

## MASH Competitive Landscape – June 27, 2025

The table below includes an overview of the MASH competitive landscape. It includes all companies we are aware of with MASH candidates in phase 2b development and later, as well as many earlier stage companies. We acknowledge that the list may be incomplete, particularly in these earlier development stages.

- **Wins:** FDA [approves](#) first MASH therapy, Madrigal’s resmetirom under brand name Rezdiffra; positive phase 3 results of [NN’s semaglutide](#) for MASH, with US and EU [regulatory filing](#) completed in 1Q25; positive phase 2 results from [BI/Zealand](#), [Viking](#), [Ionis](#), [Akeru](#), and [89bio](#).
- **Losses:** Intercept’s obeticholic acid (OCA) received negative feedback from the FDA Advisory Committee Meeting in [May 2023](#), given the safety profile and the risk-benefit tradeoffs. In [June 2023](#), the FDA issued a Complete Response Letter to Intercept for OCA in MASH, indicating the NDA cannot be approved in its current state. In response, Intercept has decided to discontinue all investments related to MASH and focus on rare and serious liver disease.

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### Approved drugs with MASH indication

Sponsor	Drug Name	Class	Status	Other Remarks
Madrigal	Rezdiffra (resmetirom)	THR-β agonist	Received <a href="#">FDA approval</a>	Plans to expand reach to Europe in 2H25, pending EMA approval; Ongoing 54-month outcomes phase 3 <a href="#">MAESTRO-NASH</a> trial in F2/F3 fibrosis scheduled for completion in January 2028; Ongoing phase 3 <a href="#">MAESTRO-NASH-OUTCOMES</a> study in people with cirrhosis (stage F4 fibrosis) with expected completion in <a href="#">January 2027</a> ; initiated August 2022 and completed enrollment October 2024; <a href="#">MAESTRO-NAFLD-OLE</a> positive two-year study data on people with F4c announced <a href="#">4Q24</a> ; Received FDA approval in <a href="#">March 2024</a> ; Priority Review of NDA granted in <a href="#">September 2023</a> , with PDUFA date of March 14, 2024; NDA completed <a href="#">July 2023</a> ; Madrigal announces positive results from phase 3 MAESTRO-MASH trial in <a href="#">December 2022</a> ; Phase

				3 <a href="#">MAESTRO-MASLD</a> data shows “significant and clinically relevant reductions in liver fat; 52-week Phase 3 trial announced <a href="#">March 2019</a> . Phase 2 results announced <a href="#">May 2018</a> .”
Novo Nordisk	Semaglutide	GLP-agonist	Received FDA approval	<p>In August 2025, the FDA <a href="#">approved</a> Wegovy (semaglutide 2.4 mg) for MASH in adults with moderate to advanced liver fibrosis (stages F2 to F3 fibrosis).</p> <p>This approval was based on Part 1 of the phase 3 ESSENCE trial (n=1,200), in which Wegovy conferred a statistically significant and superior improvement in liver fibrosis, as well as resolution of steatohepatitis with no worsening of liver fibrosis compared to placebo.</p> <p>Part 1 of phase 3 trial met primary endpoint for MASH in November 2024; Phase 2 semaglutide trial in cirrhotic MASH failed to meet primary endpoint in June 2022; Phase 3 trial initiated in March 2021 and expected to complete in 2029; Fast Track designation granted by FDA in 3Q20; Positive phase 2b multiple dose trial completed in 1Q20.</p> <p>Novo Nordisk previously granted \$9.57 million to support phase 2 semaglutide trial (SAMARA); expected to complete in June 2025</p>

**Approved drugs seeking MASH indication (SGLT-2/GLP-1/PPAR)**

Sponsor	Drug Name	Class	Status	Other Remarks
Zydus	Saroglitazar 4 mg	TZD	P4	<a href="#">EVIDENCES-XI</a> 56-week trial, investigating saroglitazar in people with MASLD, was announced in <a href="#">June 2023</a> ; trial expects to enroll 1500 participants, establishing one of the largest prospective registry of patients with MASH in the world
BI/Zealand	Survodutide	GLP-1/ glucagon dual agonist	P3	Two global phase 3 trials initiated as of <a href="#">4Q24</a> : (i) <a href="#">LIVERAGE</a> evaluating survodutide in MASH with stage 2/3 fibrosis with expected completion in 2031; (ii) <a href="#">LIVERAGE-Cirrhosis</a> trial for compensated cirrhosis (stage 4) with expected completion 2029;

