

# Understand the clinical landscape of a drug

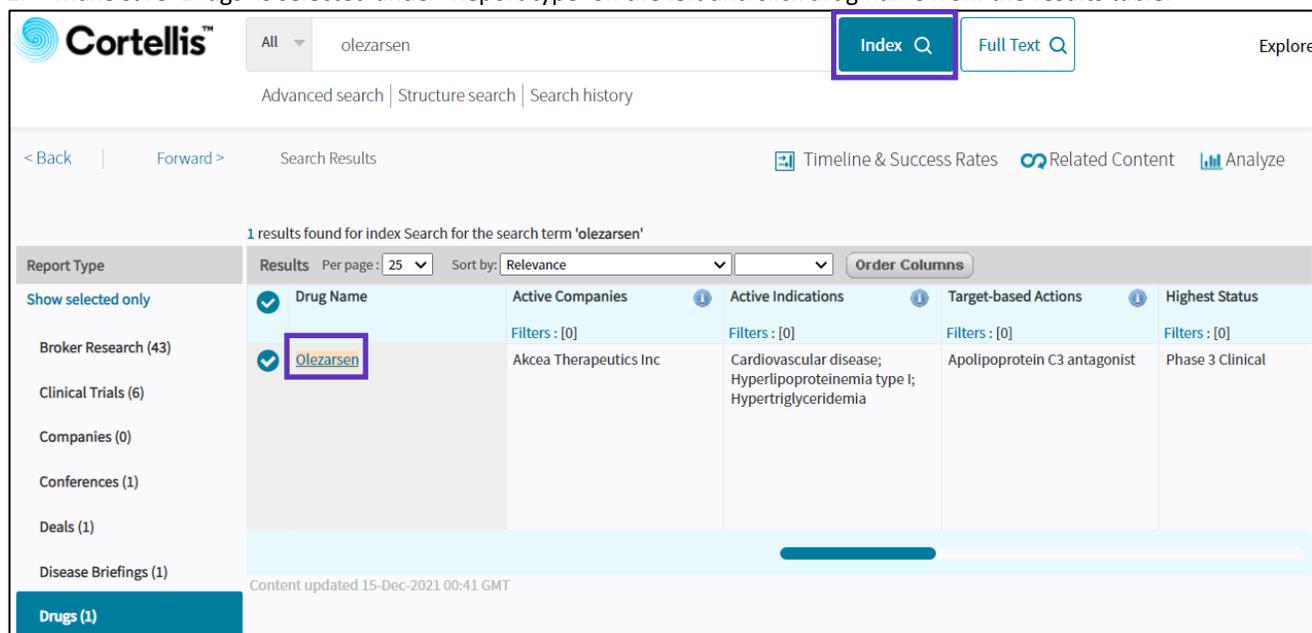
## Cortellis Competitive Intelligence

This guide explains how to find clinical information in drug reports in Cortellis.

Drug profiles are overviews written and manually curated by Cortellis editors summarizing the history of the drug. When a drug is in early stage, its profile focuses on conferences where the drug has been presented at and clinical trials starting soon. As the drug moves into clinical phases, more details can be found highlighting clinical trial results, efficacy, reported adverse events, trials starting for other indications as well as applications for approval.

**Example:** Understand the clinical landscape for Olezarsen.

1. Type the drug name at the top and click 'Index' search.
2. Make sure 'Drugs' is selected under 'Report type' on the left and click drug name from the results table.



The screenshot shows the Cortellis search interface. At the top, the search bar contains 'olezarsen' and the 'Index' button is highlighted with a red box. Below the search bar, there are navigation options like '< Back' and 'Forward >'. The main content area displays '1 results found for index Search for the search term 'olezarsen''. A table of results is shown with columns: Drug Name, Active Companies, Active Indications, Target-based Actions, and Highest Status. The 'Drugs' report type is selected on the left sidebar, and the 'olezarsen' entry in the 'Drug Name' column is highlighted with a red box.

Report Type	Results	Per page: 25	Sort by: Relevance	Order Columns
<input checked="" type="checkbox"/> Show selected only Broker Research (43) Clinical Trials (6) Companies (0) Conferences (1) Deals (1) Disease Briefings (1) <input checked="" type="checkbox"/> <b>Drugs (1)</b>	<input checked="" type="checkbox"/> Drug Name <input checked="" type="checkbox"/> <b>Olezarsen</b>	Active Companies Filters : [0] Akcea Therapeutics Inc	Active Indications Filters : [0] Cardiovascular disease; Hyperlipoproteinemia type I; Hypertriglyceridemia	Target-based Actions Filters : [0] Apolipoprotein C3 antagonist
		Highest Status Filters : [0] Phase 3 Clinical		

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3. Select 'Development Profile' tab from the menu on the left to read the history of the drug.

