

# AZ LICENSES ZURAMPIC TO GRÜNENTHAL GMBH

## ASTRAZENECA LICENSES ZURAMPIC TO GRÜNENTHAL GMBH IN EUROPE AND LATIN AMERICA

***Agreement includes rights to the fixed-dose combination of lesinurad and allopurinol in gout***

AstraZeneca today announced that it has entered into a licensing agreement with Grünenthal GmbH for the exclusive rights to *Zurampic* (lesinurad) in Europe and Latin America. *Zurampic* was approved by the European Medicines Agency (EMA) [in February 2016](#), in combination with a xanthine oxidase inhibitor (XOI), for the adjunctive treatment of hyperuricemia (excess of uric acid in the blood) in adult patients with uncontrolled gout.

Grünenthal will acquire the exclusive rights to *Zurampic* in all 28 European Union member states, Switzerland, Iceland, Norway and Lichtenstein, and in all Latin-American countries including Mexico, the Dominican Republic and Cuba. In addition, Grünenthal will also obtain the exclusive rights to the fixed-dose combination of lesinurad and allopurinol in these markets. This combination is currently in clinical trials.

Under the terms of the agreement, Grünenthal will submit the fixed-dose combination programme for regulatory review and will pay AstraZeneca up to \$230 million in sales and other related milestones over the lifetime of the contract. Grünenthal will also pay tiered, low double-digit royalties on annual Product Sales. AstraZeneca will initially manufacture and supply *Zurampic* to Grünenthal and will undertake the European post-approval commitment on Grünenthal's behalf. From 1 October 2021, Grünenthal has the option to take over manufacturing of *Zurampic*.

Luke Miels, Executive Vice President, Global Product and Portfolio Strategy, AstraZeneca, said: "Grünenthal has an established presence across European and Latin American markets and extensive expertise in inflammatory diseases. This agreement allows us to further focus our resources on our strategic priorities."

Prof. Dr. Eric-Paul Pâques, CEO, Grünenthal, said: "We are highly committed to the research, development and commercialisation of innovative therapies that bring true benefits to patients. *Zurampic* is a strong addition to our existing portfolio of innovative therapies in the areas of inflammatory diseases and chronic pain. We will thus use our capabilities to provide patients in our markets with this innovative new medicine to better control their condition."

Gout is a serious, chronic, progressive and potentially debilitating form of inflammatory arthritis that affects more than 7.8 million people in the major European and Latin American markets<sup>1</sup>.

### **Financial considerations**

Revenue from the licensing agreement will provide AstraZeneca with future recurring Externalisation Revenue from expected milestone payments and tiered, low double-digit percent royalty payments on Product Sales. The agreement does not impact AstraZeneca's financial guidance for 2016.

<sup>1</sup> Markets include France, Germany, Italy, Spain, United Kingdom, Brazil, Mexico, Colombia, and Argentina. Source: Decision Resources Group, Community Oriented Programme for Control of Rheumatic Diseases.

### **About *Zurampic***

*Zurampic* (lesinurad) is the first in a new class of medicines called Selective Uric Acid Reabsorption Inhibitors (SURI) that work selectively to complement xanthine oxidase inhibitors (XOIs) in the treatment of hyperuricemia associated with uncontrolled gout. *Zurampic* is not recommended for the treatment of asymptomatic hyperuricemia and should not be used as monotherapy. XOIs reduce the production of uric acid; *Zurampic* increases the excretion of uric acid. Together, the combination of *Zurampic* and an XOI provides a dual mechanism of action that both decreases production and increases excretion of uric acid, thereby lowering serum uric acid (sUA) levels in patients who have not achieved target serum acid levels with XOI treatment alone. *Zurampic* selectively inhibits the function of transporter proteins urate transporter (URAT1) and organic anion transporter 4 (OAT4), involved in uric acid reabsorption in the kidney. In people, *Zurampic* does not inhibit OAT1 and OAT3, which are drug transporters in the kidney associated with drug-drug interactions. The efficacy of *Zurampic* was established in three Phase III clinical trials that evaluated a once daily dose of *Zurampic* in combination with the XOI allopurinol or febuxostat compared to XOI alone.

In April 2016, AstraZeneca entered into a [licensing agreement](#) with Ironwood Pharmaceuticals for the exclusive US rights to *Zurampic* and the fixed-dose combination of lesinurad and allopurinol.

### **About Grünenthal**

The Grünenthal Group is an independent, family-owned, international research-based pharmaceutical company headquartered in Aachen, Germany. We are an entrepreneurial specialist delivering true benefits to patients. By sustainably investing in research and development above the industrial average, we are committing to innovation in order to treat unmet medical needs and bring value adding products to markets. Grünenthal is a fully integrated research & development company with a long track record of bringing innovative pain treatments and state-of-the-art technologies to patients. Altogether, the Grünenthal Group is present in 32 countries with affiliates in Europe, Latin America and the US. Grünenthal products are sold in more than 155 countries and approx. 5,300 employees work for the Grünenthal Group worldwide. In 2015, Grünenthal achieved revenues of €1.2 bn. More information: [www.grunenthal.com](http://www.grunenthal.com).

## About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: [www.astrazeneca.com](http://www.astrazeneca.com)

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*Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal*

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