				Received Breakthrough Therapy Designation by FDA for MASH with stages 2 or 3 fibrosis in <a href="#">October 2024</a> ; Full phase 2b results presented at <a href="#">EASL 2024</a> and published in <a href="#">NEJM</a> ; Positive topline results announced in <a href="#">February 2024</a> ; Fast track designation received from the FDA in <a href="#">June 2021</a>
CymaBay Therapeutics	Seladelpar	PPAR $\delta$ agonist	<a href="#">P3</a>	Primary completion date November 2022; Clinical development for PBC resumed in <a href="#">July 2020</a> ; MASH on hold, with potential development in combination with partner.
Inventiva	Lanifibranor	PPAR agonist	<a href="#">P3</a>	Phase 3 <a href="#">NATiV3 trial</a> is underway and expected to complete in 2028; <a href="#">Phase 2</a> results published in the <a href="#">Journal of Hepatology</a> in <a href="#">January 2025</a> ; <a href="#">Phase 2</a> investigator-led trial announces positive results in <a href="#">June 2023</a> ; Breakthrough designation from FDA in <a href="#">October 2020</a> ; Positive phase 2 NATiVE trial results announced in <a href="#">June 2020</a>
Lilly	Tirzepatide	GIP/GLP-1 agonist	<a href="#">P3</a>	<a href="#">SYNERGY-NASH</a> full results presented at <a href="#">EASL 2024</a> ; Topline results in <a href="#">February 2024</a> ; <a href="#">SURPASS 3 substudy</a> shows significant improvements in liver fat in <a href="#">April 2022</a> ; <a href="#">Study</a> began Nov <a href="#">2019</a> , results expected 2H2023
Hanmi	HM151211	GLP-1/GIP/ glucagon triple agonist	<a href="#">P2</a>	FDA Fast Track Designation granted in <a href="#">July 2020</a> ; Positive phase 1 data in <a href="#">February 2020</a>
Inventiva	IVA337	Triple PPAR a/b/g agonist	<a href="#">P2b</a>	<a href="#">Phase 2b</a> positive results announced <a href="#">June 2020</a> ; safety and efficacy study completed March 2020

### Other candidates

Sponsor	Drug Name	Class	Status	Other Remarks
89Bio	pegozafermin	Long-acting glycopegylated FGF21 analog	<a href="#">P3</a>	Phase 3 trial initiated in <a href="#">March 2024</a> ; <a href="#">Post-hoc data</a> from phase 2b trial showed meaningful improvements in liver specific biomarkers of stiffness and fibrosis, inflammation, and other key non-invasive markers; FDA <a href="#">granted</a> Breakthrough Therapy Designation for pegozafermin in September 2023; Full phase 2 <a href="#">ENLIVEN trial</a> results in <a href="#">September 2023</a> find that treatment with pegozafermin at doses of 30

				<p>mg once weekly and 44 mg every 2 weeks for 24 weeks led to significant improvements, as compared with placebo, in fibrosis without worsening of MASH, published in <a href="#">NEJM</a>; topline results in <a href="#">March 2023</a> find that 44 mg every-two-weeks dosing conferred placebo-adjusted effect size of 20%, with full results published in <a href="#">NEJM</a> in <a href="#">June 2023</a>; phase 3 development expected to begin “pretty rapidly”; Enrollment for phase 2b ENLIVEN trial complete in <a href="#">August 2022</a>; Positive topline phase 1b/2a results shared in <a href="#">September 2020</a>. Positive preclinical data presented <a href="#">April 2019</a>.</p>
Akero Therapeutics	efruxifermin (EFX, formerly EXR, AKR-001)	FGF21 analog	<a href="#">P3</a>	<p>Ongoing phase 3 <a href="#">SYNCHRONY</a> clinical trial program consisting of (i) <a href="#">SYNCHRONY Histology</a>, evaluating EFX in biopsy-confirmed pre-cirrhotic MASH, with data expected in <a href="#">2027</a>; (ii) <a href="#">SYNCHRONY Real-world</a>, evaluating EFX safety and tolerability for non-invasively diagnosed MASH and MASLD; Enrollment completed in <a href="#">January 2025</a>, data expected in <a href="#">1H26</a>; (iii) <a href="#">SYNCHRONY Outcomes</a>, investigating EFX in compensated cirrhosis due to MASH. The study will assess clinical outcomes over 5 years, first patient enrolled in September 2024;</p> <p>Positive topline 96-week phase 2b results from <a href="#">SYMMETRY</a> study of EFX for compensated cirrhosis due to MASH announced in <a href="#">January 2025</a>; Positive results from phase 2b <a href="#">HARMONY</a> study of EFX in stage F2 and F3 fibrosis announced in <a href="#">March 2024</a>; See publication in <a href="#">The Lancet Gastroenterology and Hepatology</a> – see press release <a href="#">here</a>; results from the phase 2b expansion cohort released in <a href="#">June 2023</a>; 24-week HARMONY results announced in <a href="#">September 2022</a>; Phase 2b HARMONY study launched in <a href="#">February 2021</a> with expected completion in 2027; Additional positive phase 2a data presented at <a href="#">The Liver Meeting 2020</a>; Positive phase 2a histological results from <a href="#">BALANCED</a> in <a href="#">July 2020</a></p>
Cirius	MSDC-0602K	Mitochondrial pyruvate carrier modulator/insulin sensitizer	<a href="#">P3</a>	<p>Phase 3 trial announced May 2019 with unknown status as of <a href="#">July 2021</a>; Positive <a href="#">phase 2b EMMINENCE trial</a> announced <a href="#">Nov 2019</a>; Significant improvements in metabolic endpoints; Non-significant improvement in liver histopathology.</p>
Galmed Pharma	Aramchol	Oral SCD1 modulator	<a href="#">P3</a>	<p>Phase 3 trial recruitment suspended “due to Aramchol Meglumine being formulated” in</p>

