No. 24-889

In the Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC. AND
HIKMA PHARMACEUTICALS PLC, PETITIONERS

v.

AMARIN PHARMA, INC., ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

JOINT APPENDIX

VOLUME 1 of 2

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Petition for Certiorari Filed February 14, 2025
Certiorari Granted January 16, 2026

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Exhibit A

hikma.

Press Release

Hikma receives FDA approval for its generic Vascepa®

London, May 22, 2020 – Hikma Pharmaceuticals PLC (Hikma), the multinational generic pharmaceutical company, today announces that its wholly owned U.S. subsidiary Hikma Pharmaceuticals USA Inc. has received approval from the US Food and Drug Administration (FDA) for its Icosapent Ethyl Capsules, 1 gm, the generic equivalent to Vascepa®[1].

In March 2020, the United States District Court for the District of Nevada invalidated six key Vascepa® patents owned by Amarin. The District Court decision is currently being appealed.

Brian Hoffmann, President of Generics said, "The approval for our generic version of Vascepa® is an important milestone towards bringing this product to market. This approval demonstrates the strength of our regulatory capabilities and our commitment to provide patients and healthcare providers in the US with the high-quality medicines they need."

- ENDS -

Enquiries

Hikma Pharmaceuticals PLC

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[1] Vascepa® is a registered trademark of Amarin Pharmaceuticals Ireland Limited.

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About Hikma

(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1/stable Moody's and BB+/positive S&P)

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non- branded generic medicines. Together, our 8,600 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

Exhibit G

NDA 202057/S-035

SUPPLEMENT APPROVAL

Amarin Pharma Inc.
US Agent for Amarin Pharmaceuticals Ireland Limited
Attention: Alex Giaquinto, Ph.D.
Senior Director, Regulatory Affairs
440 Route 22, Suite 300
Bridgewater, NJ 08807

Dear Dr. Giaquinto:

Please refer to your supplemental new drug application (sNDA) dated and received March 28, 2019, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Vascepa (Icosapent ethyl) capsules.

We acknowledge receipt of your major amendment dated September 5, 2019, which extended the goal date by three months.

This "Prior Approval" supplemental new drug application provides for the addition of a new indication to the US labeling for Vascepa based on the results of the clinical study AMR01-01-0019, the Reduction of Cardiovascular Events with EPA – Intervention Trial (REDUCE-IT): as an adjunct to maximally tolerated

statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and

- established cardiovascular disease or
- diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Patient Package Insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE)

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in

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[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter

requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the Prescribing Information to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA

[3] When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5] For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see FDA.gov.[6]

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

NDA 202057/S-035
Page 4

If you have any questions, call Martin White, M.S., Regulatory Project Manager, at (240) 402-6018.

Sincerely,

{See appended electronic signature page}

John Sharretts, M.D.
Deputy Director (Acting)
Division of Metabolism and
Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling

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[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf

[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

[6] http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm

- Prescribing Information
- Patient Package Insert

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOHN M SHARRETTS
12/13/2019 03:22:54 PM

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

Reference ID: 4533779w

Case 1:20-cv-01630-RGA-JLH Document 17-9
Filed 01/25/21 Page 1 of 5 PageID #: 542

Exhibit H

Amarin Corporation

REDUCE-IT™ Cardiovascular Outcomes Study of Vascepa® (icosapent ethyl) Capsules Met Primary Endpoint

September 24, 2018

REDUCE-IT Is First Outcomes Study to Assess Treatment of Patients with LDL-C Controlled by Statin Therapy, Persistent Elevated Triglycerides and Other Cardiovascular Risk Factors

Results Specific to Pure EPA Vascepa at 4 Grams Daily

Conference Call Scheduled for Today, Monday, September 24, 2018 at 8:00 am ET

BEDMINSTER, N.J. and DUBLIN, Ireland, Sept. 24, 2018 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), announced today topline results from the Vascepa® cardiovascular (CV) outcomes trial, REDUCE-IT™, a global study of 8,179 statin-treated adults with elevated CV risk. REDUCE-IT met its primary endpoint demonstrating an approximately 25% relative risk reduction, to a high degree of statistical significance ($p<0.001$), in major adverse CV events (MACE) in the intent-to-treat patient population with use of Vascepa 4 grams/day as compared to placebo.

Patients enrolled in REDUCE-IT had LDL-C between 41-100 mg/dL (median baseline LDL-C 75 mg/dL) controlled by statin therapy and various cardiovascular risk factors including persistent elevated triglycerides (TGs) between 150-499 mg/dL (median baseline 216 mg/dL) and either established cardiovascular disease (secondary prevention cohort) or diabetes mellitus and at least one other CV risk factor (primary prevention cohort).

Key topline results include:

- Efficacy: Approximately 25% relative risk reduction, demonstrated to a high degree of statistical significance ($p<0.001$), in the primary endpoint composite of the first occurrence of MACE, including cardiovascular death, nonfatal myocardial infarction (MI), nonfatal stroke, coronary revascularization, or unstable angina requiring hospitalization. This result was supported by robust demonstrations of efficacy across multiple secondary endpoints.
- Safety: Vascepa was well tolerated with a safety profile consistent with clinical experience associated with omega-3 fatty acids and current FDA-approved labeling. The proportions of patients experiencing adverse events and serious adverse events in REDUCE-IT were similar between the active and placebo treatment groups. Median follow-up time in REDUCE-IT was 4.9 years.

Amarin is eager to share REDUCE-IT data in greater detail with both the medical community and regulatory authorities. REDUCE-IT results have been accepted for presentation at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018 in Chicago, Illinois. The presentation,

classified as late breaking clinical trial results, is scheduled to commence at 2:16 pm Central Time and listed as Main Event 1 for the time frame. This acceptance as a presentation of late-breaking clinical trial results was granted based on the ability of REDUCE-IT to address a critical question in cardiovascular prevention.

"I look forward to the publication of these detailed REDUCE-IT results in a major peer-reviewed journal and to presenting them at the AHA in November," stated Deepak L. Bhatt, MD, MPH, Professor of Medicine at Harvard Medical School, Executive Director of Interventional Cardiovascular Programs in the Heart and Vascular Center at Brigham and Women's Hospital, and the Principal Investigator and Steering Committee Chair for REDUCE-IT.

"Amarin expresses its great appreciation for all the people that brought REDUCE-IT to completion, especially the patients and investigators and their colleagues at clinical sites that participated in this study for many years," stated Steven Ketchum, PhD, president of research and development and chief scientific officer of Amarin. "Amarin is also grateful to the U.S. Food and Drug Administration (FDA) for its continued encouragement and support toward study design and completion. REDUCE-IT was conducted under a special protocol assessment agreement with FDA that was re-affirmed in 2016."

