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## Sunovion Enters Agreement to Divest Asthma and Allergy Products to Covis Pharma

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### Terms:

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MARLBOROUGH, Mass.

MARLBOROUGH, Mass.--(BUSINESS WIRE <sup>[1]</sup>)--Sunovion Pharmaceuticals Inc. <sup>[2]</sup> (Sunovion) today announced that it has entered into a definitive agreement to divest the U.S. market rights to Sunovion's ciclesonide products ALVESCO<sup>®</sup> (ciclesonide) Inhalation Aerosol, OMNARIS<sup>®</sup> (ciclesonide) Nasal Spray, and ZETONNA<sup>®</sup> (ciclesonide) Nasal Aerosol to Covis Pharma B.V. (Covis Pharma). Ciclesonides are included in the corticosteroids class of medications, and are approved to treat asthma (ALVESCO) and allergic rhinitis (OMNARIS and ZETONNA).

"We are excited to announce this transaction and look forward to engaging with patients, physicians and customers in the continued support of these important products as we build out our respiratory franchise," said Michael Porter, CEO of Covis Pharma.

"With the divestiture of asthma and allergy products, Sunovion is reinforcing its strategic focus on chronic obstructive pulmonary disease (COPD) in the respiratory area. Sunovion has the broadest COPD portfolio in the U.S., offering both handheld and nebulized treatment options that can be tailored to individual needs," said Nobuhiko Tamura, Chairman and Chief Executive Officer, Sunovion. "We are committed to working closely with Covis Pharma to ensure a smooth transition of the divested products. Sunovion is well-positioned to continue to advance our robust respiratory portfolio and help people with serious medical conditions."

Covis Pharma plans to ship all products immediately upon closing the transaction and will work with Sunovion to ensure uninterrupted access to patients.

The transaction is expected to close during the first half of Fiscal Year 2017, subject to customary closing conditions.

Covis Pharma, headquartered in Zug, Switzerland, is a global specialty pharmaceutical company that markets therapeutic solutions for patients with life-threatening conditions and chronic illnesses. Additional information is available on the Covis Pharma website at [covispharma.com](http://covispharma.com) <sup>[3]</sup>.

### About ALVESCO, OMNARIS and ZETONNA

ALVESCO, OMNARIS and ZETONNA were licensed from Takeda GmbH (formerly Nycomed) by Sunovion (formerly Sepracor) in 2008. ALVESCO and OMNARIS were launched in 2008 and ZETONNA was launched in 2012 in the United States.

### Indication and Important Safety Information for ALVESCO<sup>®</sup> (ciclesonide) INHALATION AEROSOL

#### Indication

ALVESCO<sup>®</sup> (ciclesonide) Inhalation Aerosol is for the long-term treatment of asthma as preventative therapy in adults and adolescents 12 years of age and older. ALVESCO is NOT indicated for the relief of acute bronchospasm.

#### Important Safety Information

ALVESCO is NOT a rescue inhaler and should not be used for relief of sudden symptoms of shortness of breath during an asthma attack. Use a fast-acting rescue medicine (such as a levalbuterol or albuterol inhaler) to relieve sudden symptoms if you have an asthma attack. You should contact your healthcare professional if an asthma attack does not respond to your rescue medicine or you need to use your rescue medicine more often than usual.

You should not use ALVESCO if you are allergic to ciclesonide or any of the ingredients in ALVESCO. Rare cases of severe allergic reactions, including swelling of the lips, tongue and throat, have been reported.

Yeast infections of the mouth and throat (thrush) have occurred in some ALVESCO patients. Rinse your mouth after you inhale each dose of ALVESCO.

Patients taking ALVESCO are at a possible increased risk of infection due to a weakened immune system that may occur when taking a steroid medicine. Tell your healthcare professional if you have had tuberculosis (TB) or any other infections before or while using ALVESCO, or if you are exposed to chickenpox or measles.

If you took an oral (by mouth) steroid previously and are having the dose decreased, or you have been switched to ALVESCO from an oral steroid, tell your healthcare professional right away about any symptoms such as feeling tired or exhausted, weakness, nausea, vomiting, or symptoms of low blood pressure (such as dizziness or faintness). These may be symptoms of a potentially life-threatening condition in which your body does not produce enough natural steroids.

Using inhaled steroid medicines for a long time may put you at greater risk for decreased bone mass (which can cause bones to become weaker). Inhaled corticosteroids including ALVESCO may cause slowed growth in children and adolescents. Your healthcare professional should monitor your bone health and the growth of children and adolescents taking ALVESCO.

Glaucoma, increased pressure in the eye, and cataracts have been seen in patients who received inhaled steroid medications, including ALVESCO. Your healthcare professional should monitor you especially if you have a change in vision or have a history of increased pressure in the eye, glaucoma, and/or cataracts.

As with other inhaled asthma medicines, bronchospasm (a sudden squeezing of the airways) can occur, with wheezing, right after you inhale your dose of ALVESCO. If this happens, stop using ALVESCO and use a rescue medicine right away, such as levalbuterol or albuterol. You should also inform your healthcare professional right away so that your asthma medicine can be re-evaluated.