				<a href="#">August 2022</a> ; Primary completion date delayed to December 2024; <a href="#">Phase 3 study</a> with primary completion date estimated June 2022. <a href="#">ARMOR phase 3 trial</a> announced <a href="#">Sep 2019</a> ; Phase 2b results announced <a href="#">June 2018</a> showing mixed results
Sagimet Biosciences	Denifanstat (TVB-2640)	Fatty acid synthase (FASN)	P3	Two phase 3 trials underway <a href="#">FASCINATE-3</a> in patients with MASH and F2/F3 and <a href="#">FASCINIT</a> for patients with MASLD and MASH; Positive 52-week <a href="#">phase 2b</a> results published on <a href="#">The Lancet Gastroenterology and Hepatology</a> in <a href="#">October 2024</a> , showing significant improvement in MASH and NAS (MASLD activity score) without worsening fibrosis.
Altimune	Pemvidutide	GLP-1/ glucagon dual agonist	<a href="#">P2b</a>	Phase 2b <a href="#">IMPACT</a> trial completed enrollment in <a href="#">September 2024</a> , topline results expected in 2Q25; pemvidutide received US FDA Fast Track designation for MASH in <a href="#">October 2023</a> ; IMPACT trial initiated in <a href="#">August 2023</a> ; Phase 1b topline results announced in <a href="#">December 2022</a>
Arrowhead	ARO-HSD	RNAi	P2	Phase 2a <a href="#">SKYLINE</a> trial and Phase 2b <a href="#">HORIZON</a> trial are currently recruiting; Preliminary <a href="#">phase ½</a> results published in <a href="#">December 2022</a> suggest ARO-HSD was well tolerated and led to improvements in MASH biomarkers. GSK partnered with Arrowhead in \$1 billion exclusive licensing agreement for ARO-HSD; Phase 1 study expected to complete in <a href="#">February 2022</a> , topline results presented at <a href="#">The Liver Meeting</a> in August 2021 establish proof-of-concept
AstraZeneca	AZD2693 (formerly IONIS-AZ6-2.5-LRx)	PNPLA3 inhibitor	<a href="#">P2</a>	Progressed to <a href="#">phase 2b</a> (FORTUNA) in <a href="#">July 2023</a> , expected completion September 2025 with data in 2026; Added to AZ pipeline in 2Q19; Acquired from Ionis in <a href="#">April 2018</a>
Axcella	AXA1125 and AXA1957	Endogenous metabolic modulators	<a href="#">P2b</a>	<a href="#">Phase 2b trial</a> with AZA1125 initiated in May 2021 with unknown status as of <a href="#">September 2022</a> ; Poster presented at <a href="#">ADA 2021</a> showing greater reductions from in metabolic and fibroinflammatory biomarkers relative to placebo; Study published in <a href="#">Aug 2021 study</a> results favors AXA1125 over AXA1957; Positive phase 2a data for AXA1125 presented at The <a href="#">Liver Meeting 2020</a> ;
Can-Fite	Namodenoson (CF102)	Adenosine A3 receptor agonist	<a href="#">P2b</a>	<a href="#">Phase 2b trial</a> initiated in December 2021, ongoing enrollment with estimated completion October 2025; Phase 2a trial results shared <a href="#">October 2021</a> ; <a href="#">Phase 2a trial</a> results published in 2020
Galectin Therapeutics	GR-MD-02	Belapectin (polysaccharide polymer that	<a href="#">P2b/3</a>	Enrollment for <a href="#">P2b/3</a> trial completed <a href="#">January 2023</a> ; trial began June 2020 with December 2023 completion date. Phase 2