"We are delighted with these topline study results," said John F. Thero, president and CEO of Amarin. "Given Vascepa is affordably priced, orally administered and has a favorable safety profile, REDUCE-IT results could lead to a new paradigm in treatment to further reduce the significant cardiovascular risk that

remains in millions of patients with LDL-C controlled by statin therapy, as studied in REDUCE-IT."

"Considered against the backdrop of multiple unsuccessful cardiovascular outcomes studies of earlier generation drug therapies, including multiple recent failed cardiovascular studies of omega-3 mixture products that contain the omega-3 acid DHA, REDUCE-IT topline results stand alone as positive and confirm our hypothesis that pure EPA Vascepa at 4 grams/day can provide additional cardiovascular risk reduction benefit on top of LDL-C control with standard of care statin therapy in studied patients," added Craig Granowitz, MD, PhD, senior vice president and chief medical officer of Amarin. "REDUCE-IT results cannot be generalized to fenofibrate, fish oil or omega-3 mixture products that contain DHA. The most relevant comparator study to REDUCE-IT is the Japan EPA lipid intervention study (JELIS), the 18,645 patient, open label, blinded endpoint outcomes study of EPA added to low-dose statin therapy, which showed cardiovascular event reduction in Japanese hypercholesterolemic patients of 19% in the overall population and 53% in a subgroup of patients with elevated TG levels and low HDL-C." [1, 2, 3]

Commercial Expansion and Next Steps

As previously described, given the successful topline results of REDUCE-IT, Amarin is in the process of increasing the number of company sales representatives promoting Vascepa to over 400 people in the United States. This will provide a greater concentration of coverage in current sales territories and provide new coverage where Amarin currently does not have sales representatives.

In addition to sales force expansion in the United States, Amarin plans to work with its international partners to support regulatory efforts outside the United States based on REDUCE-IT results. As previously described in the months leading up to REDUCE-IT results, Amarin increased its Vascepa inventory levels in preparation for positive results.

Overall managed care insurance coverage for Vascepa has been broad. Amarin looks forward to working with insurance carriers to increase understanding of REDUCE-IT results and the potential benefits Vascepa could bring to many millions of patients.

REDUCE-IT Study Background

The REDUCE-IT cardiovascular outcomes study commenced in 2011, enrolled and followed 8,179 randomized patients, and was conducted based on a special protocol assessment agreement with FDA.

REDUCE-IT is the first global cardiovascular outcomes study to prospectively evaluate the effect of Vascepa, or any therapy, in adult patients with LDL-C controlled to between 41-100 mg/dL (median baseline 75 mg/dL) by statin therapy and various cardiovascular risk factors including persistent elevated TGs between 150-499 mg/dL (median baseline 216 mg/dL) and either established cardiovascular disease (secondary prevention cohort) or diabetes mellitus and at least one other CV risk factor (primary prevention cohort). The design of the REDUCE-IT cardiovascular outcomes study was published in March 2017 in *Clinical Cardiology*[4] and can be found in the R&D section on the company's website at www.amarincorp.com.

The REDUCE-IT hypothesis tested whether additional cardiovascular risk reduction beyond LDL-C controlled with statin therapy could be achieved in

high risk patients with the putative cardioprotective effects of Vascepa 4 grams/day. Independent of REDUCE-IT, Amarin has worked to further support the REDUCE-IT hypothesis with published scientific findings based on various degrees of evidence that show EPA may interrupt the atherosclerotic process (e.g., plaque formation and instability) by beneficially affecting cellular functions thought to contribute to atherosclerosis and cardiovascular events and by beneficially affecting lipid, lipoprotein and inflammation biomarkers.[5, 6, 7, 8, 9]

Financial Disclosure

Funding from Amarin was provided to Brigham and Women's Hospital for Dr. Deepak L. Bhatt's work as the REDUCE-IT study chair and international principal investigator.

Conference Call and Webcast Information

Amarin will host a conference call at 8:00 a.m. ET, September 24, 2018 to discuss this information. The call will be accessible through the investor relations section of the company's website at www.amarincorp.com. The call can also be heard via telephone by dialing 877-407-8033. A replay of the call will be made available for a period of two weeks following the conference call. To hear a replay of the call, dial 877-481-4010 (inside the United States) or 919-882-2331 (outside the United States). A replay of the call will also be available through the company's website shortly after the call. For both dial-in numbers please use conference ID 37638.

About Amarin

Amarin Corporation plc. is a rapidly growing, innovative pharmaceutical company focused on developing

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) is Amarin's first FDA-approved drug and is available by prescription in the United States, Lebanon and the United Arab Emirates. Amarin's commercial partners are pursuing additional regulatory approvals for Vascepa in Canada, China and the Middle East. For more information about Amarin, visit www.amarincorp.com.

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.[10, 11]

Multiple primary and secondary prevention trials have shown a significant reduction of 25% to 35% in the risk of cardiovascular events with statin therapy, leaving significant persistent residual risk despite the achievement of target LDL-C levels.[5]

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. [12, 13, 14, 15]

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.

Indication and Usage Based on Current FDA-Approved Label (not including REDUCE-IT results)

- 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 Based on Current FDA-Approved Label (not including REDUCE-IT results) (Includes Data from Two 12-Week Studies (n=622) (MARINE and ANCHOR) of Patients with Triglycerides Values of 200 to 2000 mg/dL)

- Vascepa is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy. 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.

- Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.
- Patients receiving treatment with Vascepa and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- Patients should be advised to swallow Vascepa capsules whole; not to break open, crush, dissolve, or chew Vascepa.

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.

Important Cautionary Information About Topline Results

Existing and prospective investors are cautioned not to place undue reliance on topline results. As with any topline cardiovascular outcomes study result, further REDUCE-IT data assessment and data release will yield additional useful information to inform greater understanding of the study outcome. Aspects that could change and impact the final evaluation of the totality of the efficacy/safety data from REDUCE-IT may include: the magnitude of the treatment benefit on the primary composite endpoint, its components, secondary endpoints and the primary and secondary risk prevention cohorts; consideration of which components of

the composite or secondary endpoints have the most clinical significance; the consistency of the primary and secondary endpoints; the consistency of findings across cohorts and subgroups; tolerability and safety considerations and risk/benefit considerations; consideration of REDUCE-IT results in the context of other clinical studies; and study conduct and data quality, integrity and consistency.

