AstraZeneca licenses gout drug Zurampic to Grünenthal in Europe and Latin America

UK drugmaker AstraZeneca said it has entered into a licensing agreement worth up to $230 million giving Grünenthal GmbH rights to the gout drug Zurampic (lesinurad) in Europe and Latin America.

Under the terms or the agreement, Germany-based Grünenthal will pay AstraZeneca up to $230 million in sales and other related milestones over the contract period. 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 October 1, 2021, Grünenthal has the option to take over manufacturing of Zurampic.

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.

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."

Grünenthal will acquire 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 get the exclusive rights to the fixed-dose combination of lesinurad and allopurinol in these markets. This combination is currently in clinical trials.

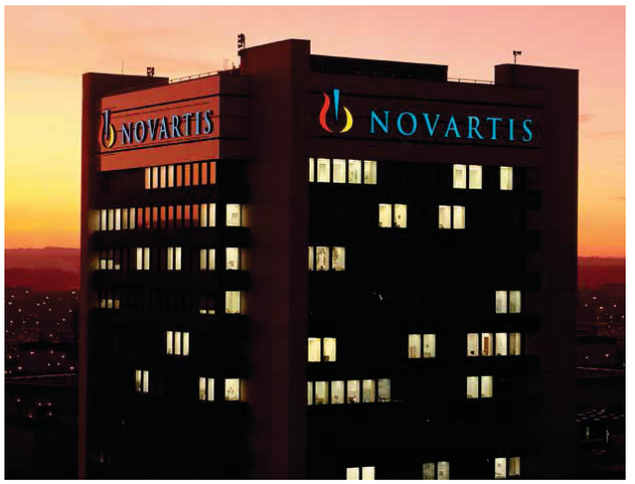
Gout is a chronic, progressive and potentially debilitating form of inflammatory arthritis that affects more than 7.8 million people in the major European and Latin American markets.

Grünenthal Chief Executive Eric-Paul Pâques, said: "Zurampic is a strong addition to our existing portfolio of innovative therapies in the areas of inflammatory diseases and chronic pain."

Novartis aims to launch five major global **biosimilars by 2020**

Swiss pharma major Novartis has announced plans to triple its biosimilar portfolio by 2020, with the launch of five major versions of blockbuster drugs.

Through its Sandoz division, the Swiss pharma company will invest more than $1 billion in state-of-the-art biomanufacturing facilities and leverage its expertise to deliver biosimilars on a large scale.



Pending regulatory submissions, Sandoz plans to launch biosimilar versions of Enbrel (etanercept), Humira (adalimumab), Neulasta (pegfilgrastim), Remicade (infliximab) and Rituxan (rituximab). These drugs treat conditions ranging from rheumatoid arthritis to chronic lymphocytic leukaemia and have generated combined sales of $44 billion in 2015.

At the recent EULAR congress, the company presented data showing how its inflammatory disease biosimilars demonstrated comparable safety and efficacy with the originators.

To facilitate these launches, Sandoz is pursuing what it calls an "aggressive regulatory submissions" strategy.

Richard Francis, division head and CEO at Sandoz, says: "Despite the impressive medical advances of the past century, access to medicines remains the single largest unmet healthcare need in developed and developing countries alike. Biologics have revolutionised treatment of many disabling and life-threatening diseases, but far too many people who need these medicines are not able to access them.

"At Sandoz, we are committed to significantly broadening patient access to biologics with a series of major biosimilar launches over the next few years."

According to a recent IMS Health report, biosimilars have the potential to save EU and US healthcare systems up to $100 billion by 2020.

Antibiotic resistance: are new antibiotics the answer?

synergy vision

Katie Greenhalgh
Senior Medical Writer

Antibiotics are cheap and widely available. And therein lies the problem. The factors that have enabled antibiotics to save millions of lives have accelerated the emergence of drug-resistant strains of bacteria. As a result, deaths from sepsis are predicted to outnumber those from cancer in a few decades.

Society clearly wants and expects pharmaceutical companies to develop new antibiotics. But is that the answer, especially when policy makers will not want doctors (or farmers) to use them in the same prolific way as before?

A global threat of this magnitude requires governments, health organisations and pharmaceutical companies to work together.

International leaders in healthcare are clearly focused on combatting antibacterial resistance and the need to remove the financial and regulatory barriers that hinder drug development.

The recent UK government review, chaired by economist Jim O'Neill, recommends paying pharmaceutical companies up to $3 billion for developing a new antibiotic. Breaking the link between research and development and the cost of a drug is to be welcomed, as is the report's proposal to incentivise pharmaceutical companies to turn their attention away from lucrative drugs to antibiotics.

A €223.7 million project to develop and fund an 'antimicrobial discovery hub', bringing together pharmaceutical companies and academics, has been launched in the European Union. The European Medicines Agency has already announced a new approach to assessing antibiotics using smaller clinical trials to speed up development.

Some new antibiotics are already in development. Most are variations on drugs already available, but some companies are working on a new generation of antibiotics that work in a completely different way to their predecessors.

But it's not just new drugs that we need. We need a new system for using antibiotics or we risk repeating past mistakes. Until we tackle global misuse, we will still be facing a post-antibiotic era in which common infections and simple injuries become killers. Developing a new generation of antibiotics could well prove to be the easy part.