



Press Release

Duzallo[®], a fixed-dose combination therapy for gout, approved in Europe

Aachen, Germany, 28 August 2018 – Today, Grünenthal announced that the European Commission has followed the positive opinion of the Committee for Medicinal Products for Human Use (CHMP) and granted Duzallo[®] marketing authorization for the EU/EEA. Duzallo[®] is a fixed-dose combination (FDC) therapy that combines allopurinol and lesinurad. It is indicated for the treatment of hyperuricaemia in adult gout patients who have not been able to reach target levels of uric acid serum with a dose of allopurinol alone. Lesinurad is the first innovative uricosuric in gout treatment for over 40 years.

“The unmet need in gout treatment is extremely high: The disease is under-diagnosed, under-treated and significantly reduces the quality of life for patients,” explains Philip Just Larsen, Chief Scientific Officer at Grünenthal. “An acute attack of gout is a highly painful episode for a patient to experience. Numerous studies show that gout and hyperuricemia are conditions associated with an increased risk of all-cause mortality and in particular cardiovascular events, compared with a non-gout population. However, the existing standard of care is insufficient to keep patients’ uric acid levels under control. Lesinurad, with its innovative and selective action, has the potential to help improve control of uric acid serum levels – which may substantially improve patients’ quality of life.”

Mark Fladrich, Chief Commercial Officer at Grünenthal, adds: “We are proud to bring Duzallo[®], a fixed-dose combination, to patients as it has the potential to elevate the standard of care in gout. While allopurinol decreases the production of uric acid, lesinurad increases its excretion by the kidneys, leading to better control of uric acid levels. Moreover, the fixed-dose combination has an additional benefit for patients by reducing the burden of taking multiple pills. For these reasons, we believe that Duzallo[®] may become a standard and more convenient treatment option for both patients and healthcare professionals.”

“Gout has traditionally been seen as an acutely painful arthritic attack. However, it is a serious chronic disease that may lead to early death, mainly due to cardiovascular events. Until now, the treatment options that target the major pathology, renal inefficiency in excreting uric acid, have been limited. Lesinurad targets exactly this pathology and along with allopurinol, which reduces production, leads to a greater decrease in uric acid levels,” Professor Fernando Pérez-Ruiz, Senior Rheumatologist in the Rheumatology Division at Hospital de Cruces, Vizcaya, Spain, states. He further adds: “As an FDC, Duzallo will be a welcome solution for this complex disease.”

The marketing authorization has been granted for the 28 European Union member states, as well as for the EEA countries Norway, Iceland and Liechtenstein. The approval by the European Commission is based on the positive opinion adopted by the CHMP of the European Medicines Agency (EMA) in June 2018.



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This is a key milestone in Grünenthal's ambition to build a strong portfolio in gout, where there is a high unmet patient need. In March 2018, Grünenthal's first gout product Zurampic® was launched in Switzerland and Italy. By the end of this year, it will have been launched in other European countries. Duzallo® is planned to be launched in most European countries in 2019.

About Grünenthal

Grünenthal is an entrepreneurial, science-based pharmaceutical company specialized in pain, gout and inflammation. Our ambition is to deliver four to five new products to patients in diseases with high unmet medical need by 2022 and become a € 2 bn company. We are a fully integrated research & development company with a long track record of bringing innovative pain treatments and state-of-the-art technologies to patients. By sustainably investing in our R&D above the industrial average, we are strongly committed to innovation.

Grünenthal is an independent, family-owned company headquartered in Aachen, Germany. We are present in approx. 30 countries with affiliates in Europe, Latin America and the US. Our products are sold in more than 100 countries and approx. 5,200 employees are working for Grünenthal worldwide. In 2017, Grünenthal achieved revenues of approx. € 1.3 bn.

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