Forward-Looking Statements

This press release contains forward-looking statements, including expectations regarding planned publication, scientific presentation, regulatory review and related timing thereof; expectations that REDUCE-IT results could lead to a new treatment paradigm in the patient population studied; plans for sales force, international and insurance coverage expansion. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In addition, Amarin's ability to effectively commercialize Vascepa will depend in part on its ability to continue to effectively finance its business, efforts of third parties, its ability to create market demand for Vascepa through education, marketing and sales activities, to achieve market acceptance of Vascepa, to receive adequate levels of reimbursement from third-party payers, to develop and maintain a consistent source of commercial supply at a competitive price, to comply with legal and regulatory requirements in connection with the sale and promotion of Vascepa and to maintain patent protection for Vascepa. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that sales may not meet

expectations and related cost may increase beyond expectations; the risk that patents may not be upheld in patent litigation and applications may not result in issued patents sufficient to protect the Vascepa franchise. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent quarterly report on Form 10-Q. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

Availability of Other Information About Amarin

Investors and others should note that Amarin communicates with its investors and the public using the company website http://www.amarincorp.com/), the investor relations website (http://investor.amarincorp.com/), including but not limited to investor presentations and investor FAQs, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that Amarin posts on these channels and websites could be deemed to be material information. As a result, Amarin encourages investors, the media, and others interested in Amarin to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on Amarin's investor relations website and may include social media channels. The contents of Amarin's website or these channels, or any other website that may be accessed

from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

References

[1] Yokoyama M, Origasa H, Matsuzaki M, et al. Effects of eicosapentaenoic acid on major coronary events in hypercholesterolaemic patients (JELIS): a randomised open-label, blinded endpoint analysis. *Lancet*. 2007;369(9567):1090-1098.

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[3] Matsuzaki M, Yokoyama M, Saito Y, et al. Incremental effects of eicosapentaenoic acid on cardiovascular events in statin-treated patients with coronary artery disease. *Circ J*. 2009;73(7):1283-1290.

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[6] Borow KM, Nelson JR, Mason RP. Biologic plausibility, cellular effects, and molecular mechanisms of eicosapentaenoic acid (EPA) in atherosclerosis. *Atherosclerosis*. 2015;242(1):357-366.

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[10] American Heart Association. 2018. Disease and Stroke Statistics-2018 Update.

[11] American Heart Association. 2017. Cardiovascular disease: A costly burden for America projections through 2035.

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[14] Nordestgaard BG. Triglyceride-rich lipoproteins and atherosclerotic cardiovascular disease - New insights from epidemiology, genetics, and biology. *Circ Res.* 2016;118:547-563.

[15] Nordestgaard BG, Varbo A. Triglycerides and cardiovascular disease. *Lancet*. 2014;384:626–635.

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Source: Amarin Corporation plc

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Exhibit I

Amarin Corporation

Amarin Receives FDA Approval of VASCEPA® (icosapent ethyl) to Reduce Cardiovascular Risk

December 13, 2019

VASCEPA ***becomes the first and only FDA-approved medication for reducing cardiovascular risk beyond cholesterol lowering therapy in high-risk patients approved for treatment***

- ***Millions of people in the United States qualify as treatment candidates for*** **VASCEPA**
- ***Cardiovascular disease events, including heart attack, stroke and cardiovascular death, occur in the United States every 14 seconds and are economically, physically and emotionally costly***
- **VASCEPA** ***has been assessed by independent bodies as priced cost effectively as a cardiovascular risk reduction treatment***
- **VASCEPA** ***total net revenue guidance increased for 2019 to a range of $410 to $425 million and for 2020 is newly guided to a projected range of $650 to $700 million***

Amarin to host webcast on Monday, December 16 at 7:30 a.m., Eastern Time

DUBLIN, Ireland and BRIDGEWATER, N.J., Dec. 13, 2019 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ: AMRN) today announced that the U.S. Food and Drug Administration (FDA) has approved a new indication and label expansion for VASCEPA® (icosapent ethyl) capsules. After more than a decade of development and testing, VASCEPA is now the first and only drug approved by the FDA "as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥150 mg/dL) and established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease." It is estimated that millions of high-risk patients in the United States could benefit from this one-of-a-kind prescription therapy.[1]

"We at Amarin are excited and gratified to now have the opportunity to introduce VASCEPA as a new FDA-approved treatment option to reduce the persistent cardiovascular risk that many patients face despite use of statins with other contemporary standard-of-care therapies," said John F. Thero, president and chief executive officer of Amarin. "We aim to help millions of high-risk patients, including statin-treated patients and statin-intolerant patients. For the first time, physicians, patients and payers have an FDA-approved treatment option beyond cholesterol lowering that has been demonstrated to significantly reduce major adverse cardiovascular events when used on top of a statin. We look forward to helping educate physicians and patients on the value of VASCEPA. The expanded indication and related clinical study labeling is broadly worded, informative on the many effects of

VASCEPA and will empower physicians with critical information to help them apply their clinical judgment in addressing cardiovascular disease risk for patients in need."

Amarin reaffirmed its intention to promptly launch VASCEPA in the United States for this important new preventative care indication. As previously disclosed, Amarin doubled the size of its sales force near the beginning of 2019 and is on track to double the size of its sales force again to a total of 800 sales representatives near the beginning of 2020.

"The FDA approval of icosapent ethyl as an addition to statin therapy to reduce the risk of cardiovascular events is a major milestone in cardiovascular prevention," said Deepak L. Bhatt, M.D., M.P.H., executive director of Interventional Cardiovascular Programs at Brigham and Women's Hospital, professor of medicine at Harvard Medical School, and lead investigator of the REDUCE-IT study which served as the basis for the supplemental New Drug Application to the FDA for VASCEPA. "Nothing this significant has happened in the world of cardiovascular prevention since the introduction of statins nearly three decades ago. Many patients stand to benefit from this historic advance in care."