< Back | Forward > Drug Report Timeline & Success Rates Alert

Olezarsen

Paragraphs in drug profiles start with month/year followed by the update/news and source of the information at the end.

Snapshot	Highlight <input type="checkbox"/> Search Terms & Synonyms <span style="float: right;">&lt; Previous</span>
Latest Press Releases	DEVELOPMENT PROFILE
Latest Event Transcripts	New Content: <span style="border: 1px solid #ccc; padding: 2px;">Highlight Off</span> <span style="font-size: 1em;">⌵</span>
Broker Research Reports	Summary
<b>Development Profile</b>	<p><a href="#">Akcea</a>, a wholly-owned subsidiary of <a href="#">Ionis Pharmaceuticals</a> (formerly Isis Pharmaceuticals), is developing Olezarsen (AKCEA-APOCIII-LRx, ISIS-678354; IONIS-APOCIII-LRx; formerly ISIS-APOCIII-LRx), an inhibitor of apolipoprotein C-III (apo-CIII) production, using Ionis' advanced Ligand Conjugated Antisense (LICA) technology, for the potential treatment of hypertriglyceridemia (HTG) including familial chylomicronemia syndrome (FCS) [ <a href="#">1644153</a> ], [ <a href="#">1722606</a> ], [ <a href="#">1730651</a> ], [ <a href="#">1731462</a> ], [ <a href="#">1778325</a> ], [ <a href="#">1890876</a> ], [ <a href="#">1976596</a> ], [ <a href="#">1995370</a> ], [ <a href="#">2235522</a> ], [ <a href="#">2559559</a> ]. In December 2020, a phase III trial was initiated in patients with FCS [ <a href="#">2334320</a> ], [ <a href="#">2370288</a> ]; later that month, phase III data were expected in 2023 [ <a href="#">2375474</a> ]; this was still the case December 2021 [ <a href="#">2580196</a> ]. In November 2021, another phase III trial was expected to begin later that month for Familial Chylomicronemia Syndrome (FCS). At that time, the trial was expected to complete in March 2025 [ <a href="#">2572916</a> ]. In November 2021, a phase III trial (CORE) for severe hypertriglyceridemia (sHTG) was initiated [ <a href="#">2558791</a> ]; in December 2021, data from phase III trial in sHTG was expected in 2024 [ <a href="#">2580196</a> ]. In January 2020, the company expected to file a NDA for FCS from 2021 to 2025 [ <a href="#">2237211</a> ]; in November 2020, this was still the case and the company also expected to file a NDA for severe hypertriglyceridemia from 2021 to 2025 [ <a href="#">2357588</a> ]. In December 2020, the company expected to file a NDA for FCS in 2023 and for triglyceride-driven disease in 2024 [ <a href="#">2375474</a> ]. In December 2021, Ionis expected to have the products in the market for FCS and sHTG in early to mid 2020's [ <a href="#">2580196</a> ].</p> <p>In January 2017, <a href="#">Novartis</a> gained an exclusive and worldwide option to develop and prior to initiation of a phase III trial [ <a href="#">1890448</a> ]. However, in December 2019, <a href="#">Novartis</a> and <a href="#">Akcea</a> retained rights to the drug [ <a href="#">2230244</a> ].</p>
<ul style="list-style-type: none"> <li>■ Summary</li> <li>■ Patents &amp; Generics</li> <li>■ Regulatory</li> <li>■ Postmarketing</li> <li>■ Premarketing</li> </ul>	

Click blue links to see the source of information.