It is important to take ALVESCO regularly, as prescribed. Do not stop treatment even if you are feeling better, unless told to do so by your healthcare professional. You should contact your healthcare professional if your symptoms do not improve after 4 weeks, or if your condition worsens at any time during treatment. DO NOT inhale more doses or use your ALVESCO inhaler more often than you have been directed.

The most common side effects with ALVESCO include headache, pain or irritation of the nose and throat, sinus infection, upper respiratory infection (such as the common cold), joint pain, stuffy nose, leg or arm pain, and back pain.

For additional information, please see the full Prescribing Information for ALVESCO at [www.ALVESCO.com](http://www.ALVESCO.com) [4].

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) [5], or call 1-800-FDA-1088.

## Indication and Important Safety Information for OMNARIS® (ciclesonide) NASAL SPRAY

### Indication

OMNARIS® (ciclesonide) Nasal Spray is for the treatment of nasal allergy symptoms associated with seasonal allergies in adults and children 6 years of age and older, and with year-round allergies in adults and adolescents 12 years of age and older. It is for use in the nose only. OMNARIS is used 1 time each day, 2 sprays per nostril.

### Important Safety Information

Do not spray OMNARIS Nasal Spray in your eyes or directly onto your nasal septum (the wall inside your nose between your two nostrils).

OMNARIS Nasal Spray may cause serious side effects, including:

- **nose bleeds and nasal ulcers.** Call your healthcare provider right away if you start to have more nose bleeds or nasal ulcers.
- **hole in the cartilage in the nose (nasal septal perforation).** Stop using OMNARIS Nasal Spray and call your doctor right away if you have symptoms of a nasal perforation. Symptoms of nasal perforation may include: crusting in the nose, nosebleeds, runny nose, and a whistling sound when you breathe.
- **thrush (Candida), a fungal infection in your nose, mouth, or throat.** Tell your healthcare provider if you have any redness or white colored patches in your mouth or throat.
- **slow wound healing.** You should not use OMNARIS Nasal Spray until your nose has healed, if you have a sore in your nose, if you have had surgery in your nose, or if your nose has been injured.
- **eye problems such as glaucoma and cataracts.** If you have a history of glaucoma or cataracts or have a family history of eye problems, you should have regular eye exams while you use OMNARIS Nasal Spray.
- **immune system problems that may increase your risk of infections.** You are more likely to get infections if you take medicines that may weaken your body's ability to fight infections. Avoid contact with people who have contagious diseases such as chicken pox or measles while you use OMNARIS Nasal Spray. Symptoms of an infection may include: fever, pain, aches, chills, feeling tired, nausea, and vomiting.
- **adrenal insufficiency.** Adrenal insufficiency is a condition in which the adrenal glands do not make enough steroid hormones. Call your healthcare provider right away if you experience the following symptoms of adrenal insufficiency: tiredness, weakness, dizziness, nausea, and vomiting.
- **slowed or delayed growth in children.** A child's growth should be checked regularly while using OMNARIS Nasal Spray.
- **allergic reactions.** Call your healthcare provider right away if you experience swelling of the lips, tongue, or throat.

The most common side effects that may occur with OMNARIS Nasal Spray are headache, nosebleed, sore throat and ear pain.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of OMNARIS Nasal Spray.

For additional information, please see the OMNARIS Full Prescribing Information and the OMNARIS Patient Information at [www.OMNARIS.com](http://www.OMNARIS.com) [6]. You may also call 1-888-394-7377.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) [7], or call 1-800-FDA-1088.

OMNARIS® (ciclesonide) Nasal Spray is available by prescription. Ask your healthcare professional if OMNARIS Nasal Spray is appropriate for you.

## Indication and Important Safety Information for ZETONNA® (ciclesonide) NASAL AEROSOL

### Indication

ZETONNA® (ciclesonide) Nasal Aerosol is a prescription medicine that treats seasonal and year-round allergy symptoms in adults and children 12 years of age and older. It is for use in the nose only. ZETONNA Nasal Aerosol is used 1 time each day, 1 spray per nostril.

### Important Safety Information

Do not spray ZETONNA® (ciclesonide) Nasal Aerosol in your eyes or directly onto your nasal septum (the wall inside your nose between your two nostrils).