In the global REDUCE-IT® cardiovascular outcomes study, approximately 28 percent of patients in the control arm treated with statins and other contemporary therapy but not treated with VASCEPA experienced a major adverse cardiovascular event (MACE), defined as the first occurrence of either myocardial infarction (heart attack), stroke, coronary revascularization, unstable angina requiring hospitalization or cardiovascular death.[2] As evidenced by this MACE occurrence,

there is a group of patients who, despite controlling their cholesterol on statin therapy, continue to have a high need for additional preventative cardiovascular care. For those adult patients in this group who have elevated triglycerides (TG) ≥150 mg/dL and established cardiovascular disease or diabetes and two or more additional risk factors for cardiovascular disease, VASCEPA is the first drug approved to help reduce this persistent cardiovascular risk. In a published exploratory analysis of the REDUCE-IT study, examining total (first and subsequent) cardiovascular events over a period of approximately five years, patients taking VASCEPA on average experienced one fewer MACE per six patients studied, representing a 30 percent risk reduction in total MACE compared to placebo.[3]

The overall rates of adverse events and serious adverse events in the 5-year REDUCE-IT study were similar between VASCEPA-treated patients and placebo-treated patients. As reflected in VASCEPA's expanded label and described below, VASCEPA has been associated with increased risks of bleeding and atrial fibrillation/flutter, the latter being more prevalent in patients with a previous history of atrial fibrillation or flutter. It is recommended that patients taking VASCEPA and concomitant anticoagulants and/or anti-platelet agents for bleeding be monitored. Also noted in the REDUCE-IT study is that patients for whom bleeding and/or atrial fibrillation/flutter were reported appeared to obtain a similar reduction in MACE as patients not reporting such adverse events. Such findings are consistent with published results of the study, which noted that the increased rates of such adverse events were low, notably lower than the reduction in MACE.[3]

Recurrent event analyses were conducted of the total primary endpoint events and total key secondary endpoints in REDUCE-IT using a series of statistical models and published in the Journal of the American College of Cardiology. These analyses are not in FDA labeling, were tertiary or exploratory endpoints; most of the models used were prespecified and one was post hoc. Each recurrent event statistical model has inherent strengths and weaknesses, with no single model considered definitive or outperforming the other models, and this is an evolving field of science. Nonetheless, results from these analyses are consistent across the various models; they also are consistent with the original primary and secondary endpoint results. Together, the REDUCE-IT recurrent event analyses and the original primary and key secondary endpoint analyses support the robustness of the clinical benefit of VASCEPA therapy in reducing cardiovascular risk.

Need Is Acute for a Cost-Effective, Preventative-Care Therapy Like VASCEPA

Despite current treatment options, in the United States, there is one stroke and one heart attack each occurring on average every 40 seconds, and one cardiovascular death occurring on average every 38 seconds, or, in aggregate one such cardiovascular event every 14 seconds.[4,5] Cardiovascular disease costs in the United States are in excess of $500 billion each year, making it the nation's most expensive disease.[6] The number of cardiovascular deaths is also increasing, serving as the No. 1 cause of death for men and women in the United States.[7] These facts point to an acute need for more innovation in the cardiovascular disease therapeutic area.

Since statin therapy was introduced nearly three decades ago, healthcare professionals have sought effective preventative care treatment options to reduce persistent cardiovascular risk beyond management of cholesterol. Many potential solutions failed to show favorable effects in cardiovascular outcomes studies. The development of VASCEPA included learnings from these failures and now VASCEPA is the first and only drug to succeed in reducing that risk in the patient group included in the new VASCEPA label.

Recently, a health economics study conducted by an expert group presented at the American Heart Association 2019 Scientific Sessions showed that use of VASCEPA offers potential cost savings for the overall healthcare system (i.e., the cost of VASCEPA is offset by cost savings from reducing the occurrence of high-cost major adverse cardiovascular events).[7] This rare finding follows conclusions from a separate independent drug pricing watchdog group that found VASCEPA cost effective for cardiovascular risk reduction, a result seldom achieved in this organization's analyses.[8]

Based on the unprecedented results of the REDUCE-IT outcomes study, multiple professional societies have updated guidelines or issued advisories to incorporate icosapent ethyl, including the American Diabetes Association,[9] the European Society of Cardiology, The European Atherosclerosis Association,[10] and the National Lipid Association.[11]

Today's announced new indication for VASCEPA is incremental to its indication for which it was initially FDA approved, as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. The effect of VASCEPA on the

risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

"In achieving this expanded indication, Amarin appreciates the FDA's guidance in the design and conduct of multiple clinical trials of VASCEPA across the past decade and for its diligence in reviewing the results of these studies," said Steven Ketchum, Ph.D., senior vice president and president, research & development and chief scientific officer, Amarin. "Moreover, Amarin is grateful to the thousands of patients and clinical sites who participated in the extensive study of VASCEPA, which exceeded 37,000 patient-years of study in the clinical development program. Amarin also thanks its dedicated employees and advisors who overcame many challenges to achieve this important life-saving accomplishment."

Revenue Guidance Updated for 2019 and Provided for 2020

Amarin last updated its revenue guidance for 2019 in its press release dated July 2, 2019. Amarin now makes the following update to that guidance and issues its first guidance for 2020:

With respect to the year ending December 31, 2019, while the year is not yet complete, Amarin increases its guidance for total net revenue to a range of $410 to $425 million. Prior guidance for this period given in July 2019 was total net revenue in a range of $380 to $420 million. The midpoint of this new full-year 2019 guidance, $417.5 million, would represent an increase of approximately 82% over full year 2018 results.

With respect to 2020, Amarin projects that total net revenue will be in a range of $650 to $700 million, mostly from sales of VASCEPA in the United States. Amarin is providing this projected revenue guidance

for 2020 and has based its projection on a number of factors, including, but not limited to, expectations on market acceptance of the newly expanded label for VASCEPA and current plans for expanded promotion. VASCEPA revenues are anticipated to continue to increase in 2020, accompanied by quarterly industry variability, including recurring seasonal factors, particularly in the first quarter. Given that it takes time to educate providers and patients, Amarin expects a delayed impact from planned promotional programs either because they are new, such as the impact of new sales representatives, or, in the case of direct-to-consumer promotion, because separate regulatory approval is required and not currently expected until mid-2020. In addition, while multiple studies have concluded that VASCEPA is cost effective, how managed care organizations will react to a cost-effective therapy lacks adequate precedent.

Beyond 2020, Amarin believes that VASCEPA total net revenue will grow to reach multiple billions of dollars. However, the history of other therapies for chronic conditions suggests that growth builds over multiple years. At this time, the company is not providing guidance regarding annual revenue levels beyond 2020.

Conference Call and Webcast Information:

Amarin will host a conference call Monday, December 16, at 7:30 a.m. ET to discuss this information. The conference call can be heard live on the investor relations section of the company's website at www.amarincorp.com, or via telephone by dialing 877-407-8033 within the United States, 201-689-8033 from outside the United States, or by using the call back feature at https://bit.ly/35nxY8k. A replay of the call will be made

available for a period of two weeks following the conference call. To hear a replay of the call, dial 877-481-4010, PIN: 56897. A replay of the call will also be available through the company's website shortly after the call.