		targets extracellular galectins)		trials in <a href="#">MASH cirrhosis</a> and <a href="#">advanced fibrosis</a> completed October 2017 and September 2016.
HighTide Therapeutics	Berberine Ursodeoxycholate (HTD1801)	Anti-inflammatories	<a href="#">P2b</a>	Ongoing Phase 2b <a href="#">CENTRICITY</a> study, now fully-enrolled, evaluates histologic benefit of HTD1801; Results expected 1H25; Post-hoc <a href="#">analysis</a> of <a href="#">phase 2a</a> results presented at EASL 2024 further characterizing efficacy of HTD1801; <a href="#">Positive topline results</a> from phase 2a study announced in May 2020
Lipocine	LPCN 1144	Oral prodrug of bioidentical testosterone	<a href="#">P2</a>	Fast track designation granted in <a href="#">November 2021</a> ; <a href="#">Positive results</a> announced following phase 2 trial completion in <a href="#">February 2022</a> ; Interim phase 2 results announced <a href="#">January 2019</a>
Merck/Hanmi	MK-6024 (efinopegdutide) (formerly JNJ-5111/HM12525A)	GLP-1/ glucagon dual agonist	<a href="#">P2b</a>	Ongoing <a href="#">Phase 2b</a> trial with expected completion in <a href="#">December 2025</a> ; FDA Fast Track designation received in <a href="#">June 2023</a> ; <a href="#">Phase 2a</a> results presented at <a href="#">EASD 2023</a> ; See outline of phase 2a trial design <a href="#">here</a> ; License agreement with Merck in <a href="#">August 2020</a> to commercialize in US and outside of Korea; Originally licensed to Janssen in <a href="#">November 2015</a> , but returned development rights in <a href="#">July 2019</a> following subpar phase 2 results in obesity ( <a href="#">with</a> and <a href="#">without</a> diabetes)
NGM Biopharma	NGM282 (Aldafermin)	FGF19 agonist	<a href="#">P2b</a>	Full phase 2b <a href="#">APLINE 4</a> results announced in <a href="#">November 2023</a> and published in <a href="#">Hepatology</a> showed dose dependent improvements in liver fibrosis and secondary endpoints correlated with liver fibrogenesis, inflammation, and injury. Topline phase 2b results announced in <a href="#">May 2023</a> ; Phase 2 ALPINE2/3 study did not meet primary endpoint and has been discontinued in MASH patients; Fibrosis effectiveness confirmed in <a href="#">Feb 2020</a> and <a href="#">Nov 2019</a> . Multiple dose 2b <a href="#">ALPINE</a> results expected 1H2021. Cirrhosis study commencing 2H20.
Pfizer	PF-06865571 (ervogastat)	DGAT2 inhibitor	<a href="#">P2</a>	Phase 2 trial initiated June 2020 with estimated completion January 2024; <a href="#">New phase 1 trial</a> launched May 2018, expected to complete February 2019; Prior <a href="#">phase 1 trial</a> completed July 2017; Other phase 1 studies <a href="#">completed</a> and ongoing in subjects <a href="#">with</a> and <a href="#">without</a> MASH
Poxel	PXL065	AMPK activator	<a href="#">P2b</a>	Trial completed in March 2023; Positive topline results for <a href="#">phase 2b study</a> reported in <a href="#">August 2022</a> ; Poxel receives patent protection through 2041 in <a href="#">June 2022</a> ; Phase 2 trial completed October 2021; Phase 2a STAMP-MASLD reported December 2020 with 2b in 2021 planned; raise of €17.7 million to advance of PXL 770 (and 065) in

