Current Agreements

## Dealdoc

# Collaboration and licensing agreement for EPA-based drug products and indications

Amarin
Mochida Pharmaceutical

Jun 12 2018

# Collaboration and licensing agreement for EPA-based drug products and indications

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| **Companies:** | Amarin<br>Mochida Pharmaceutical |
| **Announcement date:** | Jun 12 2018 |
| **Deal value, US$m:** | n/d |


- Details
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- Termsheet
- Press Release
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- Contract


## Details

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|---|---|
| **Announcement date:** | Jun 12 2018 |
| **Industry sectors:** | Pharmaceutical |
| **Compound name:** | EPA (eicosapentaenoic acid) |
| **Exclusivity:** | Exclusive<br>Compound |
| **Asset type:** | Intellectual property<br>Technology |
| **Therapy areas:** | Cardiovascular |
| **Technology types:** | Small molecules<br>Collaborative R&D |
| **Deal components:** | Development<br>Licensing |
| **Stages of development:** | Formulation |
| **Geographic focus:** | North America » United States |

## Financials

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|---|---|
| **Deal value, US$m:** | n/d |

## Termsheet

Amarin has entered into a multi-faceted collaboration with Mochida Pharmaceutical.

The collaboration is focused on the development and commercialization of early-stage drug products and indications based on the omega-3 acid, EPA (eicosapentaenoic acid).

Amarin and Mochida are recognized worldwide as the leading, innovation-driven companies committed to the research and development of EPA-based drug products to treat the needs of tens of millions of patients who are at-risk of cardiovascular disease.

Amarin obtained an exclusive license to certain Mochida intellectual property to advance Amarin’s interests in the United States and certain other territories and the parties will collaborate to research and develop new products and indications based on EPA for Amarin’s commercialization in the United States and certain other territories.

The potential new product and indication opportunities contemplated under this agreement are in relatively early stages of development.

## Press Release

Amarin and Mochida Announce Collaboration on Future Development of EPA-based Drug Products and Indications

BEDMINSTER, N.J. and DUBLIN, Ireland, June 12, 2018 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, announced today that it has entered into a multi-faceted collaboration with Mochida Pharmaceutical Co., Ltd. (“Mochida”, TYO:4534), an integrated Japanese pharmaceutical company. The collaboration is focused on the development and commercialization of early-stage drug products and indications based on the omega-3 acid, EPA (eicosapentaenoic acid). Amarin and Mochida are recognized worldwide as the leading, innovation-driven companies committed to the research and development of EPA-based drug products to treat the needs of tens of millions of patients who are at-risk of cardiovascular disease.

Amarin developed and markets Vascepa® (icosapent ethyl) capsules in the United States, the first and only FDA-approved, prescription pure EPA drug product. Vascepa is indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. Amarin's clinical development program for Vascepa includes the REDUCE-IT cardiovascular outcomes study, an 8,175-patient study commenced in 2011.1 REDUCE-IT is the first multinational cardiovascular outcomes study evaluating the effect of prescription pure EPA therapy, or any triglyceride lowering therapy, as an add-on to statins in patients with high cardiovascular risk who, despite stable statin therapy, have elevated triglyceride levels (150-499 mg/dL). Amarin expects to announce top-line results of this landmark study before the end of Q3 2018.

Mochida is an integrated Japanese pharmaceutical company that developed and markets a prescription pure EPA drug product, Epadel, as a treatment for hyperlipidemia and arteriosclerosis obliterans in Japan. Mochida sponsored and successfully completed a cardiovascular outcomes trial with Epadel in Japan, JELIS. JELIS was the world’s first large-scale randomized controlled cardiovascular outcomes trial of a prescription pure EPA drug product and showed beneficial effects of the drug in further reducing cardiovascular events in statin-treated, hypercholesterolemic Japanese patients.2, 3, 4

“We are excited to enter into a collaboration with Mochida given our common mission to create preventative healthcare solutions on a worldwide basis, and our mutual commitment to continued innovation in the EPA research and development area,” stated John F. Thero, president and chief executive officer of Amarin. “This collaboration seeks to leverage the decades of successful research and development experience at Amarin and Mochida towards expediting the development of new products and indications.”

“Mochida is delighted to partner with Amarin,” stated Mr. Naoyuki Mochida, president of Mochida. “Both Mochida and Amarin have demonstrated strong capabilities in developing and commercializing EPA-based products and we believe that together we can achieve much more to improve patient care in the years to come.”

Among other terms in the agreement, Amarin obtained an exclusive license to certain Mochida intellectual property to advance Amarin’s interests in the United States and certain other territories and the parties will collaborate to research and develop new products and indications based on EPA for Amarin’s commercialization in the United States and certain other territories. The potential new product and indication opportunities contemplated under this agreement are in relatively early stages of development.