About VASCEPA® (icosapent ethyl) Capsules

VASCEPA (icosapent ethyl) capsules are the first-and-only prescription treatment approved by the FDA comprised solely of the active ingredient, icosapent ethyl (IPE), a unique form of eicosapentaenoic acid. VASCEPA was initially launched in the United States in 2013 based on the drug's initial FDA approved indication for use as an adjunct therapy to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. Since launch, VASCEPA has been prescribed over eight million times and is covered by most major medical insurance plans. The new, cardiovascular risk indication for VASCEPA was approved by the FDA in December 2019.

Indications and Limitation of Use

VASCEPA is indicated:

- As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
    - established cardiovascular disease or
    - diabetes mellitus and two or more additional risk factors for cardiovascular disease.

- As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

Important Safety Information

- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.
- VASCEPA was associated with an increased risk (3% vs 2%) of atrial fibrillation or atrial flutter requiring hospitalization in a double-blind, placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter.
- It is not known whether patients with allergies to fish and/or shellfish are at an increased risk of an allergic reaction to VASCEPA. Patients with such allergies should discontinue VASCEPA if any reactions occur.
- VASCEPA was associated with an increased risk (12% vs 10%) of bleeding in a double-blind, placebo-controlled trial. The incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel or warfarin.
- Common adverse reactions in the cardiovascular outcomes trial (incidence ≥3% and ≥1% more frequent than placebo): musculoskeletal pain (4% vs 3%), peripheral edema (7% vs 5%),

constipation (5% vs 4%), gout (4% vs 3%), and atrial fibrillation (5% vs 4%).

- Common adverse reactions in the hypertriglyceridemia trials (incidence ≥1% more frequent than placebo): arthralgia (2% vs 1%) and oropharyngeal pain (1% vs 0.3%).
- Adverse events may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.
- Patients receiving VASCEPA and concomitant anticoagulants and/or anti-platelet agents for bleeding should be monitored.

Key clinical effects of VASCEPA on major adverse cardiovascular events are included in the Clinical Studies section of the prescribing information for VASCEPA, as set forth below:

Effect of VASCEPA on Time to First Occurrence of Cardiovascular Events in Patients with Elevated Triglyceride Levels and Other Risk Factors for Cardiovascular Disease in REDUCE-IT

	VASCEPA		Placebo		VASCEPA vs Placebo
	N = 4089 n (%)	Incidence Rate (per 100 patient years)	N = 4090 n (%)	Incidence Rate (per 100 patient years)	Hazard Ratio (95% CI)
Primary composite endpoint					
Cardiovascular death, myocardial infarction, stroke, coronary revascularization, hospitalization for unstable angina (5-point MACE)	705 (17.2)	4.3	901 (22.0)	5.7	0.75 (0.68, 0.83)
Key secondary composite endpoint					
Cardiovascular death, myocardial infarction, stroke (3-point MACE)	459 (11.2)	2.7	606 (14.8)	3.7	0.74 (0.65, 0.83)
Other secondary endpoints					
Fatal or non-fatal myocardial infarction	250 (6.1)	1.5	355 (8.7)	2.1	0.69 (0.58, 0.81)
Emergent or urgent coronary revascularization	216 (5.3)	1.3	321 (7.8)	1.9	0.65 (0.55, 0.78)
Cardiovascular death [1]	174 (4.3)	1.0	213 (5.2)	1.2	0.80 (0.66, 0.98)
Hospitalization for unstable angina [2]	108 (2.6)	0.6	157 (3.8)	0.9	0.68 (0.53, 0.87)
Fatal or non-fatal stroke	98 (2.4)	0.6	134 (3.3)	0.8	0.72 (0.55, 0.93)

] Includes adjudicated cardiovascular deaths and deaths of undetermined causality.
] Determined to be caused by myocardial ischemia by invasive/non-invasive testing and requiring emergent hospitalization.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

About Amarin

Amarin Corporation plc. is a rapidly growing, innovative pharmaceutical company focused on developing and commercializing therapeutics to cost-effectively improve cardiovascular health. Amarin's lead product, VASCEPA® (icosapent ethyl), is available by prescription in the United States, Lebanon and the United Arab Emirates. Amarin, together with its commercial partners in select geographies, is pursuing additional regulatory approvals for VASCEPA in Canada, China, the European Union and the Middle East. For more information about Amarin, visit www.amarincorp.com.

Forward-Looking Statements

This press release contains forward-looking statements, including expectations regarding commercial expansion and the use of VASCEPA to potentially help millions of patients, revenue and prescription growth, including updated revenue guidance for 2019 and guidance for 2020 and beyond; sales force expansion and marketing initiatives expected in 2019 and beyond; managed care acceptance; the applicability and reliability of REDUCE-IT results and cost effectiveness data. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In addition, Amarin's ability to effectively commercialize VASCEPA will depend in part on its ability to continue to effectively finance its business, efforts of third parties, its ability to gain regulatory approvals, create market demand for VASCEPA through education, marketing and sales activities, to achieve market acceptance of VASCEPA, to receive

adequate levels of reimbursement from third-party payers, to develop and maintain a consistent source of commercial supply at a competitive price, to comply with legal and regulatory requirements in connection with the sale and promotion of VASCEPA and to maintain patent protection for VASCEPA. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with acceptance of clinical trial results and related regulatory approvals; the risk that sales may not meet expectations and related cost may increase beyond expectations; the risk that patents may not be upheld in patent litigation and applications may not result in issued patents sufficient to protect the VASCEPA franchise. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent quarterly report on Form 10-Q. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

Availability of Other Information About Amarin
Investors and others should note that Amarin communicates with its investors and the public using the company website (www.amarincorp.com), the investor relations website (investor.amarincorp.com), including but not limited to investor presentations and investor FAQs, Securities and Exchange Commission filings, press releases, public conference calls and

webcasts. The information that Amarin posts on these channels and websites could be deemed to be material information. As a result, Amarin encourages investors, the media, and others interested in Amarin to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on Amarin's investor relations website and may include social media channels. The contents of Amarin's website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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(Note for reporters: if you require additional assets to accompany your stories, including

product photos or b-roll, please contact Gwen Fisher at the above email address.)

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[1] Fan W, Philip S, Toth PP, et al. Prevalence of United States adults with triglycerides ≥ 135 mg/dL: NHANES 2007–2014. Cardiol J. 2019;26(5). DOI: 10.5603/CJ.2019.0000.

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[4] American Heart Association: Heart Disease and Stroke Statistics -- 2019 At-a-Glance.