				MASH announced in <a href="#">May 2020</a> .
Poxel	PXL770	AMPK activator	<a href="#">P2</a>	Phase 2a study in adrenoleukodystrophy withdrawn in <a href="#">December 2024</a> due to lack of funding; <a href="#">Phase 2 proof-of-concept</a> trial complete in November 2020; phase 1 results announced <a href="#">June 2016</a>
Shenzhen Chipscreen Biosciences	chiglitazar	peroxisome proliferator activation related receptor (PPAR)	<a href="#">P2</a>	Positive phase 2 results of CGZ203 study of chiglitazar monotherapy announced in <a href="#">March 2024</a>
Viking Therapeutics	VK2809	Liver-selective thyroid beta receptor agonist	<a href="#">P2b</a>	End-of-phase-2 FDA meeting completed as of <a href="#">4Q24</a> ; Full VOYAGE phase 2b results presented in <a href="#">November 2024</a> ; Positive histologic data announced in <a href="#">June 2024</a> ; Positive topline phase 2b results announced in <a href="#">May 2023</a> ; Enrollment completed in <a href="#">January 2023</a> ; <a href="#">VOYAGE</a> trial <a href="#">announced</a> Dec 2019; phase 2 results announced <a href="#">September 2018</a>
Devonian Health Group	Thykamine	Oral anti-inflammatory drug	Preclinical	Positive preclinical results in mice announced in <a href="#">February 2025</a>
Novo Nordisk / Cellarity	N/A	Small Molecule Therapy	N/A	The Novo Nordisk / Cellarity collaboration aims to investigate novel biological drivers and develop a small molecule therapy for MASH. Notably, this collaborations is one of the first two programs signed under the framework <a href="#">collaboration</a> between Novo Nordisk and <a href="#">Flagship Pioneering</a> – a Cambridge, MA-venture capital firm devoted to building new life sciences businesses.

### Combination Studies

Sponsor	Drug Name	Class	Status	Other Remarks
AstraZeneca	Zibotentan + dapagliflozin	Endothelin A receptor antagonist + SGLT-2 inhibitor	<a href="#">P2</a>	<a href="#">ZEAL</a> phase 2 trial estimated completion in August 2025, with data anticipated in 1H25
Inventiva	Lanifibranor + empagliflozin	PPAR agonist + SGLT2 inhibitor	<a href="#">P2</a>	Phase 2 <a href="#">LEGEND</a> study of lanifibranor and empagliflozin significantly reduced A1c levels and hepatic steatosis in <a href="#">March 2024</a>
Novo Nordisk	NNC0194-0499 + Semaglutide + cagrilintide	FGFR agonist + GLP1-RA + amylin analog	<a href="#">P2</a>	Ongoing 39-week phase 2 trial with expected completion in <a href="#">June 2025</a>
Novo Nordisk	NNC0194-0499 + Semaglutide	FGFR agonist + GLP1-RA	<a href="#">P2</a>	Phase 2 combination trial completed in March 2025
Novo Nordisk/ Gilead	Injectable Semaglutide + cilofexor +	GLP-1+ FXR agonist + ACC inhibitor	<a href="#">P2b</a>	<a href="#">Phase 2b trial</a> listed as completed on <a href="#">clinicaltrials.gov</a> in January 2025; Ongoing enrollment at 212 in sites <a href="#">February 2023</a> ; initiation

	fircostat			in <a href="#">March 2021</a> with estimated completion date <a href="#">March 2024</a> ; Mixed phase 2 results announced in <a href="#">November 2020</a> ; Partnership announced in <a href="#">April 2019</a>
Pfizer	ervogastat + clesacostat	DGAT2i+ACC inhibitor	<a href="#">P2b</a>	<a href="#">Phase 2b</a> trial expected to complete in 2024; Received fast track designation from the FDA in <a href="#">May 2022</a> ; <a href="#">Phase 2a</a> trial completed in April 2022

## Discontinued Studies

Sponsor	Drug Name	Class	Status	Other Remarks
AbbVie	Cenicriviroc (CVC)	CCR2/CCR5 inhibitor	<a href="#">P3</a>	Phase 3 trial <a href="#">terminated</a> due to lack of efficacy in February 2021; <a href="#">AURORA</a> trial in F2-F3 fibrosis, completion expected Oct 2021; Allergan acquired Tobira <a href="#">September 2016</a> ; AbbVie acquired Allergan May 2020
Genfit	Elafibranor (GFT505)	Dual PPAR alpha/delta agonist	<a href="#">P3</a>	Program terminated in <a href="#">2Q20</a> ; will continue in PBC; <a href="#">RESOLVE-IT</a> in F1-F3 fibrosis failed phase 3 interim analysis in <a href="#">May 2020</a>
Gilead	Selonsertib (GS-4997)	ASK-1 inhibitor	<a href="#">P3</a>	Removed from MASH pipeline in <a href="#">2Q20</a> ; Missed primary endpoint in <a href="#">STELLAR 4</a> announced <a href="#">1Q19</a> ; <a href="#">STELLAR 3</a> trial in F3 fibrosis missed endpoint June 2019
Intercept Pharma	Obeticholic acid	FXR agonist	NDA; <a href="#">P3</a>	FDA issues CRL in <a href="#">June 2023</a> , indicating the NDA cannot be approved in its current state; in response, Intercept decided to discontinue all investments related to MASH and focus on rare and serious liver diseases; FDA Advisory Committee meeting votes against Intercept's approval in <a href="#">May 2023</a> ; FDA accepts the NDA resubmission for the NDA in <a href="#">January 2023</a> ; Intercept resubmits NDA to FDA for OCA in MASH in <a href="#">December 2022</a> ; OCA <a href="#">fails to meet primary endpoint</a> in phase 3 REVERSE trial for compensated cirrhosis in <a href="#">September 2022</a> ; Intercept announces positive topline results of OCA in F2/F3 fibrosis in <a href="#">July 2022</a> ; Intercept <a href="#">continues</a> to work on response to CRL, including a new adjudication process of all liver biopsies by a panel of three independent pathologists; FDA issued CRL in <a href="#">June 2020</a> ; Company had October 2020 FDA meeting to clarify CRL; <a href="#">REGNERATE</a> and <a href="#">REVERSE</a> trials in F1-F3 fibrosis/cirrhosis expected to complete September 2025 and August 2021, respectively
Albireo	Elobixitat	Oral ileal bile acid transporter inhibitor	<a href="#">P2a</a>	Discontinued <a href="#">August 2020</a>