ZETONNA Nasal Aerosol may cause serious side effects, including:

- **nose bleeds and nasal ulcers.** Call your healthcare provider right away if you start to have more nose bleeds or nasal ulcers.
- **hole in the cartilage in the nose (nasal septal perforation).** Stop using ZETONNA Nasal Aerosol and call your doctor right away if you have symptoms of a nasal perforation. Symptoms of nasal perforation may include: crusting in the nose, nosebleeds, runny nose, and a whistling sound when you breathe.
- **thrush (Candida), a fungal infection in your nose, mouth, or throat.** Tell your healthcare provider if you have any redness or white colored patches in your mouth or throat.
- **slow wound healing.** You should not use ZETONNA Nasal Aerosol until your nose has healed, if you have a sore in your nose, if you have had surgery in your nose, or if your nose has been injured.
- **eye problems such as glaucoma and cataracts.** If you have a history of glaucoma or cataracts or have a family history of eye problems, you should have regular eye exams while you use ZETONNA Nasal Aerosol.
- **immune system problems that may increase your risk of infections.** You are more likely to get infections if you take medicines that may weaken your body's ability to fight infections. Avoid contact with people who have contagious diseases such as chicken pox or measles while you use ZETONNA Nasal Aerosol. Symptoms of an infection may include: fever, pain, aches, chills, feeling tired, nausea, and vomiting.
- **adrenal insufficiency.** Adrenal insufficiency is a condition in which the adrenal glands do not make enough steroid hormones. Call your healthcare provider right away if you experience the following symptoms of adrenal insufficiency: tiredness, weakness, dizziness, nausea, and vomiting.
- **slowed or delayed growth in children.** A child's growth should be checked regularly while using ZETONNA Nasal Aerosol.
- **allergic reactions.** Call your healthcare provider right away if you experience swelling of the lips, tongue, or throat.

The most common side effects with ZETONNA Nasal Aerosol include nasal discomfort, headache and nose bleeds.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ZETONNA Nasal Aerosol.

For more information, please see the ZETONNA Full Prescribing Information and the ZETONNA Patient Information at [www.ZETONNA.com](http://www.ZETONNA.com) [8]. You may also call 1-888-394-7377.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) [9], or call 1-800-FDA-1088.

ZETONNA® (ciclesonide) Nasal Aerosol is available by prescription. Ask your healthcare professional if ZETONNA is appropriate for you.

#### About Sunovion Pharmaceuticals Inc. (Sunovion)

Sunovion is a global biopharmaceutical company focused on the innovative application of science and medicine to help people with serious medical conditions. Sunovion's vision is to lead the way to a healthier world. The company's spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. With patients at the center of everything it does, Sunovion has charted new paths to life-transforming treatments that reflect ongoing investments in research and development and an unwavering commitment to support people with psychiatric, neurological and respiratory conditions. Sunovion's track record of discovery, development and/or commercialization of important therapies has included Utibron™ Neohaler® (indacaterol/glycopyrrolate) inhalation powder, Brovana® (arformoterol tartrate) inhalation solution, Latuda® (lurasidone HCl) and Aptiom® (eslicarbazepine acetate).

Headquartered in Marlborough, Mass., Sunovion is an indirect, wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. Sunovion Pharmaceuticals Europe Ltd., based in London, England, Sunovion Pharmaceuticals Canada Inc., based in Mississauga, Ontario are wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. Additional information can be found on the company's web sites: [www.sunovion.com](http://www.sunovion.com) [10], [www.sunovion.eu](http://www.sunovion.eu) [11] and [www.sunovion.ca](http://www.sunovion.ca) [12]. Connect with Sunovion on [Twitter](https://twitter.com/sunovion) [13], [LinkedIn](https://www.linkedin.com/company/sunovion) [14], [Facebook](https://www.facebook.com/sunovion) [15] and [YouTube](https://www.youtube.com/user/sunovion) [16].

#### About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is among the top-ten listed pharmaceutical companies in Japan operating globally in major pharmaceutical markets, including Japan, the United States, China and the European Union. Sumitomo Dainippon Pharma aims to create innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has about 6,500 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at [www.ds-pharma.com](http://www.ds-pharma.com) [17].

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#### Sunovion Forward-Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including all statements regarding the intent, belief or current expectation of the companies' and members of their senior management team. Forward-looking statements include, without limitation statement associated with the following: the timing of the closing of Sunovion's agreement with Covis Pharma; Sunovion's ability to divest ALVESCO® (ciclesonide) Inhalation Aerosol, OMNARIS® (ciclesonide) Nasal Spray, and ZETONNA® (ciclesonide) Nasal Aerosol to Covis Pharma; whether the transaction will result in the best outcome for Covis Pharma; the parties' ability to receive the required court and regulatory approvals, satisfy other customary closing conditions and close the transaction. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties and are cautioned not to place undue reliance on these forward-looking statements. Actual results may differ materially from those currently anticipated due to a number of risks and uncertainties. Risks and uncertainties that could cause the actual results to differ from expectations contemplated by forward-looking statements include: the effects of the transaction on relationships with employees, customers, other business partners or governmental entities; other business effects, including the effects of industry, economic or political conditions outside of the companies' control; actual or contingent liabilities; and other risks and uncertainties detailed by Sunovion's parent company Sumitomo Dainippon Pharma in the Summary of Consolidated Financial Results [Japanese GAAP] (Unaudited) for quarterly earnings. All forward-looking statements are based on information currently available to Sunovion, and Sunovion assumes no obligation to update any such forward-looking statements.

For a copy of this release, visit Sunovion's web site at [www.sunovion.com](http://www.sunovion.com) [18]

#### Language:

English

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