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Exhibit L

hikma.

Press Release

Hikma confirms favourable ruling in generic Vascepa® patent suit

London, March 31, 2020 – Hikma Pharmaceuticals PLC (Hikma, Group), the multinational generic pharmaceutical company, today confirms that the United States District Court for the District of Nevada has ruled that Hikma's generic version of Amarin Corporation's Vascepa® (icosapent ethyl) 1 gm capsules does not infringe six United States Patents, as asserted by Amarin, because the asserted claims of these patents were held to be invalid.

Hikma is working closely with the U.S. Food and Drug Administration (FDA) to gain approval for its Abbreviated New Drug Application (ANDA) for its generic version of Vascepa®. The company is evaluating its options for launching the product following FDA approval, including an at-risk launch in the event the District Court's decision is appealed.

"We are very pleased with the District Court's decision, which demonstrates our continued ability to successfully litigate to bring greater value to our customers and patients in the US," said Brian Hoffmann, President of Generics, Hikma. "We look forward to providing patients and health care providers in the US with a generic version of this important medicine."

Vascepa® is a prescription medicine that is indicated, in part, as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.

According to IQVIA, US sales of Vascepa® were approximately $919 million in the 12 months ending February 2020.

- ENDS -

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About Hikma

(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1/stable Moody's and BB+/positive S&P)

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across the United States (US), the Middle East and North

Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,600 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

Sensitivity: General

Exhibit M

hikma.

Press Release

Hikma receives favourable court ruling for its generic Vascepa®

London, September 3, 2020 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, announces that the US Court of Appeals for the Federal Circuit today upheld a ruling by the US District Court for the District of Nevada finding that Hikma's generic version of Vascepa®[1] (icosapent ethyl) 1gm does not infringe any valid claim of six key Amarin-owned patents. Hikma received FDA approval for the product in May 2020 and is working towards a launch.

Vascepa® is a prescription medicine that is indicated, in part, as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. According to IQVIA, US sales of Vascepa® were approximately $1.1 billion in the 12 months ending July 2020.

"We are very pleased with the Federal Circuit's swift decision and to be one step closer to launching a generic version of this important medicine for US patients and healthcare providers, helping us to continue putting better health, within reach, every day," said

[1] Vascepa® is a registered trademark of Amarin Pharmaceuticals Ireland Limited

Brian Hoffmann, President of Hikma Generics. "Today's decision demonstrates Hikma's ability to successfully challenge patents on important medicines and to provide value to our customers and millions of patients across the United States."

- ENDS -

Enquiries

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About Hikma

(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P and Ba1/stable Moody's)

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives.

We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,600 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

Exhibit N

hikma.

Press Release

Hikma launches Icosapent Ethyl Capsules

London, 5 November, 2020 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, has launched Icosapent Ethyl Capsules, 1gm, in the US through its US affiliate, Hikma Pharmaceuticals USA Inc.

Following an earlier than expected favorable court ruling, Hikma has accelerated the launch of its Icosapent Ethyl Capsules in order to quickly provide patients with access to this important medicine. Initially, Hikma will be releasing limited quantities to ensure a consistent supply for customers. The Company is working to scale up manufacturing and increase availability as soon as possible.

"Hikma's launch of this important medicine for US patients and healthcare providers once again underscores our ability to put better health, within reach, every day for millions of people who rely on our medicines," said Brian Hoffmann, President of Hikma Generics. "Today's launch demonstrates Hikma's ability to successfully challenge patents and launch complex products, bringing greater value to our customers and patients."

Hikma's FDA-approved Icosapent Ethyl Capsule product is indicated for the following indication: as an adjunct to diet to reduce triglyceride levels in adult

patients with severe (≥500 mg/dL) hypertriglyceridemia. Hikma's product is not approved for any other indication for the reference listed drug VASCEPA®.

- ENDS -

Enquiries

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About Hikma

(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P, BBB-/stable Fitch and Ba1/stable Moody's)

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they

care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,600 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

Important Safety Information for Icosapent Ethyl Capsules, 1gm:

CONTRAINDICATIONS

Icosapent ethyl is contraindicated in patients with known hypersensitivity (eg, anaphylactic reaction) to icosapent ethyl or any of its components.

WARNINGS AND PRECAUTIONS

- **Atrial Fibrillation/Flutter**

In a double-blind, placebo-controlled trial, icosapent ethyl was associated with an increased risk (3% vs 2%) of atrial fibrillation or atrial flutter requiring hospitalization. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter.

- **Potential for Allergic Reactions in Patients With Fish Allergy**

It is not known whether patients with allergies to fish and/or shellfish are at increased risk of an allergic reaction to icosapent ethyl. Inform patients with known hypersensitivity to fish and/or shellfish about the potential for allergic reactions and advise them to discontinue use and seek medical attention if any reactions occur.

- **Bleeding**

In a double-blind, placebo-controlled trial, icosapent ethyl was associated with an increased risk (12% vs 10%) of bleeding. The incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel or warfarin.

ADVERSE REACTIONS

The following important adverse reactions are described in the full Prescribing Information for Icosapent Ethyl capsules:

- Atrial Fibrillation or Atrial Flutter
- Potential for Allergic Reactions in Patients With Fish Allergy
- Bleeding

Common adverse reactions (incidence ≥3% on icosapent ethyl and ≥1% more frequent than placebo) included musculoskeletal pain, peripheral edema, constipation, gout and atrial fibrillation.

In hypertriglyceridemia trials, adverse reactions reported with icosapent ethyl (incidence ≥1% more frequent than placebo) included arthralgia and oropharyngeal pain.

DRUG INTERACTIONS

- **Increased Bleeding Risk With Anticoagulants and Antiplatelet Agents**

Monitor patients receiving icosapent ethyl and concomitant anticoagulants and/or antiplatelet agents for bleeding.

USE IN SPECIFIC POPULATIONS

- **Lactation**

Lactating women receiving oral omega-3 fatty acids for supplementation have resulted in higher levels of omega-3 fatty acids in human milk. There are no data

on the effects of omega-3 fatty acid ethyl esters on the breastfed infant or on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for icosapent ethyl and any potential adverse effects on the breastfed child from icosapent ethyl or from the underlying maternal condition.

- **Pediatric Use**

Safety and effectiveness in pediatric patients have not been established.

- **Hepatic Impairment**

In patients with hepatic impairment, alanine aminotransferase and aspartate aminotransferase levels should be monitored periodically during therapy with icosapent ethyl.

INDICATIONS AND USAGE

Icosapent ethyl is indicated:

- as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.