Allergan	AGN-242266	FXR agonist	<a href="#">P2</a>	Presumed discontinued as of February 2020; Acquired from <a href="#">Akarna Therapeutics</a> September 2016
Allergan	Evogliptin	DPP-4 inhibitor	<a href="#">P2</a>	Presumably discontinued following Abbvie's acquisition of Allergan in 2020; evogliptin no longer in pipeline; Acquired from Tobira Therapeutics September 2016; Phase 1 trial investigating evogliptin in combination with CVC <a href="#">initiated</a> September 2016
AstraZeneca	Mitiperstat	MPO inhibitor	P2	Phase 2 <a href="#">COSMOS trial</a> discontinued in <a href="#">4Q24</a>
AstraZeneca	cotadutide (MEDI0382)	GLP-1/glucagon dual agonist	<a href="#">P2b/3</a>	Discontinued in <a href="#">1Q23</a> ; Phase 2b/3 <a href="#">PROXYMO-ADV</a> study initiated in July 2022; Phase 2 trial completed in <a href="#">2Q21</a> ; Safety/PD trial initiated in <a href="#">3Q19</a> .
AstraZeneca/ Regulus Therapeutics	AZD4076/ RG-125	Anti-microRNA (anti-miR103/107 oligonucleotide)	<a href="#">P2</a>	AZ pulled out of partnership 2Q17; Phase 2 trial <a href="#">initiated</a> 3Q16; Phase 1 trial completed <a href="#">December 2016</a>
BMS	BMS-986036	Pegylated FGF21 analog	<a href="#">P2b</a>	Discontinued in <a href="#">November 2021</a> following disappointing results in phase 2b FALCON study; Two phase 2 studies in <a href="#">F4</a> (completion expected Oct 2021) and <a href="#">F3</a> (completion expected December 2021); Phase 2a data presented at <a href="#">EASL 2017</a>
Enanta Pharma	EDP-305	FXR Agonist	<a href="#">P2b</a>	Discontinued internal development of MASH candidates in <a href="#">October 2021</a> after interim analysis of phase 2b ARGON-2; <a href="#">Phase 2b</a> to complete in December 2022; Positive phase 2a results announced <a href="#">September 2019</a> ; Fast Track designation in <a href="#">January 2017</a>
Genentech	BFKB8488A	bispecific FGFR1/Klothoβ antibody	<a href="#">P2</a>	Phase 2 trial terminated <a href="#">March 2024</a> ; Trial completed March 2023; Completed recruiting for <a href="#">phase 1b</a> trial as of <a href="#">3Q19</a> ; Phase 1 study in MASH and type 2 diabetes recruiting, expected to complete <a href="#">June 2019</a>
Gilead	Simtuzumab	LOXL2 monoclonal antibody	<a href="#">P2</a>	Discontinued <a href="#">3Q16</a>
Ionis	ION224	DGAT2 antisense inhibitor	<a href="#">P2</a>	ION224 no longer listed on Ionis pipeline as of <a href="#">4Q24</a> ; Topline phase 2 results announced in <a href="#">March 2024</a> .
Merck (from NGM Bio)	MK-3655 (formerly NGM313)	KLB-FGFR1c receptor complex agonist	<a href="#">P2b</a>	Trial terminated in <a href="#">late 2022</a> ; <a href="#">Phase 2b</a> study began November 2020, est completion September 2023 ; Merck optioned from NGM Bio in <a href="#">January 2019</a> .
Novartis	LJN452 (tropifexor)	FXR agonist	<a href="#">P2/3</a>	Terminated in <a href="#">2021</a> ; Phase 2 <a href="#">FLIGHT-FXR</a> study completed April 2020
Novartis	LIK066	SGLT-1/	<a href="#">P2a</a>	Presumed discontinued 3Q21;

