	PF-05221304		Prevents liver lipogenesis	2
Fibrogen (connective tissue)	PXS-5328A	LOXL2 inhibitor	Prevents fibrogen formation within liver	1

Clin.



Treatment Target	Working Name	Mechanism	Treatment Outcome	Clin. Trial Phase
Insulin resistance, immunoresponse, fibrosis	OPRX-106	Anti-tumor necrosis factor	Reduces levels of AST, ALT, and liver triglycerides	1
	Aramchol	Stearoyl-CoA desaturase inhibition	Reduced adipose levels, increased energy expenditure, increased beta-oxidation levels	2
	DS-102	5-lipoxygenase inhibitor	Anti-fibrotic, anti-inflammatory, anti-apoptotic effects	2
	GRI-0621	Natural killer T-cell inhibitor	Prevents inflammation through immunoresponse modification	2
	BI-1467335	Mine oxidase, copper containing 3 inhibitor	Blocks leukocyte adhesion and infiltration	2
	MN-001	Leukotriene receptor antagonism, inhibition of phosphodiesterases and 5-lipoxygenase	Reduces liver fibrosis and inflammation	2
	Cenicrivoc	Macrophage accumulation inhibitor	Prevents recruitment of monocytes and macrophages to liver, reducing fibrosis	3
	Selonsertib	Apoptosis signal-regulating kinase 1 inhibitor	Prevents phosphorylation stress response pathway that worsens inflammation and fibrosis	3