4. Click 'Premarketing' to read highlights from clinical trials.

<b>Premarketing</b>	Regulatory
■ Preclinical	In January 2020, the company expected to file a NDA for FCS from 2021 to 2025 [ <a href="#">2237211</a> ]. In November 2020, this was still the case and the company also expected to file a NDA for severe hypertriglyceridemia from 2021 to 2025 [ <a href="#">2357588</a> ]. In December 2020, the company expected to file a NDA for FCS in 2023 and for triglyceride-driven disease in 2024 [ <a href="#">2375474</a> ], [ <a href="#">2375474</a> ]. In December 2021, Ionis expected to have the products in the market for FCS and sHTG in early to mid 2020's [ <a href="#">2580196</a> ].
■ Additional Information	
Literature Review	Premarketing
Development Status	PHASE III
Regulatory Designations	In November 2021, a single group assignment, open-label phase III trial ( <a href="#">NCT05130450</a> ; ISIS 678354-CS13; 2021-003280-95 ) was expected to begin later that month to evaluate efficacy of AKCEA-APOCIII-LRx administered subcutaneously to patients (expected n = 60) with Familial Chylomicronemia Syndrome (FCS). The primary endpoint was percent change from baseline in fasting TG at 6 months (average of weeks 23, 25, and 27) compared to baseline. At that time, the trial was expected to complete in March 2025 [ <a href="#">2572916</a> ].
Milestones	
Chemical Structures	In December 2020, a phase III study in triglyceride-driven disease was expected to be initiated in the 2H 2021 [ <a href="#">2375474</a> ]; in January 2021, the company expected to initiate a second phase III study in a second cardiovascular indication in 2H 2021 [ <a href="#">2392153</a> ], [ <a href="#">2411615</a> ]; in June 2021, a phase III trial in severe hypertriglyceridemia (sHTG) was planned for 2H 2021; at that time, phase III data from that trial were expected in 2024 [ <a href="#">2467264</a> ]. In October 2021, a multicenter, randomized, double-blind, placebo-controlled, phase III study ( <a href="#">NCT05079919</a> ; ISIS 678354-CS5; 2021-002192-19) was planned to initiate in the US in November 2021, to evaluate the efficacy of ISIS-678354 in patients (expected n = 450) with severe hypertriglyceridemia. The primary endpoint was percentage change from baseline in fasting TG at 6 months compared to placebo. At that time, the trial was expected to complete in July 2024 [ <a href="#">2563808</a> ]. In November 2021, the registrational trial (CORE) was initiated [ <a href="#">2559559</a> ], [ <a href="#">2558791</a> ]. In December 2021, data from phase III trial in severe hypertriglyceridemia was expected in 2024 [ <a href="#">2580196</a> ].
Drug Names	
Sales and Forecasts	
Clinical Trials	In May 2020, a phase III study in patients with FCS was to begin 2020 [ <a href="#">2274540</a> ]. In August 2020, the trial was expected to begin later that year [ <a href="#">2312681</a> ]. In September 2020, an interventional, multi-center, double-blind, randomized, parallel-assigned, double-masked, placebo-controlled phase III trial ( <a href="#">NCT04568434</a> ; ISIS 678354-CS3; 2020-002536-67; BALANCE) was expected to begin in October 2020 to assess the efficacy of AKCEA-APOCIII-LRx as compared to placebo on the percent change in fasting triglycerides (TG) from baseline in patients (expected n = 60) with FCS. The primary endpoint measure was percent change from baseline in fasting TG at six months (average of weeks 23, 25, and 27) compared to placebo. At that time, the trial was expected to complete in December 2022 [ <a href="#">2334320</a> ]. In November 2020, the phase III study in patients with FCS was still expected to begin in 2020 [ <a href="#">2357588</a> ]. In December 2020, the trial was initiated [ <a href="#">2334320</a> ], [ <a href="#">2370288</a> ]. Later that month, phase III data were expected in 2023 [ <a href="#">2375474</a> ]; this was still the case in June 2021 [ <a href="#">2467264</a> ]. In December 2021, phase III data were still expected for 2023 [ <a href="#">2580196</a> ].
Deals and Patents	
SWOT Analysis	
Safety Intelligence	

Latest updates can be found at the top.

5. Go to 'Development Status' tab to identify companies involved in clinical trials, phases reached as well as indications and countries.

Olezarsen						
Snapshot	Highlight <input type="checkbox"/> Search Terms & Synonyms	< Previous	Next >	Filters are available to display specific indications, companies, phases of development and countries.		
Latest Press Releases	CURRENT DEVELOPMENT STATUS					
Latest Event Transcripts	Companies	Indication	Country/Territory	Status	Date	Source
Broker Research Reports	Akcea Therapeutics Inc	Hypertriglyceridemia	US	Phase 3 Clinical	02-Nov-2021	<a href="#">[2558791]</a>
Development Profile	Akcea Therapeutics Inc	Hyperlipoproteinemia type I	US	Phase 3 Clinical	01-Dec-2020	<a href="#">[2334320]</a>
Literature Review	Akcea Therapeutics Inc	Hyperlipoproteinemia type I	Canada	Phase 3 Clinical	01-Dec-2020	<a href="#">[2334320]</a>
<b>Development Status</b>	Akcea Therapeutics Inc	Hypertriglyceridemia	Canada	Phase 2 Clinical	05-Jan-2018	<a href="#">[1995320]</a>
<ul style="list-style-type: none"> <li>Current</li> <li>Historical</li> </ul>	Akcea Therapeutics Inc	Cardiovascular disease	US	Phase 2 Clinical	05-Jan-2018	<a href="#">[1995320]</a>
Regulatory Designations	Akcea Therapeutics Inc	Cardiovascular disease	Canada	Phase 2 Clinical	05-Jan-2018	<a href="#">[1995320]</a>
Milestones	Akcea Therapeutics Inc	Cardiovascular disease	Canada	Phase 2 Clinical	05-Jan-2018	<a href="#">[1995320]</a>
Chemical Structures	Ionis Pharmaceuticals Inc	Hypertriglyceridemia	US	Outlicensed	06-Jan-2015	<a href="#">[1624262]</a>

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