		SGLT-2 inhibitor		Completed <a href="#">Nov 2019</a> ;
Novartis/ AbbVie	Tropifexor + Cenicriviroc	FXR agonist + CCR2/5	<a href="#">P2b</a>	Removed from pipeline and presumably discontinued; Study completed 1Q21, results posted on clinicaltrials.gov but not yet published; <a href="#">Phase 2b study</a> expected completion September 2020
Novartis Pharmaceuticals	Tropifexor (LJN452) + Licogliflozin	FXR agonist + SGLT1/2 inhibitor	<a href="#">P2b</a>	Study listed as terminated on clinicaltrials.gov as of October 2023; Phase 2 <a href="#">ELIVATE</a> study expected to complete in 2023; <a href="#">Safety study</a> (LDL elevation) begun May 2020 and est end in <a href="#">March 2021</a> .
Pfizer	PF-06835919	Ketohexokinase (KHK) inhibitor	<a href="#">P2a</a>	<a href="#">Discontinued in 3Q21</a> ; <a href="#">Phase 2 study</a> with metformin in MASH/diabetes patients;
Pfizer	PF-05221304	ACC inhibitor	<a href="#">P2a</a>	Discontinued in October 2020; possible future combination product
Shire	SHP626	Apical sodium bile acid cotransporter inhibitor	<a href="#">P2</a>	<a href="#">Phase 1 trial</a> completed July 2015
Terns	TERN-501	THR-beta agonist	<a href="#">P2a</a>	Discontinuation announced at <a href="#">JPM 2024</a> ; Positive phase 2a results announced in <a href="#">August 2023</a> ; Recruitment complete in April 2023; phase 2a combination study with FXR agonist TERN-101 initiated <a href="#">July 2022</a>
GSK	GSK3008356	DGAT-1 inhibitor	<a href="#">P1</a>	No longer appears in GSK pipeline as of 1Q23; Added to GSK's <a href="#">pipeline</a> in <a href="#">1Q16</a>
Lilly	LY3885125	SCAP siRNA	P1	<a href="#">phase 1 trial</a> terminated March 2025
J&J	JNJ-0795	undisclosed	P1	Discontinued in <a href="#">1Q23</a> ; Announced in <a href="#">2Q22</a>
Novartis	RLX030	Relaxin receptor	Undisclosed	No further mention of RLX030 for MASH after initial discussion in <a href="#">4Q16</a> ;
Pfizer	PF-06667272	Myeloperoxidase Inhibitor	<a href="#">P1</a>	Discontinued <a href="#">4Q17</a>

### Early Phase Studies

Sponsor	Drug Name	Class	Status	Other Remarks
Arrowhead	ARO-ANG3	Angiopoietin-like protein 3 inhibitor	<a href="#">P2</a>	<a href="#">Phase 2 study</a> estimated completion in December 2024; Phase 1 study completed <a href="#">December 2019</a> ; potential treatment for dyslipidemia and other metabolic diseases, including MASH
Boston Pharmaceuticals	BOS-580	FGF21	<a href="#">P2a</a>	Positive phase 2a poster presented at <a href="#">EASL 2024</a> ; Positive phase 2a results announced in <a href="#">November 2023</a> supporting once-monthly dosing; Positive phase 2a results announced in <a href="#">June 2023</a>