Limitations of use

The effect of icosapent ethyl on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

For more information, please see the full Prescribing Information and Medication Guide.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit https://www.fda.gov/medwatch or call 1-800-FDA-1088.

Manufactured by: Catalent Pharma Solutions, LLC., St. Petersburg, Florida 33716

Distributed by: Hikma Pharmaceuticals USA Inc., Eatontown, NJ 07724

Document Identification Number: WW40034v4

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Exhibit Y

'Phenomenal' REDUCE-IT establishes triglyceride theory | CHEST Physician

CHEST Physician

LATEST NEWS

'Phenomenal' REDUCE-IT establishes triglyceride theory

Publish date: November 20, 2018

By Catherine Hackett; **MDedge News**

REPORTING FROM THE AHA SCIENTIFIC SESSIONS

CHICAGO — REDUCE-IT is a phenomenal trial and a game changer because it has shown for the first time that triglyceride reduction with an appropriate therapy – in this case – icosapent ethyl – when used in appropriate doses can make a significant difference.

That's according to Prakash C. Deedwania, MD, chief of the cardiology division at the Veterans Affairs Medical Center/University of California San Francisco Program in Fresno, who joined MDedge reporter Richard Mark Kirkner for a video interview at the American Heart Association scientific sessions.

RELATED
REDUCE-IT: FISH-derived agent cut CV events 25%

In the large, placebo-controlled REDUCE-IT trial in patients with or at high risk for cardiovascular disease received 2 g of icosapent ethyl (Vascepa) twice daily or placebo saw a 25% lower risk of cardiovascular death or an ischemic event, compared with placebo.

https://www.mdedge.com/chestphysician/article/189309/lipid-disorders/phenomenal-reduc...
2/27/2019

Exhibit Z

11/28/2018 Fish Oil Drug May Prevent Heart Attack and Strokes in High-Risk Patients – The New York Times

The New York Times

Fish Oil Drug May Prevent Heart Attack and Strokes in High-Risk Patients

Large doses of an omega-3 fatty acid in fish oil sharply reduced the rate of cardiovascular events in people with a history of heart disease or Type 2 diabetes.

By Anahad O'Connor

Sept. 25, 2018

Cardiologists may one day have a new tool to help prevent heart attacks and strokes in some high-risk patients: a prescription drug that contains large doses of EPA, an omega-3 fatty acid contained in fish oil.

A large clinical trial found that the drug, called Vascepa, sharply reduced the rate of cardiovascular events in people with a history of heart disease or Type 2 diabetes, according to early results that were announced on Monday.

The findings were particularly relevant for people with high triglycerides, a type of fat in the blood that has been linked to an increased risk of heart disease. The new trial, called Reduce-IT, focused on people whose cholesterol levels were well controlled with statins but

whose triglyceride levels remained very high. Many cardiovascular experts were doubtful that adding fish oil on top of statins would produce much if any benefit because a number of smaller and less rigorous studies over the years had failed.

But the new trial showed that statin-treated adults with elevated triglycerides who were prescribed high doses of the purified EPA had a 25 percent reduction in their relative risk of heart attacks, strokes and other cardiac events compared to a control group of patients who received placebo.

"I'm very surprised by the magnitude of the results, which quite frankly are large," said Dr. Michael J. Blaha, the director of clinical research at the Ciccarone Center for the Prevention of Heart Disease at Johns Hopkins Medical School, who was not involved in the study. "My expectations were very low. A lot of people are legitimately surprised by this."

Fish oil has long been a popular supplement to protect against heart disease. It contains high levels of omega-3 fatty acids, primarily EPA and DHA, which reduce inflammation and lower triglyceride levels. Omega-3 fatty acids also have blood-thinning effects similar to those of aspirin.

But until now most of the clinical trials that have looked at fish oil in heart patients had not found convincing evidence that it helps. Some argued that the trials were deeply flawed, saying they relied on doses that were too small or that they failed to recruit the patients who were most likely to benefit, like those with high triglycerides. Some of the studies were observational which are less rigorous than clinical trials, in which different groups of patients receive different treatments. They also used various types of fish oil.

The new trial differed from previous ones in a number of ways. It focused specifically on two groups of high-risk patients: People with a history of cardiovascular events, such as heart attacks, strokes and angina; and those with Type 2 diabetes and other risk factors like high blood pressure. The patients also had to have high triglycerides. The median baseline level of triglycerides among the subjects was 216 milligrams per deciliter — well above the cutoff for what is considered a normal level, which is 150 milligrams per deciliter. In addition, all of the patients were on statins which lower cholesterol.

The intervention in this trial, which was sponsored by Amarin, was not the typical fish oil supplement that can be purchased at any supermarket or pharmacy. Vascepa is a prescription drug that contains highly purified EPA. Fish oil supplements, on the other hand, often contain a mixture of both EPA and DHA and in some cases other oils as well. EPA and DHA are similar but have slightly different effects. Both can lower triglycerides, for example, but DHA also tends to raise LDL cholesterol, the so-called bad kind associated with heart disease.

The trial enrolled 8,179 adults and followed them on average for about five years. In addition to lowering cardiovascular events, the trial found that Vascepa was safe and well tolerated. Amarin announced the findings on Monday and is expected to present the full results and data at an annual American Heart Association conference in November.

Dr. Ethan Weiss, a cardiologist and associate professor at the University of California, San Francisco, who was not involved in the study, said that the findings confirm the role that high triglycerides play in heart

disease but that they nonetheless came as a shock because so many earlier trials of fish oil found little or no benefits. He pointed to several caveats: He and others need to see all of the data, and the patient population that is likely to benefit from Vascepa is very specific. Diet and exercise can also lower triglycerides — especially very low carbohydrate diets — and whether the outcome on heart risk might be similar to the effect produced by Vascepa should be studied, he said.

"Lots of questions remain," he said. "But the takeaway is that this is really big and I was wrong. And I am happy I was wrong and am excited we have a new pathway and set of tools to explore for our patients."

Some experts cautioned that Vascepa is not for everyone who has heart disease or risk factors for it. The drug is currently approved for certain patients with unusually high triglyceride levels.

"The worried well shouldn't run out and take fish oil." said Dr. Michael Shapiro, a site investigator for the Reduce-IT trial and the director of Oregon Health and Science University's Atherosclerosis Imaging Program. But the group that is likely to benefit includes a large proportion of patients in heart clinics.

"The amount of people around the world who have atherosclerotic disease or diabetes who take a statin and still have elevated triglycerides is enormous," he said. "This has huge implications."