About Amarin

Amarin Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in lipid science and the potential therapeutic benefits of polyunsaturated fatty acids. Vascepa® (icosapent ethyl), Amarin's first FDA-approved product, is a highly-pure, omega-3 fatty acid product available by prescription. For more information about Vascepa visit www.vascepa.com. For more information about Amarin visit www.amarincorp.com.

About Mochida

Mochida Pharmaceutical Co. Ltd. has been committed to research and development of innovative pharmaceutical products since its establishment thereby providing distinctive medicines to the medical field. Currently, the core pharmaceutical business focuses resources on the targeted areas of cardiovascular medicine, obstetrics and gynecology, dermatology, psychiatry and gastroenterology while also providing medicine for intractable disease as well as generics including biosimilars, to meet medical needs.

Mochida markets the world's first high-purity EPA drug, Epadel, developed and launched by Mochida as an ethical drug. Epadel has been the leading drug in its class in Japan over the past two decades with indications of hyperlipidemia and arteriosclerosis obliterans. Epadel has been broadly studied in Japan including the JELIS study which was successfully conducted to investigate the long-term administration of Epadel in statin-treated patients with hypercholesterolemia and the results are described as evidence-based medicine information on treatment with EPA pharmaceutical products in various clinical guidelines.

For more information about Mochida Pharmaceutical Co., Ltd., visit http://www.mochida.co.jp/english/

About REDUCE-IT

Amarin's clinical development program for Vascepa includes a trial known as the REDUCE-IT cardiovascular outcomes study, an 8,175-patient study commenced in 2011. REDUCE-IT is the first multinational cardiovascular outcomes study evaluating the effect of prescription pure EPA therapy, or any triglyceride lowering therapy, as an add-on to statins in patients with high cardiovascular risk who, despite stable statin therapy, have elevated triglyceride levels (150-499 mg/dL). A large portion of the male and female patients enrolled in this outcomes study are anticipated

to also be diagnosed with type 2 diabetes. As reported previously, Amarin expects to announce top-line results of this important study before the end of Q3 2018. The REDUCE-IT trial is being conducted under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration.

Additional information on clinical studies of Vascepa can be found at www.clinicaltrials.gov.

About VASCEPA® (icosapent ethyl) Capsules

Vascepa® (icosapent ethyl) capsules are a single-molecule prescription product consisting of the omega-3 acid commonly known as EPA in ethyl-ester form. Vascepa is not fish oil, but is derived from fish through a stringent and complex FDA-regulated manufacturing process designed to effectively eliminate impurities and isolate and protect the single molecule active ingredient. Vascepa, known in scientific literature as AMR101, has been designated a new chemical entity by the FDA. Amarin has been issued multiple patents internationally based on the unique clinical profile of Vascepa, including the drug's ability to lower triglyceride levels in relevant patient populations without raising LDL-cholesterol levels.

FDA-Approved Indication and Usage

Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. The effect of Vascepa on the risk for pancreatitis and cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined. Important Safety Information for Vascepa

Vascepa is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components. Use with caution in patients with known hypersensitivity to fish and/or shellfish. The most common reported adverse reaction (incidence > 2% and greater than placebo) was arthralgia (2.3% for Vascepa, 1.0% for placebo). There was no reported adverse reaction > 3% and greater than placebo. Patients receiving treatment with Vascepa and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically. In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy. Patients should be advised to swallow Vascepa capsules whole; not to break open, crush, dissolve, or chew Vascepa. Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088. FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

Vascepa has been approved for use by the United States Food and Drug Administration (FDA) as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. Nothing in this press release should be construed as promoting the use of Vascepa in any indication that has not been approved by the FDA. In particular, JELIS study results, while supportive of the potential for cardiovascular risk benefit in the statin-treated patients studied, are not to be directly extrapolated to apply to statin-treated patients in the United States due to various elements in the JELIS study design and various differences in the patient populations.

About Cardiovascular Disease

Worldwide, cardiovascular disease (CVD) remains the #1 killer of men and women. In the United States CVD leads to one in every three deaths – one death approximately every 38 seconds – with annual treatment cost in excess of $500 billion.5, 6

Beyond the cardiovascular risk associated with LDL-C, genetic, epidemiologic, clinical and real-world data suggest that patients with elevated triglycerides (TG) (fats in the blood), and TG-rich lipoproteins, are at increased risk for cardiovascular disease. 7, 8, 9, 10

Leading clinical investigations seeking to address cardiovascular risk reduction beyond lowering LDL-C focus on interrupting the atherosclerotic process (e.g., plaque formation and instability) by beneficially affecting other lipid, lipoprotein and inflammation biomarkers and cellular functions thought to be related to atherosclerosis and cardiovascular events.

## Filing Data

*Not available.*

## Contract

*Not available.*