Chemomab	CM-101	CCL24-neutralizing monoclonal antibody (MAb)	<a href="#">P2a</a>	Further phase 2 data shared in <a href="#">November 2023</a> demonstrated significant reductions in liver-related pathology pathways linked to liver damage and steatosis. Phase 2a topline results announced <a href="#">January 2023</a> – no information on future trials shared to date
D&D Pharmatech	DD01	GLP-1/glucagon dual agonist	<a href="#">P2</a>	Phase 2 initiated in <a href="#">August 2024</a> for overweight or obesity with MASLD or MASH; FDA Fast Track Designation granted in <a href="#">April 2024</a> ; approval based on positive <a href="#">phase 1</a> results
Hepagene	HPG1860	FXR agonist	<a href="#">P2a</a>	Positive results from <a href="#">phase 2a RISE trial</a> announced in <a href="#">January 2023</a>
Hepion	rencofilstat	cyclophilin inhibitor	<a href="#">P2a</a>	Phase 2a results from the <a href="#">AMBITION</a> study in participants with MASH-induced F2 and F3 published in <a href="#">October 2022</a> ; <a href="#">Phase 2a results</a> from the ALTITUDE-MASH trial (n=70) announced in <a href="#">May 2023</a>
NeuroBo Pharmaceuticals	DA-1241	GPCR 119 agonist	<a href="#">P2a</a>	Phase 2a enrollment completed in <a href="#">November 2024</a> ; Received safety review committee approval to continue phase 2a trial in <a href="#">March 2024</a> ; Finished dosing of the first patient in <a href="#">September 2023</a> ; interim analysis expected in 1H2024, and full data expected in 2H2024. Received first site IRB Approval for phase 2a trial in <a href="#">August 2023</a> ; In May 2023, NeuroBo <a href="#">announced</a> that the FDA has cleared the IND submission, with a phase 2 trial expected to begin in 3Q23; Announced FDA IND submission for phase 2 development in <a href="#">April 2023</a>
Oramed	ORMD-0801	Oral insulin	<a href="#">P2a</a>	Phase 2a topline results announced in <a href="#">November 2022</a> ; no information shared on future development
Terns	TERN-101	FXR agonist	<a href="#">P2a</a>	Topline results from phase 2a trial announced in <a href="#">June 2021</a> showing improvement in liver biomarkers; Closed an \$87 million Series C in <a href="#">January 2021</a> ; First patient dosed in phase 2a <a href="#">LIFT</a> trial in July 2020; Phase 1 results that confirm safety and efficacy announced <a href="#">February 2020</a> ; Fast Track designation in <a href="#">October 2019</a> ; Acquired from Lilly in <a href="#">April 2018</a>
Arrowhead	ARO-PNPLA3	PNPLA3 inhibitor	<a href="#">P1</a>	full rights returned to Arrowhead in <a href="#">February 2023</a> ; Acquired by J&J in <a href="#">2018</a>

AstraZeneca	AZD9950	Dual GLP-1/ glucaon RA	P1	<a href="#">CONTEMPO</a> phase 1 trial investigating safety in people with or without T2D, with estimated completion in April 2025, data anticipated 2H25.
Eccogene	ECC4703	THR-beta agnoist	<a href="#">P1</a>	Phase 1 positive data announced at AASLD in <a href="#">November 2024</a> ; Phase 1 trial investigating ECC4703 in healthy volunteers; expected completion is July 2023; announced a \$25 million Series B raise in <a href="#">June 2023</a>
J&J	JNJ-2463	CB1 inverse agonist	P1	Phase 1b study completed in <a href="#">September 2018</a> ; phase 1 study underway according to J&J's <a href="#">2017 Pharmaceutical Business Review</a> ; Collaboration with BirdRock Bio
Lilly	LY3849891	PNPLA3 siRNA	P1	<a href="#">phase 1</a> study in NAFLD initiated June 2022 with expected completion <a href="#">September 2026</a> ; Added to pipeline 2Q22
Lilly	LY3305677	GLP-1/glucagon dual agonist (oxyntomodulin analog)	P1	Phase 1 study results published <a href="#">June 2021</a> ; Phase 1 development for MASH in R&D update in <a href="#">May 2016</a> ; Advanced to phase 1 in <a href="#">4Q16</a>
Novartis	DVF890 (IFM-2427)	NLRP3 inhibitor	P1	Results from first in-human study on safety and tolerability published in <a href="#">March 2024</a> ; Acquired from <a href="#">IFM Tre</a> in April 2019
Novo Nordisk	NNC6022-0001	NLRP3 inhibitor	P1	First patient dosed in phase 1 trial <a href="#">May 2024</a> ; Trial initiated March 2024 to investigate indications across liver, kidney, and cardiometabolic disease; Novo Nordisk licensed candidate from Ventus Therapeutics <a href="#">September 2022</a>
Olix/Lilly	OLX75016	siRNA	P1	First <a href="#">phase 1</a> subject dosed in <a href="#">February 2024</a> ; Lilly and Olix enter global licensing agreement <a href="#">February 2025</a>
Pfizer	PF-07853578	Small molecule	P1	Added to phase 1 in <a href="#">1Q24</a> with an undisclosed mechanism of action
Lynkogen/ Alteogen	Undisclosed	Long-acting "GLP-1 fusion" combination therapies	Undisclosed	Partnership announced <a href="#">July 2018</a> with expansion announced <a href="#">December 2018</a>
Better Therapeutics	BT-001	Prescription cognitive behavioral therapy	<a href="#">n/a</a>	Topline results announced <a href="#">December 2022</a>
Hepagene	HPG7233	THR-beta agonist	N/A	FDA clearance of IND in <a href="#">September 2023</a> ; remarkable synergistic effect has been observed in combination groups, especially in combination

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