Anahad O'Connor is a staff reporter covering health, science, nutrition and other topics. He is also a bestselling author of consumer health books such as "Never Shower in a Thunderstorm" and "The 10 Things You Need to Eat."

A version of this article appears in print on Oct. 2, 2018, on Page D4 of the New York edition with the headline: The Helping Hand of a Fish Oil Drug

https://www.nytimes.com/2018/09/25/well/fish-oil-heart-attack-stroke-triglycerides-omega-3s.html

Exhibit GG

December 11, 2020

Dear Payer Community,

Amarin is aware that Hikma Pharmaceuticals has launched a generic version of VASCEPA® (icosapent ethyl) 1-gram capsules. According to Hikma's press release, Hikma is releasing only "*limited quantities of their generic product*" and have stated that they "*hope to have more in 2021*."[1]

The Hikma generic has a WAC price of $301.86, which is only ~9% lower than VASCEPA's WAC price.[2]

Furthermore, Hikma's generic icosapent ethyl product is indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. Severe (≥500 mg/dL) hypertriglyceridemia represents <10% of the overall utilization of VASCEPA.[3]

It is important to note that, unlike the Hikma generic, VASCEPA is also indicated for cardiovascular (CV) risk reduction on top of statin therapy.[4,5] The Hikma generic does not have an FDA-approved indication for CV risk reduction. .

In addition, Amarin has sued Hikma for patent infringement for encouraging use of its generic product in the CV risk reduction indication. Amarin maintains patent exclusivity for CV risk reduction, and the Hikma generic should not be dispensed for this indication.

Indications

VASCEPA is indicated for the following patients:

- As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
  - established cardiovascular disease or
  - diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.
- As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

Important Safety Information

- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.
- VASCEPA was associated with an increased risk (3% vs 2%) of atrial fibrillation or atrial flutter requiring hospitalization in a double-blind, placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter.

Please see additional Important Safety Information below.

On behalf of Amarin, thank you for your continued partnership as we work toward reducing the burden of CV disease. We are confident that Vascepa will continue to provide excellent value for payers and their clients, and we look forward to continuing to work together to improve patient care and reduce healthcare costs. We intend to be price competitive in this marketplace and will work with you for the good of our patients.

If I can provide additional information on VASCEPA, or its benefit to patients and the healthcare system, please do not hesitate to contact me.

Sincerely,

/s/ Rob Werner
Rob Werner
VP Managed Markets
Amarin Pharma, Inc.

Indications

VASCEPA is indicated for the following patients:

- As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
  - established cardiovascular disease or
  - diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.

- As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

Limitations of Use

The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

Important Safety Information

- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.
- VASCEPA was associated with an increased risk (3% vs 2%) of atrial fibrillation or atrial flutter requiring hospitalization in a double-blind, placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter.
- Is it not known whether patients with allergies to fish and/or shellfish are at an increased risk of an allergic reaction to VASCEPA. Patients with such allergies should discontinue VASCEPA if any reactions occur.
- VASCEPA was associated with an increased risk (12% vs 10%) of bleeding in a double-blind, placebo-controlled trial. The incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel or warfarin.
- Common adverse reactions in the cardiovascular outcomes trial (incidence ≥3% and ≥1% more

frequent than placebo): musculoskeletal pain (4% vs 3%), peripheral edema (7% vs 5%), constipation (5% vs 4%), gout (4% vs 3%) and atrial fibrillation (5% vs 4%).

- Common adverse reactions in the hypertriglyceridemia trials (incidence ≥1% more frequent than placebo): arthralgia (2% vs 1%) and oropharyngeal pain (1% vs 0.3%).
- Adverse events may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.
- Patients receiving VASCEPA and concomitant anticoagulants and/or anti-platelet agents should be monitored for bleeding.

Please see full Prescribing Information

References **1**-Hikma Website. Newsroom. https://www.hikma.com/newsroom/article-i4928-hikma-launches-icosapent-ethyl-capsules/ , **2** MediSpan, Amarin Data on File **3** Amarin analysis of Symphony Health data, Amarin Data on File **4** VASCEPA [package insert]. Bridgewater, NJ: Amarin Pharma, Inc.; 2019. **5** Generic Icosapent Ethyl [Package Insert]

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTICT OF DELAWARE

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, MOCHIDA PHARMACEUTICAL CO., LTD., Plaintiffs,	:	
v.	:	C.A. No. 20-1630-RGA-JLH
HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC, AND HEALTH NET, LLC Defendants.	:	

FINAL JUDGMENT UNDER
FEDERAL RULE OF CIVIL PROCEDURE 54(b)

THIS MATTER having come before the Court on Defendants Hikma Pharmaceuticals USA Inc. and Hikma Pharmaceuticals PLC's (collectively, "Hikma") Motion for Entry of Final and Appealable Judgment under Federal Rule of Civil Procedure 54(b), and the Court having considered Hikma's arguments and submissions in support of the Motion;

It is hereby **ORDERED** that the Motion is **GRANTED**.

For the reasons set forth by Hikma in its moving papers, the Court finds that the Court's order granting Hikma's motion to dismiss Plaintiffs' first amended complaint (D.I. 98) is a final judgment resolving Plaintiffs' claims against Hikma, and the Court expressly determines that there is no just reason for delay (*see* Fed. R. Civ. P. 54(b)).

Considering the factors set forth in *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 203 (3d Cir. 2006), the Court finds that (1) the relationship between the adjudicated claims against Hikma and the unadjudicated claims against the remaining Defendant, Health Net, LLC, is minimal because Plaintiff's theories of infringement against these respective defendants are materially different; (2) the only foreseeable possibility that the need for review might be mooted by future developments in this Court is the invalidation of the asserted patents, which is unlikely to occur for more than a year; (3) the possibility that the reviewing court might be obliged to consider the same issue a second time is minimal because any appeal of the Court's order granting Hikma's motion to dismiss does not relate to Plaintiffs' infringement theory against Health Net; (4) there is no claim or counterclaim which could result in a set-off against the judgment sought to be made final; and (5) no miscellaneous factors (such as delay, economic and solvency considerations, shortening the time of trial, frivolity of competing claims, expense, and the like) weigh against entering final judgment at this time.

Accordingly, final judgment is **ENTERED** in favor of Hikma and against Plaintiffs; Plaintiffs' claims against Hikma in this action are **DISMISSED WITH PREJUDICE**; and each party shall bear its own costs and fees.

IT IS SO ORDERED this 13th day of October, 2022.

/s/ Richard G. Andrews
Honorable Richard G. Andrews
United States District Court Judge