NASHNET Pharma Pipeline

Overview (March 2020)

Manufacturer	Drug Name	Target	Stage[1]	Likely Market Date[1]	Primary Endpoint(s)	Considerations[1]	Potential Overlap
Madrigal	Resmetirom	F2-F3[2]	Phase 3	Q2 2023	• NASH resolution and ≥ 2-point reduction in NASH Activity Score (NAS) without worsening of fibrosis[3] • Increase in time until cirrhosis, all-cause mortality, etc.[3]	• Eligible for Subpart H on intermediate results of Phase 3[4]	• Ocaliva
Intercept	Ocaliva	F2-F3[5]	Phase 3	Q2 2020	• Improvement of ≥ 1-stage of fibrosis without worsening of NASH[6] • Increase NASH resolution without worsening fibrosis[6] • Increase time until death, liver transplant, hospitalization, cirrhosis, etc.[6]	• FDA Breakthrough Therapy Status and Subpart H eligible[7]	• Elafibranor • Semaglutide • Resmetirom • Cenicriviroc
Genfit	Elafibranor	F1-F3[8]	Phase 3[8]	Q2 2021	• Increase in NASH resolution without worsening of fibrosis[8] • Increase in time until cirrhosis, all-cause mortality, etc.[8]	• FDA fast track status granted and eligible for Subpart H[9]	• Semaglutide • Ocaliva
Allergan	Cenicriviroc	F2-F3[10]	Phase 3[10]	Q1 2022	• Improvement of ≥ 1-stage of fibrosis without worsening of NASH[10] • Increase in time until cirrhosis, all-cause mortality, etc.[10]	• FDA Fast Track status and Subpart H eligible[11]	• Ocaliva • Selonsertib
Novo Nordisk	Semaglutide	F1-F3[12]	Phase 2b[12]	Q3 2023	• Increase NASH resolution without worsening of fibrosis[12]	• Taken in combination with Selonsertib	• Elafibranor • Ocaliva
Novartis	Tropifexor	F1-F3[13]	Phase 2b[13]	Q3 2023	• Decrease % fat in liver[13] • Change in Transaminase levels[13] • Increase safety (i.e. AEs, SAEs, etc.)[13]	• Collaborating with Allergan	• BMS-986036
Bristol Myers Squibb	BMS-986036	F1-F3[14]	Phase 2a[14]	Q2 2024	• Decrease in % fat in liver[15] • Increase safety (i.e. AEs, SAEs, etc.)[15] • Novel pegylated recombinant human fibroblast growth factor 21 analog[1]	• About to initiate phase 2b	• Tropifexor
Pfizer	PF-06835919	NAFLD[16]	Phase 2a	Q2 2024	• Decrease % fat in liver[16]	• About to initiate phase 2b	
Eli Lilly	Tirzepatide	F2-F3[17]	Phase 2b[17]	2025	• Increase NASH resolution without worsening of fibrosis on liver histology[18]	• Currently indicated for T2D[18] • Intended to reduce body weight and blood sugar for T2D[18]	

1) http://www.nashbiotechs.com/nash-biotech-analysis/biotechs-targeting-nash/detailledList.php **2)** https://www.globenewswire.com/fr/news-release/2019/12/18/1962086/0/en/Madrigal-Pharmaceuticals-Announces-First-Patient-Dosed-in-MAESTRO-NAFLD-1-a-Second-Phase-3-Multi-Center-Double-Blind-Randomized-Placebo-Controlled-Study-of-Resmetirom-MGL-3196-in-P.html **3)** https://clinicaltrials.gov/ct2/show/NCT03900429 **4)** https://www.madrigalpharma.com/ourapproach/mgl3196/ **5)** http://ir.interceptpharma.com/static-files/a9953fb2-f332-4ace-a6b1-567216609d65 **6)** https://clinicaltrials.gov/ct2/show/NCT02548351?cond=NASH&titles=regenerate&rank=1 **7)** https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/207999Orig1s000O-therR.pdf **8)** https://clinicaltrials.gov/ct2/show/NCT02704403?cond=NASH&titles=resolve-it&rank=1 **9)** https://www.biospace.com/article/genfit-positive-42-month-dsmb-recommendation-for-continuation-of-phase-3-resolve-it-study-of-elafibranor-in-nash/ **10)** https://clinicaltrials.gov/ct2/show/NCT03028740?term=Cenicriviroc&phase=2&rank=1 **11)** https://seekingalpha.com/article/4265101-allergan-and-cenicriviroc-in-nash-forgotten **12)** https://clinicaltrials.gov/ct2/show/NCT02970942 **13)** https://clinicaltrials.gov/ct2/show/NCT02855164 **14)** https://www.ncbi.nlm.nih.gov/pubmed/30554783?dopt=Abstract **15)** https://clinicaltrials.gov/ct2/show/NCT02413372?cond=NASH&intr=BMS-986036 **16)** https://clinicaltrials.gov/ct2/show/results/NCT03256526 **17)** https://clinicaltrials.gov/ct2/show/NCT04166773 **18)** https://seekingalpha.com/article/4270974-eli-lilly-looks-foray-of-developing-own-nash-drug

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